

**A comparative study of the patentability standards with respect to
pharmaceutical inventions in the United Kingdom and South Africa**

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ABSTRACT

Using a comparative methodology the thesis analyses the patentability of pharmaceutical and related inventions in the UK and South Africa. The viewpoint adopted is that of the industry actors, who are engaged in the conception through to the commercialisation of inventions, although this perspective is measured against the concerns of wider stakeholders.

Drawing, in particular, on the classical justifications of the patent system, the research identifies the attributes of an optimal patentability standard which can be adjusted as technology and the legislative landscape changes. Framing an optimal patentability benchmark as one that both promote and protect the invention, the thesis considers the elements that ground the judicial patentability decision-making process. As pharmaceutical patenting tends to be an emotive and contentious area, the interplay between the international and respective domestic patentability frameworks is also evaluated in its impact on the inventor within the pharmaceutical chain.

The research then turns to investigate four individual patentability limbs as applied in the two jurisdictions. The definition of the invention and excluded subject matter is evaluated in mapping out the pharmaceutical activity and the associated research output that falls within patentable subject matter. The novelty, non-obviousness and industrial application limbs to patentability are then examined, giving particular attention to the tests used by the courts in evaluating whether an invention meets the requisite criteria. The argument is made that the courts in interpreting patentability must apply principles advancing the purpose of the patent system in arriving at decisions. A systematic and robust approach is advanced that improves repeatability and precision in arriving at patentability decisions whilst preventing subjective application of the criteria. It is suggested that the application of the tests whilst aligning with the rationale and policy of the patent system, have to make sense to the scientist working in inventive pharmaceutical activities.

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ABBREVIATIONS

Chartered Institute of Patent Agents (CIPA)

Community Patent Convention (CPC)

European Patent Convention (EPC)

Intellectual property rights (IPRs)

Multi-national entity (MNE)

New molecular entity (NME)

Patent Cooperation Treaty (PCT)

Research and development (R&D)

Substantive Patent Law Treaty (SPLT)

Technical Board of Appeal (TBA)

The Agreement on Trade-Related Aspects of International Property Rights (TRIPS or TRIPS Agreement)

United Kingdom Intellectual Property Office (UKIPO)

World Intellectual Property Organisation (WIPO)

CHAPTER ONE

INTRODUCTION

1.1 The purpose of the study

1.1.1 The general purpose of the study

The aim of this study is to comparatively examine the patentability of pharmaceutical inventions as applied in South Africa and the United Kingdom with the view of making reform proposals where optimal patentability standards are not accomplished. The thesis suggests that optimal patentability standards are those that have characteristics which are simultaneously compatible with the needs of industry and the dictates of public policy.

In order for inventions to qualify for legal protection there is a threshold that they must attain before they receive patent protection. This legal threshold is evaluated by establishing whether an invention has a series of elements known as limbs to patentability. However, on one level these elements have been generally misunderstood by the public. On another level, these patentability limbs have proven to be difficult to apply in practice, which over time has resulted in numerous patent disputes and strained policy debates on current and future appropriate patentability standards.

One of the ways of eliminating the difficulties in patentability disputes is to have clearly set standards, known to potential patentees and other third parties, which the courts would use in deciding patentability cases. Ideally, these standards would be the tests that are used in approving patent applications.¹ In this thesis the legal tests and the doctrines behind these standards are analyzed, which would ultimately be used by tribunals and courts in assessing whether or not an invention is indeed patentable.

¹ The lack of consistency between patent offices and courts decisions has been referred to as ‘the notorious difference between the standards applied by the Patent Office and the courts’: *Graham v. John Deere Co.* 383 U.S. 1, 18(1966). Bessen J. and Meurer M. ‘Lessons for patent policy from empirical research on patent litigation’ (2005) *Lewis and Clark Law Review*, p.1-27, discuss how this gap can be manipulated by patentees and competitors and recommends some performance efficiency improvements for Patent Offices.

The current general limbs to patentability that are studied within the scope of this thesis are that the invention should be new, non-obvious, capable of industrial application and be of non-excluded subject matter. These patentability limbs developed over years and the tests for assessing their presence are constantly being refined and optimized by the judiciary and legislature in both jurisdictions. At the same time, globalization, international trade and the necessity of reciprocity of patent protection has added a further layer of difficulty in determining appropriate and applicable local standards.

Throughout this thesis the doctrine of patentability, and its relevance and application in the balanced and appropriate patent protection of inventions, will be analyzed and evaluated and compared between the two jurisdictions. The thesis seeks to establish whether the patentability standards allow invention and innovation and offers adequate protection for inventions.² This is the equilibrium point that is considered to be the optimal patentability standard in this thesis. Although the patentability doctrine is well established, on the contrary the approach to patentability evaluation is rather modest because many cases where the patentability standards are in issue are settled before they reach the courts.³ This is compounded by the restraint of the courts to answer wider patentability questions before them⁴ or simply too few judicial interpretation of the concept.⁵

² The distinction and legal consequence thereof, between invention and innovation ‘which is the putting of new ideas into effect’ will be analysed in chapter 4 on subject-matter excluded from patentability: Kingston W. ‘Patent protection for modern technologies’ (1997) *Intellectual Property Quarterly*, p.350-369, p.352.

³ Licensing and cross-licensing is the strategic mechanism that is usually used in commercializing patents or to settle patent disputes: Soyama D. ‘Strategic determinants of decisions not to settle patent litigation’ (2003) *Strategic Management Journal*, p.17-38. Lanjouw J.O. and Schankerman M. ‘Enforcing intellectual property rights’ (2001) *NBER working paper* N.8656, found that up to ninety-five percent of initiated patent suits are settled before trial.

⁴ The courts have been hesitant in going beyond facts of cases before them when they would be within their capacity to do so. There is the opposing view that unprecedented judicial theorising often dangers the narrow fact-based resolution of cases before the courts from which case law develops. King generally elaborates a balanced framework of practical reasoning within which courts impart predictability of decisions with some judicial restraint principles: King J.A. ‘Institutional approaches to judicial restraint’ (2008) *Oxford Journal of Legal Studies*, p.409-441.

⁵ The UK and South Africa have less patenting activity compared to some of the notable patent offices: Garg K.C. ‘Inter-country comparison of patenting activity’ (1997) *World Patent Information*, p.37-39.

Furthermore, with South Africa being a non-examining authority of granted patents under the domestic patent grant route, the doctrine is obscured only to receive focus when a dispute arises.⁶ The non-examination of South African patents does not detract from the comparative nature of the study as substantive examination is implied and incorporated into the South African system. For example, in the correction of errors in patent applications before grant, if ‘it appears to the Registrar that the correction would materially alter the scope of the document’⁷ he or she may institute proceedings to prevent the change, revealing that substantive examination does occur. Moreover, South Africa has a significant number of patents granted under the Patent Cooperation Treaty⁸ (PCT) route where limited substantive examination occurs.⁹ Moreover, it is the validity of the granted patent under the patentability conditions that is under scrutiny in this thesis rather than the means or procedural process for the grant.

There has been a trend in most jurisdictions toward considered modernizing and harmonization of the approach toward patentability standards and the recognition that the doctrine has a far-reaching role to fulfill within the legal and regulatory framework. The emergence of a more modern approach to the doctrine also manifested beyond the legal environment and infiltrates the scientific, economic and commercial world in dimensions previously unanticipated. That is to say the doctrine is well-founded in law but has vital and expanded connotations for and increased interaction with other fields in today’s knowledge society.

The resultant wider stakeholder base from the expansion of the patentability doctrine has an increasingly crucial role to play in attaining the optimal patentability standard.¹⁰ Therefore the doctrine of patentability has to be placed in a context so that

⁶ Patent Act 1978, s.34 does not provide for the substantive examination of patent applications, with examination only to formalities according to Patent Regulation 1978, R.41.

⁷ Patents Act 1978, s.50(4).

⁸ International applications under the PCT were inserted as Chapter VA by s.38 of Act no.38 of 1997 into the Patents Act 1978.

⁹ It is a limited examination because the search report is not binding on the eventual grant or rejection of an application in view of the report under the South African Patents Act, section 43C(c) electing the South African Patent Office as the elected Office.

¹⁰ Activities of pharmaceutical firms have to respond to multiple stakeholders: Kennedy C.R., Harris H. and Lord M. ‘Integrating public policy and public affairs in a pharmaceutical marketing program: The AIDS pandemic’ (2004) *Journal of Public Policy and Marketing*, p.128-139. Pharmaceutical policy making, besides organised actors, has to include even the lay public: Traulsen J.M. and Almarsdottir

it encompasses all extremities of knowledge generation and commercialization, from local to global inventions and cumulative to groundbreaking technologies in a fair and consistent manner.¹¹ International or a country's external obligations and prerequisites for global trade have caused the necessity of establishing a balance between the local patenting standards and international standards. In light of these developments, the purpose of this study is to propose that both countries actively set out their model for what would be a workable patentability standard which meets their developmental and economic needs under both domestic and international patent law.¹² The overarching reality is that the local patentee with a valuable invention can no longer simply rely on a local patent that is not in tune with international benchmarks.

1.1.2 Specific purpose of the study

1.1.2.1 The law under focus

As intellectual property (IP) law is a rapidly developing area of law,¹³ a study aimed at all stakeholders in the patenting industries is important. Although patent law is territorial, the stakeholders transcend national boundaries as inventive and innovative activities have tended to filter across jurisdictional boundaries. The patentability standards have to protect inventions by these stakeholders, both internally and externally.

A.B. 'Pharmaceutical policy and the lay public' (2005) *Pharmacy World and Science*, p.273-277, also noting at p.275, that the matrix of stakeholders has diverse interests, for instance, patient groups as the ultimate beneficiary of the ensuing invented pharmaceuticals can have different interests from patient activist groups and public health advocacy groups even though these frequently coincide.

¹¹ Vaver D. 'Reforming intellectual property law: an obvious and not-so-obvious agenda: the Stephen Stewart Lecture for 2008' (2009) *Intellectual Property Quarterly*, p.143-161, suggests overhauling of IP laws to make the system clear, just and efficient in order to gain public respect and acceptance. Ngcobo S. 'Sustaining public confidence in the judiciary: An essential condition for realising the judicial role' (2011) *South African Law Journal*, p.5-17, has noted that 'public confidence is necessary for the effective performance of judicial functions.'

¹² For instance, there have been rather volatile negotiations for the establishment of an international patentability standard under the Substantive Patent Law Treaty (SPLT), where both South Africa and the UK expressed their desire to be party to such a treaty and have made various contributions to what they perceive would be the ideal standard; for example, generally in WIPO document SCP/11/6, specifically para.40.

¹³ Soetendorp R. 'Intellectual property education- in the law school and beyond' (2005) *Intellectual Property Quarterly*, p.82-110, p.90.

Patentability standards remain at the centre of patenting systems for the protection of those inventions. The levels of patentability standards set determine whether the patenting system is effective or not in protecting industry's valuable inventions. A deeper understanding of patentability standards is pivotal at the research and development (R&D) stage if the patenting route is contemplated by scientists or industrialists. The standards determine the appropriate inventions that will pass the threshold for patentable inventions at the patent application stage.¹⁴ It is this standard that will determine if the patent system is not burdened with low quality patents that under scrutiny have little to offer as an improvement in the state of the art.¹⁵ As such, the patentability standards have a direct bearing on the quality of patents. Wagner states that '[p]atent quality is the capacity of a granted patent to meet (or exceed) the statutory standards of patentability... Thus, a "low quality" patent is one granted for an invention which does not meet these standards.'¹⁶ The disadvantage of South Africa's non-examination of applications in allowing the existence of patents falling below this benchmark has been acknowledged.¹⁷ Of the jurisdictions under study, it is only the UK that has patentability case law developed from the application stage.

¹⁴ Based on the premise that 'inconsistent assessments regarding *identical* information during the grant and the challenge phase is not desirable in *any* circumstances', it has been shown empirically, in a sample of biotechnology patent applications, that the EPO's patentability decision making on patent quality during the grant and opposition phases was inconsistent even though the patentability decisions were made based on identical information throughout the application process: Burke P.F. and Reitzig 'Measuring patent assessment quality- Analyzing the degree and kind of (in)consistency in patent offices' decision making' (2007) *Research Policy*, p.1404-1430, p.1425.

¹⁵ Patent Offices profess that they are burdened with unsustainable workloads; suggested solutions range from simple increased number of examiners, including the contracting of examination to other offices or even private companies, to radical mechanisms for bidding and auctioning of substantive examination slots, see Katopis C.J. 'Perfect happiness?: Game theory as a tool for enhancing patent quality' (2008) *Yale Journal of Law and Technology*, p.360-404.

¹⁶ Wagner R.P. 'Understanding patent-quality mechanisms' (2009) *University of Pennsylvania Law Review*, p.2135-2173, p.2138. Some define patent quality by a two-fold means:- the legal quality created by the patent's reliability as an enforceable property right or sustainability when challenged and additionally, as the techno-economic quality created by the patent's underlying invention or technological 'merit' : Thomas J. 'The responsibility of the rulemaker: Comparative approaches to patent administration reform' (2002) *Berkeley Technology Law Review*, p.728-761.

¹⁷ WIPO, *Study of patents and the public domain* (2012) Committee on Development and Intellectual Property, WIPO Publication Geneva, CDIP/8/INF/3Rev2. The South African Court of Appeal in *Bateman Equipment Ltd v The Wren Group* (case480/97), rejecting any impeding formalistic approach to amending claims or enquiry into reasons for doing so, has put it this way: 'The nature and object of amendment proceedings must be seen in the context of our patent system as a whole. Ours is a non-examining country and an alleged inventor is entitled to a patent for his supposed invention without having to satisfy anyone of its merit or validity. He does not have to give any reasons for his choice of wording. Should he sue for infringement, he has no duty to assist the alleged infringer in establishing whether his monopoly is valid or not. Why should he be saddled with a burden if he wished to reduce the scope of his protection in an attempt to render the patent valid, while in obtaining or enforcing a monopoly he bears no similar burden? As much as it is in the public interest that persons with inventive

Granting of a patent is not in itself an end of the relevance of patentability standards. These standards become significant when validity is disputed in infringement proceedings.¹⁸ The standards against which infringement is measured necessarily have to be exacting in nature.¹⁹ In addition, effective patent enforcement revolves around the exacting patentability standards, as allegations are usually made that the patent being enforced falls below the required standards, thus reverting back to the question of whether protection should have been granted in the first place.²⁰ In both the UK and South Africa, the case law on patentability has mainly developed in the context of enforcement and infringement of patents and this is usually accompanied by revocation counter-action.²¹ For the respective countries under comparison the thesis focuses mainly on the ground that the granted patent was not patentable under Patents Act 1977, s.72(1)(a) and Patents Act 1978, s.61(1)(c).

It is in light of these considerable consequences that rigorous patentability standards and the assessment methods of patentability validity are suggested as necessary in this thesis. Judging these qualities has tended to be an elusive concept, both for the layperson and legal scholars, as usually evidenced by polarised debates of seemingly simple patentability concepts, not only in patent offices and courts,²² but also in international trading and law-making forums. An overarching observation is that developed and developing countries put differing emphasis on these standards, yet

minds should be encouraged to give the results of their efforts to the public in exchange for the grant of a patent, it is in public interest that patents should be rectified or validated by way of amendment.’

¹⁸ Scholars assert that caution is to be exercised in the interpretation of patent litigation statistics as these are complex and are underlined by multiple reasons and the policy that could be derived therefrom is not straightforward because ‘patent suits probably constitute a small and uncharacteristic subset, drawn from the set of all patent disputes. Certainly, patent trials constitute a small and uncharacteristic subset of filed patent suits’: Bessen/Meuer, fn.1, p.4.

¹⁹ For divergent perspective, Dent C. ‘To see patents as devices of uncertain (but contingent) quality: A Foucaultian perspective’ (2007) *Intellectual Property Quarterly*, p.148-163, argues that the system can never eliminate uncertainty and stakeholder-contingent aspects because of the variable perspectives and action, founded on patentability requirements, that can be taken by each stakeholder within the system.

²⁰ For instance, in making the distinction between what should be a discovery and invention, pharmaceutical companies are accused of patenting developing world products as a result of ‘the glaring fallacy and inherently biased Western perception that, because significant financial resources have been invested in refining the original material, scientific trials and chemical analysis, the product has been improved and should be regarded as novel’ and are subsequently sold with the exclusion of the original holders of the knowledge: Stenton G. ‘Biopiracy within the pharmaceutical industry: a stark illustration of how abusive, manipulative and perverse the patenting process can be towards countries of the South’ (2004) *European Intellectual Property Review*, p.17-26, p.19.

²¹ Respectively under Patents Act 1977, s.72 and Patents Act 1978, s.61 and revocation counter-claim according to Patents Act 1977, s.74(1) and Patents Act 1978, s.65(4).

²² For example, as is sometimes the case with EPO granted patents, *Occlutech GmbH v AGA Medical Corporation* [2010] EWCA Civ 702 resulted in different judicial decisions in the European Patent Convention (EPC) Contracting States, of the same patent litigated under the same instrument.

there is a consensus point that would have to be reached for the system to adequately function in reality. In this study the approaches and tests as used by the courts in the two jurisdictions to determine patentability are examined. Views held by patent examiners and administrators are also analysed to suggest ways to bring them in line with what the courts would ultimately interpret as statutorily correct. The views held by legal scholars and other commentators²³ who are outside of the confines of the administration of the patent system are also analysed²⁴ for assistance in the definition and interpretation of the patentability concept. Suggestions are made on how these requirements could be improved, especially under the convenience notion of harmonising patenting laws over time.

1.1.2.2 The science under focus

An examination is made of whether these standards are perceived to help industry in encouraging and protecting their inventions and innovations in the UK and South Africa. The inventors are important stakeholders to the patent system. They not only include the parties that seek the patent, but they include competitors and third parties. It has even been suggested that the inventors' interests in a balanced patentability standard as third parties is more than when they are applicants.²⁵

²³ Braun A. 'Professors and judges in Italy: It takes two to tango' (2006) *Oxford Journal of Legal Studies*, p.665-681, p.666-670, although acknowledging that the situation has changed, concedes that formerly, comparative lawyers identified the role of academic scholars in the judicial law-making process to be the major difference between civil and common law jurisdictions, with English judges giving lower esteem and regard to academic scholarship than in other European jurisdictions. UK judicial reasoning has been shown to be increasingly receptive of and influenced by academic discourse: Duxbury N. *Jurists and judges: an essay on influence* (2001) Oxford: Hart Publishing, chapter 5. Legal scholarship is no longer confined to academics, for example, members of the judiciary have not been hesitant to comment on wider issues outside of their judicial roles, for instance in giving lectures or in journal scholarship, for example, Jacob LJ in Jacob R. 'Patents and Pharmaceuticals—a Paper given on 29th November 2008 at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry', November 2008, at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/jacob.pdf> or Lord Hoffmann 'Claim construction' (2006) *The CIPA Journal*, p.727-731.

²⁴ The influence of institutional mandates or curtailments behind academic writings by authors associated with institutions is raised for instance when Johnson reviews the book by Gervais, formerly a World Trade Organization (WTO) legal adviser, and comments that he can now write freely on the intricacies to TRIPS Agreement conclusion as he is now free of the shackles of WTO: Johnson P. 'The TRIPS Agreement: Drafting history and analysis' (2009) *European Intellectual Property Review*, p.441.

²⁵ EPO President Benoît Battistelli 'How Can Europe Be a Key Player at Global Level in the Patent Field? What is the Role of the EPO?', 8 November 2011, London: UCL, suggesting that competitors still benefit from being third parties in patent grant when the standards are optimally set.

The focus of this thesis, on the general level, is on the rapidly advancing fields based on chemical inventions as opposed to the more mechanical fields,²⁶ as these are the fields that tend to rapidly change without giving the legislature opportunity to prescribe new rules.²⁷ This is a broad field of technology characterised by the chemistry of manipulation, isolation and reaction of atoms and compounds; from identification, isolations and reactions of the pharmaceutical compounds to complex micro and macro building of compounds and complex structures in biotechnology, genetic engineering, nanotechnology and other associated technologies.²⁸ That is not to mean there will be total avoidance of other areas of science and technology because the process of inventing is usually inextricably interlinked with other fields; for example, these processes are usually automated and computer-implemented.²⁹

To further demarcate the parameters of the study, there is particular reference to pharmaceutical inventions as a subset of the broader science of chemistry.³⁰ To this end, the view held is that pharmaceutical invention generally refers to a 'process or substance used in the diagnosis or treatment of diseases or other medical conditions in humans or animals, including processes or substances used in medical research.'³¹ This sector is complemented by other related fields of technology, for example

²⁶ Another classification that has been used is referring to the former as unpredictable arts and the latter as predictable arts: Seymore S.B. 'Rethinking novelty in patent law' (2011) *Duke Law Review*, p.919-976, p.929. It has been said that 'a technology classified as pharmaceutical will also be within either the chemistry or biotechnology areas' although biotechnology has only recently developed into a distinct field separate from the chemistry field: Allison J.R. and Lemley M.A. 'Who is patenting? An empirical exploration of patent prosecution' (2000) *Vanderbilt Law Review*, p.2099-2174, p.2110.

²⁷ There is acknowledgement that the laws have to be flexible enough keep up with technological developments in some fields: Lord Irvine of Lairg 'The law: An engine of trade'(2001) *Modern Law Review*, p.333-349.

²⁸ Generally class A and C, under the International Patent Classification system, established under the 1971 Strasbourg Agreement Concerning the International Patent Classification.

²⁹ IFPMA, 'Encouraging pharmaceutical R&D in developing countries' (2003) International Federation of Pharmaceutical Manufacturers Associations, Geneva, p.13-14.

³⁰ WIPO usually reports patent filings technology groupings with chemistry as a core group with subgroups in pharmaceuticals, biotechnology, etc, for example, http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/xls/wipo_pat_filings_technology.xls. Dutfeld G., 'The pharmaceutical industry, the evolution of patent law and the public interest: A brief history', in Westkamp G. (ed) *Emerging issues in intellectual property: Trade, technology and market freedom: Essays in honor of Herchel Smith* (2007) Cheltenham: Edward Elgar Publishing Limited, reviews and examines how chemistry was central to the origin and evolution of the pharmaceutical industry and patent law development.

³¹ Allison J.R. and Lemley M.A. 'Who is patenting? An empirical exploration of patent prosecution' (2000) *Vanderbilt Law Review*, p.2099-2174, p.2110.

biotechnology, pharmacogenetics and other types of technology upon which its innovative R&D techniques are embedded.³²

There are at least four main routes by which new pharmaceutical products are developed and brought into the public sphere. The four general sources of pharmaceutical inventions, which can either be stand-alone or integrated depending on a particular R&D programme,³³ are natural products, existing drugs, computer model screenings and the identification of the physiological mechanism of the disease.³⁴ Each poses its own set of contentious issues and consequences within the patenting regime, which will be addressed throughout the thesis, but will be outlined here.

Firstly, natural products give the oldest source of new medicines as biologically active natural compounds serve as chemical leads that are refined by scientists to give more specifically acting pharmacological compounds.³⁵ In fact there have been estimates

³² Laird noted that many small biotechnology firms are often called such, yet this is a misnomer since these are frequently technically involved in small-molecule chemistry rather than biotechnological work: Laird T. 'In praise of emerging pharmaceutical companies' (2006) *Organic Process Research & Development*, p.685-686. The biotechnology-based products market is dominated by biopharmaceuticals and are predicted to increase their market share (Bostyn S.J.R. *Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: an evaluation*, 2004, European Communities, Brussels, p.6) although some have doubted the potential to deliver adequate innovative pharmaceutical in view of the heightened expectations from biotechnology and the ensuing policy aligned to this overestimation (Nightingale P. and Martin P. 'The myth of the biotech revolution' (2002) *Trends in Biotechnology*, p.564-569). Also, pharmacogenomics, the use of genomic information to inform or predict pharmaceutical activity and response, has been hailed as presenting radical change in the pharmaceutical R&D process (Bostyn S.J.R. *Patenting DNA sequences (polynucleotides) and scope of protection in the European Union: an evaluation*, 2004, European Communities, Brussels, p.6) with some cautioning the potential of pharmacogenomics to deliver innovative pharmaceuticals, depending on how it is eventually absorbed into clinical practice: (Cook J., Hunter G. and Vernon J.A. 'The future costs, risks and rewards of drug development: The economics of Pharmacogenomics' (2009) *Pharmacoeconomics* p.355-363).

³³ Ohlmeyer M. and Zhou M. 'Integration of small molecule drug discovery in academic biomedical research' (2010) *Mount Sinai Journal of Medicine*, p.350-357, describes mechanisms to integrate small-molecule academic research in the discovery process in ways that incorporate the other sources of new pharmaceuticals. The importance of process inventions that brings about these products is examined in section 4.2.

³⁴ Ganellin C.R. and Roberts S. M. *Medicinal chemistry: The role of organic chemistry in drug research* (1993) London: Academic Press, p.122.

³⁵ Ibid, p.122. Turner D.M. 'Natural products source material use in the pharmaceutical industry: the Glaxo experience' (1996) *Journal of Ethnopharmacology*, p.39-44. Schmitt E.K, Moore C.M., Krastel P. and Petersen F. 'Natural products as catalysts for innovation: a pharmaceutical industry perspective' (2011) *Current Opinion in Chemical Biology*, p.497-504. South Africa, with abundant natural resources, has expressed the desire to protect natural products from inappropriate exploitation but the resulting protection frameworks are criticised as excessively bureaucratic, stifling innovation and commercialisation of South African-sourced natural products: Van Wyk B.E. 'The potential of South African plants in the development of new medicinal products' (2011) *South African Journal of Botany*,

that up to half of medical prescription have been for pharmaceuticals derived from natural substances.³⁶ The issue to address is how far the patentability laws and tests properly demarcate patentable subject matter, in terms of, *inter alia*, excluded subject matter, prior art or requisite contribution by the inventor to what will constitute a patentable invention. Secondly, in recent decades there has been a diminishing discovery of radical new drugs, with many more new drugs resembling the old.³⁷ The patent justification as an incentive for inventing has as a result become doubtful as more new drugs are seen as simple variants of the old. Thirdly, the screening of chemical models by computational or mathematical methods is a modern approach to pharmaceutical design³⁸ although ‘there is still a strong element of speculations in drug design and considerable uncertainty in achieving success.’³⁹ As a result only a small proportion of drug models become useful synthetic therapeutic agents in practice.⁴⁰ The issue raised in this instance is how the patentability requirements address mere scientific speculation posited as actual advance in the state of the art. Fourthly, the physiological mechanism route to new pharmaceuticals entails the in-depth investigation of the target disease pathways so as to find cures.⁴¹ However there have been accusations that ‘the target diseases selected for study in the pharmacological industry are generally those prevalent in western society.’⁴²

p.812-829; Myburgh A.F. ‘Legal developments in the protection of plant-related traditional knowledge: An intellectual property lawyer's perspective of the international and South African legal framework’ (2011) *South African Journal of Botany*, p.844-849.

³⁶ Eiland, M.L. *Patenting traditional medicine* (2008) Munich: Munich Intellectual Property Law Center; Bull A.T. and Stach J.E.M. ‘Marine actinobacteria: New opportunities for natural product search and discovery’ (2004) *Trends in Microbiology*, p.491-509. Some authors have reviewed the intense use of plant-based products in South African pharmaceutical R&D: Rybicki E.P., *et al*, ‘Plant-made therapeutics: An emerging platform in South Africa’ (2012) *Biotechnology Advances*, p.449-459.

³⁷ Abbott F.A. and Graham D.G. *Global pharmaceutical policy: Ensuring medicines for tomorrow's world* (2009) Cheltenham: Edward Elgar Publishing Limited, p.64-65.

³⁸ Kapetanovic I.M. ‘Computer-aided drug discovery and development (CADD): *In silico*-chemico-biological approach’ (2008) *Chemico-Biological Interactions*, p.165–176. Other computer-related fields or tools of pharmaceutical discovery, for instance bio-informatics will be explored in chapter four.

³⁹ Ganellin/Roberts, fn.31, p.138.

⁴⁰ Scholars have demonstrated that out of five million molecules screened by these models combined, only three to six lead to clinical studies and only one is eventually approved, Cloutier L.M. and Sirois S. ‘Measurement of innovation and intellectual property: Challenging process’, in Castle D. *The role of intellectual property in biotechnology innovation* (2009) Cheltenham: Edward Elgar Publishing Limited, p.206.

⁴¹ Croston G.E. ‘Functional cell-based uHTS in chemical genomic drug discovery’ (2002) *Trends in Biotechnology*, p.110-115; Patric G.L. *Introduction to medicinal chemistry*, 4th ed (2009) Oxford: Oxford University Press, p.187-196. Debouck C. and Metcalf B. ‘The impact of genomics on drug discovery’ (2000) *Annual Review of Pharmacology Toxicology*, p.193–208 illustrates the genomic approaches to drug discovery used at SmithKline Beecham for instance.

⁴² Ganellin/Roberts, fn.34, p.128. Although there are challenges in pharmaceutical development, these are addressed for instance through public-private partnerships of scientists in academia and industry

Therefore the patent system is perceived as biased towards the needs of developed nations in the health sector and also generally in technologies which foster development only prominently in developed countries.

It is apparent from the simplistic inventive process outlined above that a study focusing on pharmaceuticals is warranted as it also encompasses patenting principles germane to other technologies.⁴³ Moreover, the pharmaceutical industry deserves closer examination as it exhibits unique qualities evoking questions of the suitability of the patents system to protect these inventions. The pharmaceutical industry claims that the risks and costs of bringing the inventions to the market are exorbitant and could not be possible without the patent.⁴⁴ Because of the demands and needs of society, stringent safety studies alone for potential drugs can take more than three years and it typically takes ten to fifteen years to invent and develop a new marketable pharmaceutical.⁴⁵ The inadequacy of the patent grant to reward the efforts of inventors could, as a result, have devastating effects on the pharmaceutical enterprise. This research considers how appropriate patentability requirements could contribute to addressing those concerns in a way that is appreciative of the reality of industry.

1.1.2.3 The stakeholder under focus

It is also intended that the study simplifies the judging of whether an inventive idea

and has introduced multifunctional drug design strategies which have already reported some novel and validated molecular targets for the neglected tropical diseases: Cavalli A., and Bolognesi M.L. 'Neglected tropical diseases: Multi-target-directed ligands in the search for novel lead candidates against *Trypanosoma* and *Leishmania*' (2009) *Journal of Medicinal Chemistry*, p.7339-7359.

⁴³ Miller H.I. 'The impact of new technology on regulation by the FDA: Recombinant DNA technology' (1981) *Food, Drug, Cosmetic Law Journal*, p.348-353, p.348 notes that technology development in one area may give rise to advancement in very diverse technological classes.

⁴⁴IFPMA 'Encouraging pharmaceutical R&D in developing countries', 2003 International Federation of Pharmaceutical Manufacturers Associations, Geneva, p.12 and Festel G., Schicker A. and Boutellier R. 'Performance improvement in pharmaceutical R&D through new outsourcing models' (2010) *Journal of Business Chemistry*, p.83-96.

⁴⁵ Ganellin/Roberts, fn.34, p.139. The Treatment Action Campaign (TAC), a company at the forefront of the campaign for access to medicine for HIV/AIDS patients has for instance taken to court firms selling medicines of disputed efficacy and not having undergone robust clinical and safety standards: *Treatment Action Campaign and another v Rath and Others* [2008] ZAWCHC 34. Political support by Government and Cabinet of clinical trials of veridine, a compound developed by medical research scientists and claimed to halt the development of HIV into AIDS turned out to be misdirected in light of the subsequently discovered toxicity of the compound: Natrass N. 'AIDS and the scientific governance of medicine in post-apartheid South Africa' (2008) *African Affairs*, p.157-176. A turning point in the approval of new pharmaceuticals, which introduced rigorous preclinical safety evaluations, was with the thalidomide crisis: Avorn J. 'Teaching clinicians about drugs-50 years later, whose job is it?' *The New England Journal of Medicine*, p.1185-1187.

will meet patentability requirements, especially by industry players themselves before seeking legal counsel. There has been much reliance on the business communities for technological innovations in the past.⁴⁶ This self-assessment is important, given the rate of emergence of new technologies and their multi-disciplinary nature, which at times requires an understanding of the underlying rationale and policy for the set patentability standards in order to make informed patentability decisions.

The skill to discern whether inventions are patentable or not, and indeed whether patenting is a viable option is important for the inventor to learn for themselves or be competent in. This applies on a continuum from the small one-time inventor to large-scale multinational routine R&D entities.⁴⁷ The inventors are the ones who, in most cases, have intimate knowledge of their activities and business, their short-term and long-term R&D and competitive strategies and other financial considerations,⁴⁸ which they may not easily translate, if at all possible, to patent practitioners' briefings when contemplating patenting.⁴⁹ Indeed patent attorney firms have admitted to giving infringement advice on what they viewed as lost-cause-cases, only to have them being successful and what they thought had guaranteed chances of success eventually failing.⁵⁰ Patent filing practitioners may not necessarily be biased toward unnecessary

⁴⁶ Ginburg D.H. 'Antitrust, uncertainty, and technological innovation' (1979) *Antitrust Bulletin*, p.635-686, p.642.

⁴⁷ It has been observed that the discovery pipeline in large pharmaceutical firms has become depleted and that 'micropharma – academia-originated biotech start-up companies that are efficient, innovative, product-focused and small (having less than 25, and frequently less than 10 employees)', is filling this crucial pharmaceutical R&D gap: Barden C.J. and Weaver D.F. 'The rise of micropharma' (2010) *Drug Discovery Today*, p.84-87, p.85. As a comparison, the South African pharmaceutical industry is noted to comprise about two-thirds of the UK pharmaceutical industry, both in terms of the total number of pharmaceutical establishments and also the number of pharmaceutical establishments that have less than ten employees: p.80-81: *Barnes Reports: 2012 Worldwide Pharmaceutical Preparation Manufacturing Industry* (2011) Barnes and Co., available at www.researchandmarkets.com/reports.

⁴⁸ Although R&D is important for generating new inventions, however, given that not all R&D intensive firms patent their inventive outcomes, there have been multiple factors identified that affect industry's patenting propensity for instance whether R&D is internal or external to the firm, the size and age of the firm, simplicity or complexity of the invention and the codifiability of the knowledge: Perez-Luno A. and Valle-Cabrera R. 'How does the combination of R&D and types of knowledge matter for patent propensity?' (2011) *Journal of Engineering and Technology Management*, p.33-48. Commentators suggest that from an industry perspective, the 'patent-trade secret decision' is more complex in chemical based industries than in mechanical industries: Munson D.C. 'The patent-trade secret decision: An industry perspective' (1996) *Journal of the Patent and Trademark Office Society*, p.689-715, p.698-700.

⁴⁹ Dent, fn.19, p.157 claims that the translation process of the essence of the invention is inherently not perfect.

⁵⁰ Simmons and Simmons Report to EC Pharmaceutical Sector Enquiry, at p.6-7, http://ec.europa.eu/competition/consultations/2009_pharma/simmons_simmons.pdf. The quality of IP advice has at times been doubted: Phillips J. 'Good business, shame about the lawyering' (2010) *Journal of Intellectual Property Law and Practice*, p.129.

and indiscriminate patent application filing for patentable inventions,⁵¹ but by virtue of their filing specialism, may functionally be compromised towards general patenting without utmost regard for other available protection mechanisms.⁵² The response to a report that legal fees are disproportionately high,⁵³ by some legal practitioners conceding that there exists bias toward high predictable success cases⁵⁴ exacerbates these concerns. Indeed some commentators have equated the patent system to a lottery where the value in patents is related to predicted success of infringement litigation.⁵⁵

1.2 The importance the research

The relevance of patentability standards has been called into question in recent years. Accusations range from their allowing into existence of patented inventions that add nothing to the public fund of knowledge to actually preventing societal progress, particularly in pharmaceuticals.⁵⁶ In view of the aforementioned effect of patentability standards, improvement suggestions for a more effective domestic protection are made for the respective jurisdictions. This is in line with continual reforms that were necessitated by limited understanding of the patent system by domestic industrialists,

⁵¹ Empirical studies show that patents are not and should not exclusively be obtained in areas perceived as ‘high technology’: Allison J.R. and Lemley M.A. ‘Who is patenting? An empirical exploration of patent prosecution’ (2000) *Vanderbilt Law Review*, p.2099-2174.

⁵² Vaver suggests there could be a bias towards patents by practitioners: Vaver D. ‘Some agnostic observations on intellectual property’ (1990) *Intellectual Property Journal*, p.125-153, at p.140-141.

⁵³ Lord Jackson Review of Civil Litigation Costs, http://www.judiciary.gov.uk/about_judiciary/cost-review/jan2010/final-report-140110.pdf. Commentators, explaining increases in rates of patent litigation have stated that ‘in the presence of a court system that allows parties to drive up each other’s costs and treats patent holders preferentially, patents are a valuable instrument for the extortion of payments - irrespective of their ultimate validity status’: Harhoff D. ‘Challenges affecting the use and enforcement of intellectual property rights’, in UKIPO ‘The economic value of intellectual property: An agenda for policy relevant research’ (2009) Newport: Intellectual Property Office, p.111.

⁵⁴ <http://news.bbc.co.uk/1/hi/uk/8459897.stm>.

⁵⁵ Katopis C.J. ‘Perfect happiness?: Game theory as a tool for enhancing patent quality’ (2008) *Yale Journal of Law and Technology*, p.360-404, p.387-388; Also, Brunel, an engineer testifying before 1829 Parliamentary Select Committee on Letters Patent, stated ‘I think that patents are like lottery offices, where people run with great expectations, and enter any thing almost’: Ford P. and Ford G. *British Parliamentary Papers: Report from Commissioners and from Select Committees on letters patent with proceedings minutes of evidence, appendices and indices, Inventions- General I* (1968) Shannon: Irish University Press, Law Relative to Patents for Inventions, 1829 (332) Vol III, Select Committee (hereafter, 1829 Select Committee) and 1851 (486) Vol XVIII (hereafter, 1851 Select Committee), p.5.

⁵⁶ For instance, Adusei P. ‘Regulatory diversity as key to the ‘myth’ of drug patenting in Sub-Sahara’ (2010) *Journal of African Law*, p.26-50, asserting that the basis for sustaining the patent system is one of deception and myth for developing countries.

high rate of new technology emergence, high rate of patent litigation and associated expense. The patent administrators have reiterated the importance of patents in innovation and that if industrialists understood patents they would have clearly vigorously utilised them.⁵⁷ Patents and IP generally has become the very survival tool in this knowledge economy, where '[t]he movement of material goods is now much less important than flows of information and knowledge.'⁵⁸ It is said that 'in the commercial and business world, the development of new tactics and new strategies for deployment of IPRs for commercial advantage has been identified as the next corporate challenge on the battlefields of the knowledge economy.'⁵⁹

At the same time the thesis makes suggestions that allow for the coexistence of the respective domestic patent systems in the global context, as without this any perfect local patenting system could easily be circumvented and made ineffective if there is no reciprocal protection from other jurisdictions. It is anticipated that the study could ease the divide between developing and developed countries, in terms of the necessity and use of the system. As the principal justification of IPRs is economic, without proper understanding of the substantive and policy considerations, it is not a far-fetched notion that developing countries would essentially insist on a conspiracy by world powers to re-colonise and monopolise development through patents.⁶⁰

Another area of importance and a source of contention is that the patentability standards have a direct bearing on invention and innovation in the health sector.⁶¹ With inappropriate standards there would be the loss of potential R&D for new drugs,

⁵⁷ Innovation report: Competing in the global economy, December 2003, Department of Trade and Industry, UK.

⁵⁸ May C. *A global political economy of intellectual property rights: The new enclosures* (2000) London: Routledge, p.2.

⁵⁹ Soetendorp, fn.13, p.84.

⁶⁰ Patenting alliances between developed nation governments, the academia and pharmaceutical and biotechnology firms are said to have unfairly extracted from and controlled developing countries' potential wealth from natural resources: Ostergard R., Tubin M. and Altman J. 'Stealing from the past: globalisation, strategic formation and the use of indigenous intellectual property in the biotechnology industry' (2001) *Third World Quarterly*, p.643-656. Also, Rahmatian A. 'Neo-colonial aspects of global intellectual property' (2009) *Journal of World Intellectual Property*, p.40-74. It is acknowledged in this thesis that the North-South divide that is commonly used when patenting issues are dealt with is a rather loose historical grouping of different patenting systems between the wealthy and poor nations, but that does not exempt countries from possessing elements from either groups or being leaders in certain patenting sectors while lagging in other sectors.

⁶¹ Kettle H.E. 'Using intellectual property regimes to meet global health R&D needs' (2003) *Journal of World Intellectual Property*, p.655-683.

and thus exacerbating neglected tropical disease drugs and shunning of orphan drugs, a phenomenon whereby rare medical conditions necessitates R&D of special and specific pharmaceutical agents.⁶² According to Roin, when the patentability limbs are perceived to make no concessions for the development costs of pharmaceuticals by the weak effective patent protection they offer, this leads the pharmaceutical firms to screen and discard those that attract weak patent protection.⁶³ The obtaining of regulatory and marketing approval for one successful chemical entity represents costs in excess of a hundred million dollars for the US and European markets,⁶⁴ which in itself is prohibitively high to be compounded with standards perceived as inadequate for inventing. The thesis seeks to suggest what is a balanced patentability standard for these needs.

1.3 Research methods, sources and approach

1.3.1 The comparative method

Intuitively, a comparative legal study entails a comparison of a legal system with a foreign one,⁶⁵ but does not reveal the necessary methodological rigors to qualify as such. There are arguments for a strict and rigid approach on one hand and a flexible one on the other hand.⁶⁶ In its essence ‘[c]omparative law denotes a method of study and research, or is a technique...used for a variety of practical or scholarly purposes...the investigation of legal rules and procedures not of one system but in harness with the examination of the equivalent rules in at least another system.’⁶⁷ It is

⁶² Hemphill T.A. ‘Extraordinary pricing of orphan drug: Is it a socially responsible strategy for the U.S. pharmaceutical industry?’ (2010) *Journal of Business Ethics*, p.225-242, p.226-227.

⁶³ Roin B.N. ‘Unpatentable drugs and the standards of patentability’ (2009) *Texas Law Review*, p.503-570.

⁶⁴ Scherer F.M. ‘Pharmaceutical industry and world intellectual property standard’ (2000) *Vanderbilt Law Review*, p.2245-2254, p.2246, whilst other less conservative estimates suggesting costs of over 1.7 billion dollars, with only one in three products recouping those investments made, Abbott/Graham, fn.37, p.66.

⁶⁵ Saidov A. Kh. *Comparative Law* (2003) London: Wildy: Simmonds & Hill, p.22-23 asserts that study of foreign law is only a foundation and precursor to comparative law although these concepts do overlap.

⁶⁶ Watson A. *Legal transplants: An approach to comparative law*, 2nd ed, (1993) Athens: University of Georgia Press p.17-18, makes the case that systematic and detailed knowledge of the systems compared may not be necessary in some comparative endeavours.

⁶⁷ *Ibid*, p.1-2.

asserted here that the exact form of method adopted for the comparative activity is predicated therefore on the purpose for the comparison.

The categories of the comparative branch of law have been identified and divided in various contexts into three broad groups:- descriptive, which is the inventory of past and present rules either at an elemental or holistic level; historical, desiring to establish a universal history, which may sometimes be obscure, predicting the development of legal institutions; and the jurisprudential, seeking to establish 'the common trunk on which present national doctrines of law are destined to graft themselves as a result of both the development of the study of law as a social science, and of the awakening of an international legal consciousness.'⁶⁸ The view held in this thesis is that these are non-exclusive of each other and can be used in combination in furtherance to the purposes of the comparative enterprise.

The comparative law method has many purposes and justifications. The comparative method has been used *inter alia*:-

1. '[t]o contribute toward knowledge of the social world through the study of its legal aspects.'⁶⁹ It is in this purpose that legal scholars have sought to analyze how the law has been applied in society and the resultant shaping of society that could be expected from similar principles. 'The prime virtue of comparative law', writes Watson, is in its informative insight into the development of law and 'by means of it we should be able to isolate the factors which have led to real innovation in a particular society.'⁷⁰
2. To enhance one's knowledge and understanding of one's legal system.⁷¹ The comparing of ones own system with another, one can have an objective and enlightened view of their own system.
3. To 'harmonize or unify areas of law on a transnational basis to promote trade and economic activity across borders...' which can in turn give insight

⁶⁸ *Ibid*, p.3.

⁶⁹ Cotterrell R. *Law, culture and society: Legal ideas in the mirror of social theory* (2006) Hampshire: Ashgate Publishing Limited, p.130.

⁷⁰ Watson, fn.66, p.16.

⁷¹ Cotterrell, fn.69, p.130.

into the ‘power of legal cultures, for example, as barriers to harmonization of law.’⁷²

In light of these, the thesis adopts the comparative law method with the aims:

1. To elucidate and improve understanding of the legal and attendant social developments in the two jurisdictions’ patentability standards.
2. To suggest improvements of the respective jurisdictions’ legal systems in the area of patentability standards in light of unique developments in the other jurisdiction.
3. Ultimately, to contribute to the harmonization of the law of patents in relation to attainment of appropriate and optimal standards in a globalised society.

This is a thesis on substantive patentability law, but the influence of some significant socioeconomic factors will be acknowledged. But as Cotterrell⁷³ points out that ‘comparists tend to distrust *broad* social or legal theory that might purport to offer matrices for the *widest* legal and social comparisons’, the thesis adopts an approach that cautions against an indiscriminate clouding of substantive rules with socioeconomic issues, solutions of which may lie in other areas of law and governance. That is to say, the thesis is not a socioeconomic ignorant approach, but it cautions against using socioeconomic issues, prevalent in the pharmaceutical industry, to compromise the substantive rules.

Since the basic principles that underpin the doctrine of patentability standards in South African law have a large influence from English law,⁷⁴ the initial part of the research for this thesis involves an historical analysis of how patentability developed through the centuries from its English roots. Thus the UK is an archetypal type model

⁷² *Ibid.*

⁷³ *Ibid.*, p.127, emphasis added. Authors indeed suggest the need to understand technological change in relation to broader societal perspectives: Elzen B., Enserink B. and Smit W.A. ‘Socio-Technical Networks: How a technology studies approach may help to solve problems related to technical change’ (1996) *Social Studies of Science*, p.95-141.

⁷⁴ Cameron E. ‘Legal chauvinism, executive-mindedness and justice- L.C. Steyn’s impact on South African Law’ (1982) *South African Law Journal*, p.38-75, explaining the significance of English law in South Africa, much against repudiation attempts by Roman-Dutch law purists.

in the historical context. This section of the thesis is important for establishing the principles that now underlie both the English and South African justifications for the patenting system and the patentability standards. Due to the fact that the aim of the thesis is not principally historical, this part of the thesis will not consist of an exhaustive historical analysis of the entire spectrum of the development of the patenting concept but will introduce the periods that have remnant patentability principles and justifications that are still operative in the modern law of the two jurisdictions or have a philosophical and theoretical impact on its future. Indeed, Watson asserts that to avoid an arbitrary and non-systematic approach to comparative law there has to exist a relationship between the systems compared although the exact boundaries of such relationship cannot always be identified or defined in all areas or in all historical periods.⁷⁵

The bulk of the thesis is a comparative analysis of the contemporary substantive patentability standards in South Africa and the UK as representative of developing and developed countries, respectively under the N-S groupings. Although there are exceptions, South Africa can be considered representative as it is a middle-income country⁷⁶ as a number of other developing countries belonging to similar trading blocs⁷⁷ or international IP forums⁷⁸ or the Commonwealth.⁷⁹ Indeed, South Africa is ranked comparably within the same group as other African developing countries when using a composite index of technology capacity incorporating patents and scientific publications,⁸⁰ or under the Global Competitiveness Index.⁸¹ Grouping countries with similar characteristics in one variable does not eliminate disparities in other variables.

⁷⁵ Watson, fn.66, p.7-8.

⁷⁶ According to the World Bank Development indicators.

⁷⁷ Kahn M. and Reddy B.D. 'Science and technology in South Africa: Regional innovation hub or passive consumer?' Why South Africa matters' *Daedalus: Journal of the American Academy of Arts and Sciences*, p.205-234.

⁷⁸ Park W.G. (2008) 'International Patent Protection, 1960–2005' (2008) *Research Policy*, p.761–766.

⁷⁹ Wadlow C. 'The British Empire patent 1901 - 1923: the "global" patent that never was' (2006) *Intellectual Property Quarterly*, p.311-346, examines the historical attempts to create a Commonwealth supra-patent.

⁸⁰ Archibugi D. and Coco A. 'A new indicator of technological capabilities for developed and developing countries' (2004) *World Development*, p.629-654. Indeed South Africa has multiple R&D development partnership with fellow SADC countries: Konde V., Kapoor S. and Thorsteinsdottir H. 'Promoting an African Renaissance? South Africa's health biotechnology collaboration with Sub-Saharan African countries', in Thorsteinsdottir H. *South-South collaborations in health biotechnology: Growing partnerships amongst developing countries* (2012) New Delhi: International Development Research Centre.

⁸¹ Global Competitive Index 2013–2014, http://www3.weforum.org/docs/GCR2013-14/GCR_CountryHighlights_2013-2014.pdf, p16-19.

More importantly, South Africa belongs in the same common law family of laws as the other members, which allows the extrapolation of conclusions to the other members of the group.⁸² The UK could be generally considered representative of the European Patent Convention (EPC) Contracting States as they have an obligation to interpret patentability in a harmonized way.⁸³

The thesis in this section therefore suggests a move away from the blanket emulation of UK standards,⁸⁴ and adopts an approach that views the UK and South Africa as broadly representative of advanced and emerging countries in the quest for a standard that can be sustained in globalised environments. There is reference to other jurisdictions as although the UK and South Africa have commendable patenting activity, it is less than what other countries have accomplished.⁸⁵ Moreover, pragmatic patentability standards have to be in line with other jurisdictions due globalization and general harmonization and convergence.⁸⁶ It is at the same time necessary to remain true to the basic principles of the South African and British common law in conducting this exercise, or the proposed reforms would make no sense in the context

⁸² Epstein L. and King G. 'The rules of inference' (2002) *University of Chicago Law Review*, p.1-133, address the proper ways of making inferences of observed results to other jurisdictions, whilst Phillips J. 'Why history matters' (2010) *Vitoria University of Wellington Law Review*, p.293-316, argues that even within a set of seemingly similar common law jurisdictions or legal doctrines, the law is contingent and shaped by unique circumstances and context.

⁸³ Moreover, and distinct from EPC membership, there is bound to be a more unified development of the law within EU members as a result of the incoming unified patent regime. See ww.unified-patent-court.org. Established by two Regulations is the Unitary Patent, which is the first piece of the EU patent package, entered into force on 20 January 2013 and which will be applicable from 1 January 2014 or the date of the entry into force of the Agreement on a Unified Patent Court, whichever is later, and the Agreement on a Unified Patent Court [2013] OJ C 175/1, is the second piece of the EU patent package, signed on 19 February 2013 and will enter into force as soon as 13 states, including France, Germany and the United Kingdom, have ratified it. Once in operation this framework is predicted to 'slowly start generating "unified" patent case law', (England P. and Parker S 'Obviousness in the new European order' (2012) *Journal of Intellectual Property Law and Practice*, p.805-815), while others have predicted lack of uniformity in case law development because of the considerable discretion in practice and procedures in the local or regional divisions of the Unified Patent Court which may impact on substantive patent law of validity or infringement (Vary R. 'The Unified Patent Court puts European businesses at a competitive disadvantage' (2013) *The CIPA Journal*, p.249-252, p.249). There was concern from some judges and practitioners on whether or not the unitary framework should allow elements of substantive patent law to fall under EU law, by virtue of inclusion in a EU legal instrument and consequently interpreted by the Court of Justice of the European Union (Callens P. and Granata S. *Introduction to the unitary patent and the Unified Patent Court: the (draft) rules of procedure of the Unified Patent Court* (2013) AH Alphen aan den Rijn: Kluwer Law International, p.10 and p.27).

⁸⁴ The extent of the rejection of western archetypical patent system varies, with some calling for the total overhaul: Adusei, fn.56, p.31.

⁸⁵ For example, each of the three most active patent offices has a patent activity greater than that of the UK and South Africa combined: WIPO *WIPO Patent Report: Statistics on worldwide patent activities, 2007 edition* (2007) Geneva: WIPO.

⁸⁶ Due to globalisation and harmonisation of patenting systems for example through the TRIPS Agreement, EPC or the draft SPLT.

of the respective legal systems. Owing to its colonial past, the South African legal system is a mixed or hybrid legal system and one is able to extract suitable authority from both systems of law without straining the patentability principle out of context.

An important issue to consider in the comparative methodology is also the procedural differences that exist between these two jurisdictions' patenting routes. This thesis mainly focuses on the resultant post-grant patent and patentability assessment methods. These ought to be comparable for the two countries as they are based on fairly similar laws. The examination granting procedures are however different because in the UK there is actual examination of the applications against a set of rules and guidelines, which is not present in South Africa. Although it is not entirely under focus in this thesis there is likely to be some correlation between post-grant patentability standards with the pre-grant models.⁸⁷ The other difference is in the alternatives that a patentee may utilize to obtain a patent. In the UK there are the national, regional and international routes, while in South Africa there are the national and international routes, with the regional route only just still being contemplated.⁸⁸ These differences should be of minor consequence, if at all, because it is the resulting quality of the patents and the patentability assessment methods that are relevant and not the purely procedural elements.

1.3.2 Research Sources

As far as specific sources are concerned, the study relies mainly on the domestic statutes that have been amended *inter alia* to meet international obligations while at the same time remaining true to internal mandates.⁸⁹ The United Kingdom's Patents Acts of 1977 (Patents Act 1977) and South Africa's Patents Act no. 57 of 1978 (Patents Act 1978), and their subsidiary rules and regulations are central to this study. Since the majority of patents granted or litigated in the UK are under the EPC, and

⁸⁷ Allison J.R., Lemley A.M., Kimberly and Trunkey R.D. 'Valuable patents' (2004) *Georgetown Law Journal*, p.435-479. There is the basic assumption, or more from an inventor's point of view an expectation, that granted patents should reasonably stand against validity challenges.

⁸⁸ Membership to ARIPO still being contemplated but no official decision has made yet.

⁸⁹ Some sections of Patents Act 1977 were promulgated to meet EPC requirements. The Constitution of the Republic of South Africa, 1996, (South African Constitution) section 231, requires international instruments to conform to the constitution before it can take effect.

there is a persuasive influence by European decisions on the local judiciary,⁹⁰ the impact of the EPC will be assessed.⁹¹ The impact of internationally negotiated instruments, for instance the Agreement on Trade-Related Aspects of International Property Rights⁹² (TRIPS Agreement) will be assessed and so will the potential impact of the interminably negotiated SPLT or an alternative substantive patent law treaty and the appropriate pre-emptive input that each jurisdiction could make to its formulation to prevent what has been called ‘negotiating fatigue’.⁹³ There is now extensive literature on the ills of the TRIPS Agreement which, more usefully, could have been raised before the instrument was concluded.

1.3.3 Research Approach

As this is a comparative study, parallels are drawn between the two jurisdictions as well contrasting their approaches to testing patentability. In view of this, common international instruments, in the form of treaties, protocols and agreements are studied, as relating to the basis of establishing similar patentability standards. Relevant regional or Community legislation and practice are also studied for influence exerted on the respective domestic laws, which are central to this research. Case law, policy documents, practice manuals, reports as well as journals are examined before conclusions are made on whether the patentability standards are adequate for their continued relevance in pharmaceutical patent protection.

An auxiliary and triangulation component of the research method in this thesis was the carrying out of data-gathering fieldwork in the form of participant observations of

⁹⁰ House of Lords in *Conor MedSystems v Angiotech* [2008] UKHL 49 (*Conor*), was mindful of the decisions on the same patent made in the Netherlands. Also the Court of Appeal and the Patent Court looked at how a patent for an identical invention was decided in other EPC Contracting States in *Occlutech GmbH v AGA Medical Corporation* [2010] EWCA Civ 702.

⁹¹ The Unitary Patent is set to become relevant for patent law in the UK (see <http://www.epo.org/law-practice/unitary.html>) although some tactical forum manoeuvring by patentees and jurisdictional tensions between the local and regional courts are predicted to occur: Johnson A. ‘Unitary Patents and the Patent Court- Forum Shopping and jurisdictional battles’ (2013) *The CIPA Journal*, p.114-116.

⁹² Agreement on Trade-Related Aspects of International Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S.

⁹³ Matthews D. ‘Lessons from negotiating an amendment to the TRIPS Agreement: Compulsory licensing and access to medicines’, in Westkamp, fn.30, p.248, in reference to lack of prerequisite skill and competence on the subject matter to maintain emerging-country advantageous mandates in negotiations.

patent stakeholders in their dealing with the patentability doctrine in patent tribunals and other public forums. This entailed observational attendance at conferences and informal interaction with delegates. Observations also include conversations with subjects and impressions the researcher forms when studying the subjects.⁹⁴ The questioning carried out under the observations method is different from interviews commonly used in survey research where there is emphasis on a systematic and structural approach, although sometimes this rigidity can lead to responses reflective of the researcher's concerns than that of the subject.⁹⁵ The underlying premise for a flexible observation approach adopted in this thesis is that if something can be observed once, its occurrence is indeterminate⁹⁶ and thus this confirmatory method is not overtly concerned about standardisation and repeatability of result observed by or on a particular subject.⁹⁷ Overall, that is to say the observation method of choice in this thesis has a dual purpose; which is to establish the perceptions and interpretation of the law by the stakeholder subjects in instantaneous, unedited settings and also confirm the validity and practical applicability of conclusions made throughout this research. This exercise is especially directed at the invaluable body of tacit knowledge or opinion that is not or cannot be articulated, transcribed or conveyed through the standard documentary records that are of primary analysis in this thesis.⁹⁸

Research data-gathering is susceptible to subjectivity, which may render it of limited use in an objective study. Therefore, data obtained from observing subjects was treated with caution; as such the researcher maintained an outsider position with

⁹⁴ Flood J. 'Participant observation', in Clark D. (ed) *Encyclopaedia of law and society: America and global perspectives* (2007) Los Angeles: SAGE Publications, p.1081.

⁹⁵ Bryman A. *Social research methods*, 2nd ed (2004) Oxford: Oxford University Press, p.318-319.

⁹⁶ '...if one quite clearly seen something happen once, it is almost certain to have happened again and again. The burden of proof is on those who claim a thing once seen is an exception; if they look hard they may find it everywhere, although with some interesting differences in each case', Hughes quoted in Banakar R. and Travers M. (eds) *Theory and method in socio-legal research* (2005) Oxford: Hart Publishing, p.48.

⁹⁷ Bryman, fn.95, p.319-320. Also, ethnography, a long-term form of observation, is not overly concerned with validity and reliability in the conventional sense, Flood J. 'Socio-legal ethnography' in Banakar R. and Travers M. (eds) *Theory and method in socio-legal research* (2005) Oxford: Hart Publishing, p.34.

⁹⁸ Commentators have even said that the inadequacies of reported decisions may lie in them being the judges' snapshot of the case at a particular time and '...extremely important matters may be totally omitted from reported decisions': Schlanger M. and Lieberman D. 'Using court records for research, teaching and policy-making: The civil rights litigation clearinghouse' (2006) *UMKC Law Review*, p.153-167, p.161. Also, Blanck P.D., Rosenthal R., Hart A.J. and Bernieri F. 'The measure of the judge: An empirically-based framework for studying a judges' behavior (1990) *Iowa Law Review*, p.653-723, p.654, suggest that verbal and nonverbal behaviour and variables may have significant effects on trial processes and outcomes.

minimal interaction with subjects. Of related susceptibility to subjectivity are in-depth interviews because of the difficulty of mitigating subjectivity as a result of the proximity of the researcher to the subject. A common drawback to these research endeavours that include interaction with subjects is that the subjects tend to act or express opinion differently under study conditions than in normal circumstances.⁹⁹ Other practical inherent limitations can also stem from tendencies of institutions instilling a restrictive official code or even opinion, for employees to abide by in relation to communications with external entities.¹⁰⁰ Even under guarantees of confidentiality there could be reluctance by subjects to be interviewed. This was therefore decisive for not carrying out in-depth interviews in this thesis because unadulterated access to institutional personnel or records could not be guaranteed for both jurisdictions to make meaningful comparisons and conclusions.

If the researcher forms conclusions with objectivity as the guiding principle,¹⁰¹ publicly available observation data is helpful. The researcher has discretion to select information that they deem relevant. The value of such activity, for example, is that it extracts or interprets the data which may have been influential to the judge's decision but not contained in the case report.¹⁰² For instance, in *Teva UK Limited v Merck &*

⁹⁹ Glod F., Duprel C. and Keenan M. 'Foresight for science and technology priority setting in a small country: the case of Luxembourg' (2009) *Technology Analysis and Strategic Management*, p. 933-951, p.939.

¹⁰⁰ The views of interest groups are susceptible to advancing the mandates of that group without regard to balanced views. There is growing concern that even academic bodies now tend to follow an approach which can compromise the integrity of opinion or research output in terms of its objectivity. Pharmaceutical firms' sponsorship of medical journals has tainted reliability of research. Authors assert that in increasing the public understanding of science and research, the presentation of scientific facts must be done in a dispassionate and objective way even if one holds a different view morally or otherwise: Bodmer C. *The public understanding of science* (1986) London: J.R. Ruddock and Sons Ltd, p.4.

¹⁰¹ Attainment of the ideals of objectivity has been doubted but on a flawed assumption equating objectivity with neutrality, the former requiring detachment, which is 'an undeniably ascetic capacity to achieve some distance from one's own spontaneous perceptions and convictions' and interrogation of competing and alternative perspectives whilst the latter is usually unnecessarily assigned an inflated value requiring scholars to 'purge themselves of external loyalties' and wrongly assumed to be a prerequisite for good scholarship and is premised on 'disengagement from life': Haskell T.L. 'Objectivity is not neutrality: Rhetoric vs. practice in Peter Novick's *That Noble Dream*' (1990) *History and Theory*, p.129-157, p.132, 139-140.

¹⁰² For example it has been said that a formalistic law interpretation approach is problematic to the extent that it 'is a false pretense to objectivity... tended to 'disguise' and 'minimize' the role actually played by policy beliefs and personal preferences', King, fn.4, p.414. Scholars assert that 'while it provides appropriate answers to guide courtroom or classroom inquiries and is useful for generating theories, case analysis is too superficial to allow scholars to prove claims about what the law *is* in a broader context' and research scholars are urged to additionally employ social science research techniques for making claims on what the law is beyond case outcomes which may not explain the complexities of the court processes and therefore not totally satisfying in making future predictions of

Co., Inc.,¹⁰³ unlike Rennie, an expert witness for Teva and a natural orator held more reliable by the court,¹⁰⁴ a transcript of evidence by Sugrue, an expert witness for Merck, would not reveal the many instances of his answering questions with head nodding or shaking and occasional confused frowning, to which only towards the end of his testimony were there frantic reminders by the defendant's legal team that the court recording system only captures audio. In the end the judge finding the patent obvious, interpreted his evidence as lacking in balance and to be viewed with suspicion,¹⁰⁵ a reason which would not be evident to one reading the court transcript, and more so in the case report. However, to a participant observer for instance, this scenario could be suggestive *inter alia* of the fact that patentability assessment methods may in practice have subjective elements intolerant of a timid but punctilious scientist, not in agreement with ambiguously-framed technical questions posed by opposing counsel, to influence or even be decisive of patentability, as opposed to the validity of the science under investigation. Using the same observation principles, public lectures by legislators, patent administrators as well as academics and judges speaking or writing extra-judicially were used in this thesis to gather stakeholder views on patentability assessment methods or factors that have a bearing on patentability.¹⁰⁶ The qualitative research method, supplemented and triangulated with observations in this way helps elicit patentability factors that could be otherwise difficult to discover.¹⁰⁷

The study sought to interpret patenting policy beyond the stated policy in official documents and examine what may be understood as policy-in-action, which is the actual implementation of policy frameworks, rather than the merely stated ones.¹⁰⁸

similar events: Levine K.L. 'The law is not the case: Incorporating empirical methods into the culture of case analysis' (2006) *University of Florida Journal of Law and Public Policy*, p.283-301, p.300.

¹⁰³ [2009] EWHC 2952 (Pat).

¹⁰⁴ *Ibid*, para.124, 125 and 134.

¹⁰⁵ *Ibid*, para.28.

¹⁰⁶ Some observers have said 'this is the mostly oral tradition that constituted the professional consensus of judges and lawyers, transmitted through their learning exercises, their legal practice, their social activities, and their writings. This ...body of law cannot be known in full, of course, and goes beyond what judges and lawyers wrote about law, beyond even what they said to each other, to include what unspoken assumptions they must have shared': Seipp D.J. 'The law's many bodies, and the manuscript tradition in English legal history' (2004) *The Journal of Legal History*, p.74-83, p.75.

¹⁰⁷ The triangulating of different methods in social sciences assists in assessing whether different approaches offer similar conclusion, with each method rigorous in its own right although illuminating different dimensions of the same subject matter under analysis: Levine fn.102, p.286.

¹⁰⁸ To coin Roscoe Pound's celebrated phrase 'law in the books and law in action', Pound R. 'Law in the books and law in action' (1910) *American Law Review*, p.12-36.

These two, the stated goals and the implemented, are not necessarily concomitant. Patent administrator's policy-in-action can, for instance, become evident when there has to be a practice change as a result of a court decision by the ease with which that change is effected¹⁰⁹ or the reasoning advanced in multilateral forums negotiations for preference of particular features in the patent system.¹¹⁰ Such holistic policy analysis is of importance because the patent administrators are the usual first point of contact for inventors and innovators desiring protection and also have more influence in patent law reforms.¹¹¹

1.4 Research Questions

The research questions can be summed up thus:

What are the fundamental criteria of patentability standards that are the appropriate measure of patents deserving of protection? That is to enquire as to what are qualities or components of an optimal patent standard that the assessment methods seek to establish.

Do patentability standards in the UK and South Africa significantly differ? This enquiry also generally seeks to uncover whether patentability standards in advanced and developing nations, fundamentally differ. The significant difference refers to the likely difference in result in the prosecution and litigation of an equivalent patent in the two jurisdictions, and not a statistical significant difference; that is no statistical assumptions are made.

What do those differences, if any, tell us about the compatibility of patentability standards with the operation of the pharmaceutical industry in a globalised society?

¹⁰⁹ Instructive of the real policy would for instance be the UKIPO ease of practice change in the case of computer-implemented inventions following EPO approach of excluded subject matter in *CFPH LLC's Patent Application* [2005] EWHC 1589.

¹¹⁰ For instance, contributions to Strasbourg Convention or statements made at SPLT forum by the representatives of the respective jurisdictions policymakers could be suggestive of their policy.

¹¹¹ Patent Bills are brought to Parliaments usually by promotion of the patent office, and as such reflect their standing policy.

What reform is needed to attain an ideal patentability standard compatible with the needs of inventors and innovators from both jurisdictions in a globalised society?

1.5 Structure of the thesis

The thesis initially focuses on the English origins of patentability standards. The 1624 Statute of Monopolies was a parliamentary intervention to curb the royal prerogative of partially granting monopolies. On the other hand, with Britain's drive to catch-up with trade and technical competitors, an unintended consequence of the patentability definition included newness as inventions 'first to be imported' into Britain. The thesis examines the evolution of UK's patentability requirements from these unclear beginnings into a leading system of encouraging genuine invention and innovation. With the advent of knowledge economies, South Africa is contrary faced with preventing expropriation of its resources, and at the same time using the system to encourage invention and innovation. The thesis explores lessons for South Africa to fine-tuning the patentability standards and policy to harness these resources in the same drive of catching up in world trade and innovation, without compromising the patentability standards. Therefore the thesis explores the historical justifications that sustain the patentability concept and suggests a patentability model based on these.

Having analyzed the historical origins of the patentability doctrine in chapter two, the international obligations that now govern much of how the patentability doctrine is applied locally will be studied in chapter three. This is because countries are now bound by regional and international obligations for the existence of acceptable minimum standards¹¹² or pre-grant examination¹¹³ for effective patent protection. There will be a study of the international instruments that have some influence or exert control on the patentability requirements. In this chapter a universal patentability standard that is simultaneously realistic to the needs of both developing and developed nations is proposed.

¹¹² Regional obligations arise from ARIPO Agreement for which South Africa is an observer member or EPC in which the UK has membership; TRIPS sets minimum standards to be attained for patent and other IPR protection as a prerequisite for WTO membership.

¹¹³ The Paris Convention and the Patent Co-operation Treaty objectives.

Discoveries, computer programs and business methods are some of the areas that are often difficult to demarcate as patentable and are encountered within the pharmaceutical industry. In chapter four, an analysis will be made of the approach taken by the legislature, patent offices and courts for assessing patentability in cases where patentable subject matter demarcation is blurred. In this study, focus will be on cases where inventions have embodiments that have both patentable and unpatentable subject matter as such cases have aspects which are dispiriting to a potential pharmaceutical patentee whose typical activities integrate a range of unpatentable subject matter.

The cornerstone of any patent system is that it should grant monopolies in reciprocate for inventions that are new. South Africa and UK are jurisdictions of absolute novelty, located at the strict end of the patentability scale. Novelty is however threatened when, for example, inherent anticipation, a doctrine stating that everything explicitly or implicitly resulting from practising prior art is anticipated, is extended as a consequence of *Synthon BV v Smithkline Beecham plc*¹¹⁴ or by the South African Patents Amendment Act of 2005 requiring origin disclosure as a *pseudo* novelty requirement. This continuous novelty reformulation has major consequences for the way the prior art is to be viewed, the role of the skilled worker, experimentation and disclosure requirements. A comparative analysis of the newness tests will be made in chapter five.

A review by the United Kingdom Intellectual Property Office (UKIPO) of whether the inventive step is applied uniformly and objectively was carried out.¹¹⁵ The consultation process sought to assess and make reform proposals on whether the approach toward non-obviousness is set at the right level to fulfil the purposes of the patenting policy and system. In these contexts, chapter six will assess legislation, case law, and especially the *Windsurfing International Inc v Tabur Marine (Great Britain)*¹¹⁶ approach that has come to be applied, sometimes blindly, over the years in the Commonwealth, often coupled with heavy criticism. Attention in chapter six will be on whether the current methods of assessment non-obviousness tackle the problem

¹¹⁴ [2005] UKHL 59 (Hereafter, *Synthon*).

¹¹⁵ <http://www.ipo.gov.uk/press-release-20060203.htm>.

¹¹⁶ [1985] RPC 59.

of hindsight whereby views of the prior art or the inventive concept or the skilled worker's qualities distort the inventive quality of an invention when assessment is carried out.

At one end, there is great interest in the patenting of biotechnological, nanotechnological and genomic inventions given the very promising potential such inventions offer for the development of new pharmaceutical products. On the other hand, there is considerable legal uncertainty with respect to the statutory requirements for the patenting of such inventions, uses and applications of which may not yet be entirely clear when making the application. It seems timely to analyse the application of the criteria of industrial applicability to these inventions, and to make a comparison between South Africa and the UK in chapter seven.

A summary of the reforms as proposed throughout this study will be made in the concluding chapter. Considered reform, a little more than cosmetic if necessary,¹¹⁷ is recommended if a legal system is not optimally functioning or does not fulfil the industry purposes for which it was designed. Substantive patent law has various influential stakeholders whose points of view are critical to acceptance and implementation of reform, unsurprisingly the statutory reforms may be long drawn out legislative processes,¹¹⁸ extending beyond the timeframe and scope of this thesis. This chapter unifies the patentability conclusions made in this thesis.

¹¹⁷ Vaver is of the view that 'the system is out of touch with both business and ordinary public sentiment, and that major rethinking and overhaul are necessary if it is to come in line', p.1 <http://papers.ssrn.com/abstract=902793>. Some state that 'a legal order that has become obsolete and antiquated is a constant source of legal difficulties, for meaningful interpretation requires adaptation to the actual situations.': Sherman B. 'Patent law in a time of change: Non-obviousness and biotechnology' (1990) *Oxford Journal of Legal Studies*, p.278 -287, p.278.

¹¹⁸ Rooklidge W.C. 'Reform of the patent laws: the US experience in forging legislation from disparate interests' (2006) *Intellectual Property Quarterly*, p.1-15, p.3.

CHAPTER TWO

PATENTABILITY HISTORY

2.1 Introduction

The carrying out of a legal historical study that unearths historical lessons that could be learnt and advance legal principles is not a straightforward venture. This is because of some fundamental differences between history and law. According to Maitland, ‘the process by which old principles and old phrases are charged with a new content is from a lawyer’s point of view an evolution of the true intent and meaning of the old law; from the historian’s point of view it is almost of necessary a process of perversion and misunderstanding.’¹¹⁹ In writing legal history it has been suggested that we have ‘to realise that concepts familiar to us may have a profoundly different colouration in that other time... It requires that we be willing to subject our own presuppositions to testing and revision. Not incidentally, that willingness is also essential to good comparative work.’¹²⁰ As such, a careful historical inquest in a comparative context can provide valuable insight for the legal scholar. Authors have said that ‘to think fruitfully about the future of the global governance of IPRs we must examine the past.’¹²¹

There are many and varied reasons for tracing and reviewing patentability history. One of the reasons for analysing the history of the patenting system is that there are lessons to be learnt from the development of the patent system in the UK by South Africa as a developing country.¹²² The conclusions from such a study can also be carefully inferred to and adapted to other developing countries on how to adjust their

¹¹⁹ Maitland F.W. ‘Why the history of English law is not written’ in Fisher H.A.L. (ed) *The collected paper of FW Maitland* (1911) Cambridge University Press, Cambridge, at p. 490. *Cf.* Some argue that there is a commonality of interest on the past between the historian and the legal historian or scholar: Rose J. ‘Studying the past: Nature and development of legal history as an academic discipline’ (2010) *Journal of Legal history*, p.101-128.

¹²⁰ Webber J. ‘The past and foreign countries’ (2006) *Legal History*, p.1-11.

¹²¹ May C. and Sell S.K. *Intellectual property rights: A critical history* (2006) London: Lynne Rienner Publishers Inc., p.5.

¹²² There are objections to this view; from unsuitability and incompatibility of the patent system to the economic and developmental needs of developing countries to views that this is the ‘downward inheritance.’ For example see Benoliel D. and Salama B. ‘Towards an intellectual property bargaining theory: The post-WTO era’ (2010) *University of Pennsylvania Journal of International Law*, p.265-368.

patent systems to meet contemporary needs and achieve what developed countries have achieved in the patenting arena.¹²³

On the other hand, through an understanding of the typical evolution of the patentability requirements, developed countries would be in a position to have objective and realistic expectations of developmental stages that emerging economies may have to go through, before expecting workable patentability standards.¹²⁴ In fact, an appreciation of the history of the South African patent system and that of other developing countries could result in the UK and the developed world, adjusting their local patentability standards if the ‘global patent’ is to be a reality.¹²⁵ A re-assessment of the patentability history could thus be seen as an enquiry that could reveal new patterns and improved interpretations from the foreign law and demonstrate vital linkages in trans-boundary concepts that were in existence in the two jurisdictions being compared. Indeed, the Law Commissions Act¹²⁶ allows Commissioners in law modernisation and reform ventures to ‘obtain such information as to the legal systems of other countries as appears to the Commissioners likely to facilitate the performance of any of their functions.’ One such tool could be the historical analysis of the laws in South Africa.

It is indeed prudent for IP policy-makers, and practitioners alike, to reflect on the history of the patentability requirements and extract the principles and justifications that made the patent system subsist, so as to continually improve the system. They should also analyse the weaknesses of the patent system, exposed in its the re-assessment of history, in order to avoid making the same mistakes, or persist in following less beneficial patent customs, in principles deducible from the historical study. A practice grounded on incorrect or imprecise historical principles could have

¹²³ Van Caenegem W. ‘Intellectual property and the idea of progress’ (2003) *Intellectual Property Quarterly*, p. 237-256, p.238-239.

¹²⁴ May/Sell, fn.121, p.97 argue that patent legislative development followed specific paths and was dependent on particular national socio-legal cultures and economic development. Also, Niosi J. ‘Complexity and path dependence in biotechnology innovation systems’ (2011) *Industrial and Corporate Change*, p.1795-1826.

¹²⁵ The global patent here refers to the continuous harmonisation of substantive and procedural patent rules that seek to standardise IP concepts worldwide. The ultimate goal seems to be supranational patentability standards. Whatever the policy reasons are for sustaining differing domestic regimes, from the perspective of the inventor or innovator there is the yearning and need to protect inventions or innovations in a global context or have the option of obtaining simple cover across borders.

¹²⁶ Law Commissions Act of 1965, s3(1)(f).

dire consequences for the pharmaceutical industry where unsuitable regulation has far-reaching adverse effects into the public sphere. These are some of the reasons that warrant a study of the history of the patentability requirements.

A cautionary note to this comparative historical analysis is that the current patentability principles may have been influenced by unknown or less understood underlying factors, which may have been wrongly attributed to a certain element of the patenting system.¹²⁷ Therefore a clear understanding of the foundational principles and underlying policies that were at play when the patent system was in its developmental stage is important. This is especially true as the retrospective viewing of the material facts of a historical legislative concept, sometimes called a revisionist approach, can blur objectivity from the overanalysis, if not exaggeration, of historical principles to the simple subjective interpretation of historical facts or legislative provisions in both jurisdictions.¹²⁸ The South African judiciary, cautioning on haphazard historical citations has put it thus: ‘it may be useful... to trace the history and wording of the corresponding and related sections of previous legislative measures passed in this country as well as in England, and to consider judicial interpretation (if such exists) thereof in both countries.’¹²⁹

In this chapter, there is an exploration of how the historical methodology can be used and reflected upon to bring about an interface in the needs and aspirations of the UK and South Africa patenting regimes in encouraging and protecting inventions by the appropriate patentability standards. This is achieved by examining the historical justifications of the patenting systems; a pivot of this chapter. From the onset, it is recognised and acknowledged that the patent system does not necessarily fit into any of the historical justification models perfectly, but that does not mean there should not be a quest for a unifying thread amongst these. This approach assumes that the

¹²⁷ There are disagreements on what exactly made the patenting system successful. There are the classical examples of countries that were successful in industry and development without patents or only introduced patents later on in their development cycle. Switzerland refused to introduce patents and Netherlands withdrew their patenting systems yet they are considered relatively developed countries.

¹²⁸ It has been argued that ‘historical facts are seen as prior to and independent of interpretation: the value of an interpretation is judged by how well it accounts for the facts; if contradicted by the facts, it must be abandoned. Truth is one, not perspectival’, Novick P. ‘That noble dream: The “Objectivity Question” and the American historical profession (1988) Cambridge: Cambridge University Press, p.6

¹²⁹ Viljoen J, in *The Advance Transformat Co v The Registrar of Patents and Basic Products Corporation* 11/1/1967 SAPJ 40, p.41.

justifications commonly employed for the subsistence of the patent system are not mutually exclusive especially under the widely accepted view that patents have a utilitarian foundation or function.¹³⁰ This chapter argues that the various classical justifications for the patenting system are all valuable in the attainment of a system that will result in balanced contemporary patentability standards. That leads to the notion that the philosophical and legal theories adopted and embraced in this thesis are mixed and non-exclusive. A synergistic approach towards patentability standards between the so-called North-South is the ideal way a functional global patent system would continue to exist and be refined.¹³¹

The approach that is taken in studying the patentability history is hinged on extracting principles underpinning or influential in patentability development or its philosophical justifications in order to develop a model based on an integrated view of the different justifications. This part of the thesis, therefore, will not be an exhaustive historical analysis of every period in the evolution of British and South African patent laws, but will be devoted only to the significant milestones in the historical development of the English patent law that was inherited into South Africa and continues to have authority, persuasive or otherwise.¹³² It is noted though that sometimes the selection of periods may lead to skewed assessments, therefore vigilance will be exercised when making extractions. Some patenting aspects unique to South Africa and developed in South African law will also be considered.

2.2 The need for the historical analysis

Intuitively, history could be viewed as the study of the past. The historical standpoints that could be taken are varied. One approach is to seek to extract objective historical meaning from the past as opposed to the intentions of the authors of the historical

¹³⁰ The leading justification is the utilitarian: Hettinger E.C. 'Justifying intellectual property' (1989) *Philosophy and Public Affairs*, p.31-52, p.47-51.

¹³¹ Phillips, fn.98, p.227.

¹³² The influence of English law in South Africa is encapsulated in *Estate Wege v Strauss* 1932 AD 76, p.80, where Wessels AJ stated that 'The draftsman of a Union statute may find it convenient to use the same words as a similar section in an English statute, but it does not follow that our legislature must be considered to have thereby not only the words of the section but the meaning which English courts have given that section as interpreted in the light of English common or statute law.'

records.¹³³ The reporting of Sir Cooke, who reported mainly on cases at the Chancery division, has been doubted by some although he is considered one of the greatest practitioners in English legal history.¹³⁴ The criticism lies in his conflation of personal observation and professional opinion in the cases he reported. Some authors have doubted the existence of objective historical recording, stating that '[w]ether a detached and unbiased history can ever exist is another question.'¹³⁵ History methodology can therefore be seen as the delicate art of selecting and describing moments from the entirety of the past to set them, not necessarily in a sequential order,¹³⁶ as significant principles in order to make deductions and inferences.¹³⁷ The analysis then attaches importance to the selected information or evidence, by the creation of informational models so as to explicate other current or future points in issue.¹³⁸ Even micro-histories, the study of relatively smaller epochs can be instructive in this regard.¹³⁹ For instance one could benefit from the study of the negotiation history in the making of a treaty that drastically changes long-established concepts even though that history may relatively span a short period compared to the longer time period of unchanged custom followed before. The models deduced from such a study may be attributed with meaning and consequences to the advancement of the patentability concept.

¹³³ Brown V. 'On some problems with weak intentionalism for intellectual history' (2002) *History and Theory*, p.198-208.

¹³⁴ Powell D. 'Coke in context: Early modern legal observation and Sir Edward Coke's Reports' (2007) *Legal History*, p.33-53.

¹³⁵ Melton B.F. 'Clio at the Bar: a guide to historical method for legists and jurists' (1998) *Minnesota Law Review*, p.377-472, p.382. Walsh W.H. 'Truth and fact in history reconsidered' (1977) *History and Theory*, p.53-71, analyses the difficulties encountered in historical narratives of events.

¹³⁶ Posner R.A. 'Past dependency, pragmatism and critique of history in adjudication and legal scholarship' (2000) *University of Chicago Law Review*, p.573-606.

¹³⁷ Spinello R.A and Bottis M. *A defence of intellectual property rights* (2009) Cheltenham: Edward Elgar Publishing Limited, at p. 37. Also Phillips J. and Simon I. 'Going down in history: Does history have anything to offer today's intellectual property lawyer' (2005) *Intellectual Property Quarterly*, p.225-235, p.227.

¹³⁸ Kang Y. H. 'An exploration into law and narratives: The case of intellectual property law of biotechnology' (2006) *Law Critique*, p. 239-265, p.257. The use of historical evidence in making persuasive arguments at adversarial settings or trials at the expense of historical scholarly standards and methodologies is identified as one source of the controversy and difficulty in the use of history in the interpretation of law which can lead the courts to 'erroneous but authoritative interpretation of historical fact': Festa M. 'Applying a usable past: The use of history in law' (2008) *Seton Law Hall Review*, p.479-553, p.538.

¹³⁹ Phillips J. 'Why legal history matters' (2010) *Victoria University Wellington Law Review*, p.293-316, p.313-314. Levi G. 'On microhistory', in Burke P.(ed.) *New Perspectives on Historical Writing* (1991) Cambridge: Polity Press, p.96, regards micro-history as 'the starting-point for a broader move towards generalization.'

The historical model-building exercise when unchecked has the tendency to be subjective.¹⁴⁰ In such a situation, it could be suspected that historical accounts from the viewpoints of historians in advanced nations would, needlessly, tend to be contextually-deficient on undesirable past moments in colonial patent development; a patriotic inclination of sorts.¹⁴¹ As a counter-measure, the legal historical narratives of European scholars have been challenged through the broadening of ‘the history of global order to encompass inter-imperial politics, including legal relations of imperial power and indigenous subjects.’¹⁴² For a more balanced and objective historical perspective, there is the need to engage the views of legal historians acquainted with the patent systems that were on the receiving end of a non-ideal colonial legal order.

The objective and the subjective elements of the legal historical methodology are susceptible of being superimposed upon one another. This would largely emanate from the purpose and the subsequent fashion in which the research is carried out. The outcomes of historical research and legal research are different as legal ‘practitioners are not usually trained to conduct historical research. The skills that are developed at law school and in practice focus upon the success for the client and not methods or techniques of historical research’,¹⁴³ such that objective and balanced policy formulation from such historical research when used in non-versarial circumstances would likely to be of limited value. This can result in the accumulation of unhelpful historical data of a subjective nature.¹⁴⁴ These superfluous tendencies are further compounded by the fact that there is a propensity for legal researchers to cite large amounts of historical data without distilling deductions or inferences relevant to

¹⁴⁰ Melton, fn.125, p.424. Also, <http://www.open2.net/historyandthearts/history/disagree.html>.

¹⁴¹ For instance, European lawyers’ accounts described legal order in colonies as settled, for example, that the British reserved the right to dictate and intervene in legal affairs, when in fact, there were still sources of conflict for imperial legislative administration or the viability of imposing imperial constitutions, *inter alia* in southern Africa. See generally, Benton L. ‘From international law to imperial constitutions: The problem of quasi-sovereignty, 1870-1900’ (2008) *Law and History Review*, p.595-619. Also see, generally, Rahmatian A. ‘Neo-colonial aspects of global intellectual property’ (2009) *Journal of World Intellectual Property*, p.40-74.

¹⁴² Benton, fn.141, p.595.

¹⁴³ Bourgeois D. ‘Role of the historian in the litigation process’ (1986) *Canadian Historical Review*, p. 195-205, p.197.

¹⁴⁴ Scholars state that ‘the court must exercise caution in its reliance on scholarship cited by appellant and appellee. While that could be said about almost anything the parties submit to the court, there can be a certain disarming veneer of objectivity-or credibility-accompanying pragmatic scholarship’: Nard C.A. ‘Toward a cautious approach to obeisance: The role of scholarship in Federal Circuit patent law jurisprudence’ (2002) *Houston Law Review*, p.667-692, p.686.

contemporary issues.¹⁴⁵ The pharmaceutical patent is sometimes cited in unfavourable light within a large body of historical patent custom without the necessary connections to an objective benchmark.

When the history of patentability standards is not properly applied, it can lead to the mere academic accumulation of unchecked and unrefined information that is not helpful to current and future patentability issues.¹⁴⁶ For instance, justifications that were in existence in one jurisdiction through statutory grounding may not necessarily be applicable in another. More precariously, as it has been observed that ‘legal educators did not train students in critical skills of historical analysis’,¹⁴⁷ it can stifle the development of IP law wherein patentability stakeholders try to fit patenting development into a rigid historical model. For example, if an obscure classical justification comes to the fore in patent debates, it may be rejected offhand whilst it may unlock some solutions in the contemporary patentability landscape. Therefore, while such historical data has a possibility of being useful, its use is optimal when its consequence or impact is clarified,¹⁴⁸ especially in such a comparative study of jurisdictions in different developmental stages, both in law and in economics.

The pharmaceutical industry in one perspective has seen gradual change over the decades, even though there have been periods of exponential growth and radical inventions.¹⁴⁹ Observers have noted how even the radical changes in technology in this sector has been comfortably absorbed by the successful firms.¹⁵⁰ As such, the

¹⁴⁵ Macleod C., Tann J., Andrew J. and Stein J. ‘Evaluating inventive activity: the cost of nineteenth-century UK patents and the fallibility of renewal data’ (2003) *Economic History Review*, p.537-562. Sometimes legal scholarship may be of limited value to the bar or the bench, and if relevance to practice is not clarified ‘academic criticism of the courts is likely to be ineffectual’: Nard C.A. ‘Empirical legal scholarship: Reestablishing a dialogue between the academy and the profession (1995) *Wake Forest Law Review*, p.348-368, p.348.

¹⁴⁶ Phillips/Simon, fn.137, p.227.

¹⁴⁷ Kirkby D. ‘Law[yer]’s history, conversationally speaking’ (2003) *Australian Journal of Legal History*, p.47-52, p.48.

¹⁴⁸ Phillips/Simon, fn.137, p.234.

¹⁴⁹ Lee J. ‘Innovation and strategic divergence: An Empirical study of the U.S. pharmaceutical industry from 1920 to 1960’ (2003) *Management Science*, p.143-159. The industry products have evolved slowly even though the operations strategies have significantly changed, especially into R&D for the successful firms. Some commentators assert that the exponential growth in technological development may be approaching either its economic limit or physical limit after which the rate of invention and innovation on technology development will diminish: Huebner J. ‘A possible declining trend for worldwide innovation’ (2005) *Technological Forecasting and Social Change* p.980–986.

¹⁵⁰ McKelvey M.D. ‘Discontinues in genetic engineering for pharmaceuticals? Firms jumps and lock-in in system innovation (1996) *Technology Analysis and Strategic Management*, p.107-116.

propositions made throughout this thesis are founded on the dynamic and evolutionary nature of the patentability standards corresponding to this type of change. For this type of research, the function of historical analysis is manifest.¹⁵¹ On the other hand, some politically or economically charged historical debates may be masquerading as legal roots of patentability requirements,¹⁵² whilst in fact, may not have that much relevance in this study. Thus, there is a need to be careful when deducting the relevance of the statutory milestones in the development of patentability standards.

In the exploration of history, the presumption that contemporary IP law and patentability assessment methods have been influenced by historical development is made.¹⁵³ However, scholars have stated that '[n]o two instances are exactly alike; they are never sufficiently identical for us to say that what was best on one occasion will also be best on another.'¹⁵⁴ Therefore as a limitation, the history of patentability requirements and the lessons it offers are not assumed to be automatically transferable without qualification to a different time period or different jurisdiction. As such, caution is exercised when making English inferences to South Africa. This is more pronounced in pharmaceutical industries where there were different competition rules, price controls, and different investor environments at play in the different localities.¹⁵⁵

Furthermore, although history is by and large descriptive, it is contended that despite its limitations when properly utilised it can also be prescriptive.¹⁵⁶ It is in this context then, that reference and reliance on other jurisdictions not in focus in this thesis can be introduced to develop the ideal patentability model sought, if they underwent similar circumstances or applied similar patentability standards. The courts in different

¹⁵¹ Phillips/Simon, fn.137, p.229.

¹⁵² See generally Aldashev G. 'Legal institutions, political economy, and development' (2009) *Oxford Review of Economic Policy*, p.257-270, arguing that the proper understanding of the legal determinants of a legal system must be accompanied by the integration of the historical, political and other factors as the understanding of the effects of substantive law requires analysis beyond the laws on paper into other complex interactions of the law with institutional characteristics and causality features outside of the law.

¹⁵³ Kang Y. H. 'An exploration into law and narratives: The case of intellectual property law of biotechnology' (2006) *Law Critique*, p.239-265, p.258. Also, Phillips/Simon, fn.137, p.228.

¹⁵⁴ Hegel G.W.F (translated by H B Nisbet B.H.) *Lectures on the Philosophy of World History: Introduction: Reason in history* (1975) Cambridge: Cambridge University Press, p.21.

¹⁵⁵ Ginburg, fn.46. Djolov G.G. 'Patents, price controls and pharmaceuticals: Considerations from political economy' (2005) *The Journal of World Intellectual Property*, p.611-63.

¹⁵⁶ Phillips/Simon, fn.137, p.229.

jurisdictions are accustomed to considering each other's previous decisions, even though they may not necessarily follow them.¹⁵⁷

The postulation that history is authoritarian to future ideal patent law developments is not absolute.¹⁵⁸ Indeed, commentators have observed that empirical analysis of originally efficient laws that are then prescribed for emerging jurisdictions suggests that sometimes there is subsequently no significant correlation between the legal protection afforded by prescribed statutes and the effectiveness of enforcement of those statutes.¹⁵⁹ This is due to the 'transplant effect' whereby countries inherit model laws developed in another jurisdiction, which are unsuited to their environment.¹⁶⁰ It is for this reason that observers¹⁶¹ are supported in their assertion that the developing countries should carefully choose only the elements that are helpful to them when they study the development of advanced nations' patent systems.

In using the historical method, the question that then arises is to what degree the application of historical methodology has influence over patentability standards in an era subject to regional and international obligations. That is to highlight that individual countries can no longer exist in isolation and are not immune to external influence, particularly because the pharmaceutical enterprise is largely global. To avoid being overambitious, this thesis does not assume that all elements of patentability standards are susceptible to the application of historical methodology. Statute-making has other considerations that may override the historical lessons from

¹⁵⁷ Mak E. 'Why do Dutch and UK judges cite foreign law?' (2011) *Cambridge Law Journal*, p.420-450.

¹⁵⁸ Liu D. 'Reflections on the lack of a patent system throughout China's long history' (2009) *The Journal of World Intellectual Property*, p.122-136, p.123. It has been noted that in the early stages in the introduction of new technology or evolution of an immature industry, there is a period of openness to various viable patentability standard that may be chosen, but once random events chose a particular path, that patentability choice becomes locked-in irrespective of the advantages of the alternative frameworks that may be considered the best: Thambisetty S. 'Increasing returns in the patent system: Institutional sources and consequences for law', LSE Law, Society and Economy Working Papers 7/2009 <http://ssrn.com/abstract=1344761>, p.3-4.

¹⁵⁹ Generally, Berkowitz, D., Pistor K. and Richard J.F. 'The transplant effect' (2003) *The American Journal of Comparative Law*, p.163-204.

¹⁶⁰ *Ibid*, p.164-165.

¹⁶¹ Maskus K.E. and Reichman J.H. 'The globalization of private knowledge goods and the privatization of global public goods' (2004) *Journal of International Economic Law*, p.279-320. UK Secretary of State for International Development has urged developing countries to carefully consider the impact of internationalization on patentability issues on their localities: Hansard written answers 24 May 2006, column 1782W.

the international arena or foreign jurisdictions.¹⁶² Moreover, the political process of promulgating laws can result in unexpected outcomes. However, the historical method is not to be abandoned just because there are now international obligations and compromises in international patent law-making or the local hurdles.¹⁶³

A delicate issue that arises in the historical analysis inference reasoning used for patentability standards of different jurisdictions in different eras is the impact of the differing socioeconomic settings.¹⁶⁴ The reality is that contemporary South Africa has different obligations and practices to that which the UK had during its development stages. The dictates of today's patent laws are centred much on international consensus and trade-offs in exchange for participation in international trade. The conception of the British patent system was in the era of colonialism when activities were mainly for the benefit of the Crown. The British and the industrialised economies were free to develop their laws as they saw fit and for the development of their economies.¹⁶⁵ The colonies were seen as extensions of the empire and the laws not particularly designed for their benefit. It has been noted that even though some colonies resisted the patent laws that they perceived as only of benefit to the UK businesses, the resultant laws they made themselves in turn resembled the UK laws.¹⁶⁶ The issue that cannot be addressed with absolute certainty therefore is the extent to which the different contemporary obligations that South Africa has a distortion of our historical analysis and conclusions.¹⁶⁷

¹⁶² Drewry G. 'Law-making systems– how to compare' (2008) *Statute Law Review*, p. 100-110, p.105-107.

¹⁶³ De Vos P. 'A bridge too far? History as context in the interpretation of the South African constitution' (2001) *South African Journal on Human Rights*, p.1-31: asserts that although the use of history in legal adjudication may be problematic, it must be deployed, not with grand narratives, but with acknowledgement of the increasing plurality of views in a more inclusive society.

¹⁶⁴ The UK Commissions to review and reform Patent Law of 1829 and 1852 was very much interested in how other countries with different socioeconomic settings to the UK set up and utilized their patent systems.

¹⁶⁵ The resources of the colonies were extracted, not with particular regard to appropriate benefit or compensation. Generally, Wadlow, fn.79.

¹⁶⁶ Finn J. 'Particularism versus uniformity: Factors shaping the development of Australasian intellectual property law in the nineteenth century' (2000) *Australian Journal of Legal History*, pp113-133, p.121.

¹⁶⁷ For example in *Genentech Inc's Patent* [1989] RPC 147, para11.02 Whitford used historical analysis as the basis for the departure from authority in light of the provisions of the Community Patent Convention obligations which were not there when the precedent was established.

There is the view that developing countries could be allowed greater freedom in developing their patent laws.¹⁶⁸ This compensation mechanism would be for the fact that Britain, together with the other advanced nations, historically had no external rules to contend with compared to what is now expected of developing nations. The difficulties in such compromises would lie in the way this could be achieved or implemented practically. To achieve the lessening of international patent obligations, an ingenious strategy by the developing countries has been to shift the patent governance regimes to forums and platforms where they have dominant power to advance the liberalisation of external encumbrances in patentability.¹⁶⁹ In any case, insofar as to the comparison of the past experiences of free developed countries with the present needs of bound developing countries, there is some degree of contrasting two different situations which the thesis is mindful of.¹⁷⁰ While using the historical method and historical concepts, there has to be vigilance in making inferences to differing jurisdictions. Thus it can be concluded that researchers and scholars should take care before applying history and the methodology of history to present and future patentability issues.

2.3 Historical development of the patent

Commentators have said that '[p]erhaps the most obvious issue that has promoted historical comparisons is the link between the protection of IP and development.'¹⁷¹ The UK is in many respects well developed and it has a longer patent history than South Africa. In addition it was a colonial ruler of South Africa, which has connotations of power and prosperity. This may be indicative of legislative

¹⁶⁸ Phillips/Simon, fn.137, p.226. Commentators have criticised some North-South IPR models, proposing compensations for the welfare losses in the South ensuing from adoption of higher IPR protection, on the basis of their disregarding of specific domestic effects from implementation of local innovation systems: Forero-Pineda C. 'The impact of stronger intellectual property rights on science and technology in developing countries' (2006) *Research Policy*, p.808–824, p.821-82

¹⁶⁹ Helfer L.R. 'Regime shifting: The TRIPS Agreement and new dynamics of intellectual property lawmaking' (2004) *The Yale Journal of International Law*, p.1-83. Sell S.K. 'TRIPS was never enough: Vertical forum shifting, FTAS, ACTA and TPP' (2010) *Journal of Intellectual Property Law*, p.447-478, suggests that the regime-shifting mechanism is more complex and is directed to a variety of ends.

¹⁷⁰ As a cross-country comparative law tool, a systems approach has been proposed, whereby divergent legal systems or countries or backgrounds can be usefully compared notwithstanding their differences: Drewry G. 'Lawmaking systems— how to compare' (2008) *Statute Law Review*, p.100-110.

¹⁷¹ May/Sell, fn.121, p.204.

differences that would be expected in a comparative study between the two jurisdictions in such a position. However, this difference does not detract from the historical comparison of the two jurisdictions.¹⁷²

The end goal is not to force similarities whilst overlooking the difference in the two systems. Attention now turns to historical elements that influenced the development of patentability limbs, within the context of progress and development, in each of these two countries' own rights.

2.3.1 The historical development of the British patent

'The law of patents...has a surprisingly long history.'¹⁷³ Although, patents are one of the old creations of law, their considered economic analysis is a relatively modern phenomenon that has considerably progressed and transposed into policies and backbones affecting every facet of the patent framework.¹⁷⁴ It is largely agreed that the patent system is a contributory catalyst for invention and technological development.¹⁷⁵ However, much of the historical justification of the system is based on a retrospective perspective through re-assessment of the historical record and economic rationale that may have been absent at the conception of the system. The thesis now traces the British evolution of the requirements of patentability from its embryonic stages to the powerful legal and largely economic tool that it is today.

The exact establishment of patenting laws almost eludes written record.¹⁷⁶ Prior to the establishment of IP laws in Europe, rulers usually used grants for the exclusive

¹⁷² Cotterrell R. 'Is it so bad to be different? Comparative law and the appreciation of diversity', in Öriücü E. and Nelken D. *Comparative law: A handbook* (2007) Worcester Place: Hart Publishing, p.133.

¹⁷³ *Synthon*, para.56.

¹⁷⁴ Encaoua D., Guellec D. and Mart'inez C. 'Patent systems for encouraging innovation: Lessons from economic analysis' (2006) *Research Policy*, p.1423–1440, p.1424. The economic dimension of the analysis and justification is not restricted to patents but is also applicable to other areas of IP law.

¹⁷⁵ For example, see Encaoua D. Guellec D. and Mart'inez C, 'Patent systems for encouraging innovation: Lessons from economic analysis' (2006) *Research Policy*, p.1423–1440.

¹⁷⁶ Mgbeoji I. 'The Juridical Origins of the International Patent System: Towards a Historiography of the Role of Patents in Industrialization (2003) *Journal of the History of International Law*, p.403-422. Ancient societies have been attributed with the origins of patent customs, including in religious settings, albeit very different from what we know now.

importation and exploitation of previously unknown arts in their domain.¹⁷⁷ The first recorded use of such monopoly was in the granting letters patent¹⁷⁸ in 1311 to John Kempe, a Flemish weaver who wanted to pursue his trade in England.¹⁷⁹ By 1326 the British monarch had been encouraging the importation of ‘new arts’ into the kingdom. It is claimed, this is the earliest period that royal protection was given to individuals, especially foreigners, for the exploitation of foreign arts.¹⁸⁰ The practice continued with for example ‘letters patent granted in 1440 to John Shiedame to introduce into England a newly-invented process of manufacturing salt.’¹⁸¹

The consideration for such protection, given the social and industrial settings then, was that the importers would instruct and teach natives in the trade or guilds such that at the expiration of the protection they would freely practice and expand the trade.¹⁸² This is why the early protection, the so-called quasi patents, was attributed with the migration of foreign skilled labour into Britain.¹⁸³ It is observed that this form of protection was used by the Crown more as political control of trade rather than the utilitarian justifications that exist today for the maintenance of the patenting system.¹⁸⁴ The grant of protection was based on the relationship between the petitioner and the authorities rather than the invention fulfilling an objective predetermined criteria.¹⁸⁵ Some authors view this as the state’s way of promoting the public interest,¹⁸⁶ although it clearly infringes the private interest of the creator of the art.

¹⁷⁷ Francis W. H. and Collins R. C. *Cases and materials on patent law including trade secrets, copyright, trademarks*, 4th ed (1995) Minn: West Publishing Co., p.67.

¹⁷⁸ These were open letters with the King’s Great Seal granting the rights and allowing those possessing such letters to practise their craft in the UK. According to the HM Treasury, *Gower Review of Intellectual Property*, December 2006, para1.13, the first recorded letters patent was in 1449, to John Utynam by King Henry VI for making stained glass.

¹⁷⁹ Bainbridge D. *Intellectual property* (1996) London, Pitman Publishing, p.268.

¹⁸⁰ May/Sell, fn.121, p.52.

¹⁸¹ Federico P. J. ‘Origin and early history of patents’ (1929) *Journal of the Patent Office Society*, p. 292-305, p.293.

¹⁸² The apprenticeship period of seven years each is apparently the basis for the initial fourteen year term of the patent grant for importing the working of the invention: Ricketson S. and Richardson M. *Intellectual property: Cases, materials and commentary*, 3rd ed, (2005) Chatswood: LexisNexis Butterworths, p.654.

¹⁸³ May/Sell, fn.121, p. 52.

¹⁸⁴ Spinello R.A. and Bottis M. *A defense of intellectual property rights*, (2009) Cheltenham, Edward Elgar Publishing Limited, p.37-38.

¹⁸⁵ May/Sell, fn.121, p.59.

¹⁸⁶ Francis W. H. and Collins R. C. *Cases and materials on patent law including trade secrets, copyright, trademarks*, 4th ed (1995) Minn: West Publishing Co, p.64.

The practice was first given statutory force outside of Britain on 19 March 1474, by the Venetian Patent Act of 1474.¹⁸⁷ Previously, the grants were awarded for new arts introduced into Britain but there was no absolute requirement for invention,¹⁸⁸ or that the petitioner should be the originator of the practice.¹⁸⁹ Some scholars suggest that this Venetian Act was to later influence statutory patentability requirement in Britain as it introduced the concept of novelty and non-obviousness in Britain.¹⁹⁰ Other commentators do not accept such views arguing that ‘[t]here is scarcely any evidence that the Venetians knew about their patent legislation and little to suggest that it influenced any legislative or commercial developments elsewhere.’¹⁹¹

In 1559, the Italian Jacobus (Giacopo) Acontius was the first inventor to receive a patent from Elizabeth I exclusively for invention,¹⁹² although this practice was the exception rather than the norm. What is interesting is that in his petition for protection he evoked the private argument for protection against copying of his invention as promoting the public interest.¹⁹³ This is a standpoint that is adopted in this thesis. The optimal balance in setting patentability standards has to be based on the individual being granted sufficient protection balanced against undue encroachment on the public sphere.

Elizabeth I used her political power to grant patriots privileges in industry that were considered unfair to the other industry players of the time.¹⁹⁴ Although she

¹⁸⁷ However, the earliest record of a decree resembling contemporary patent law is by a Venetian Major Council in 1297 to regulate the fabrication, compounding in today’s terms, and the sale of medicine, syrups and confections whereby ‘if a physician makes a medicine based on his own secret, he too must make it only of the best materials; it all must be kept secret within the guild; and all guild members must swear not to pry into it’ as noted in Mandich G. ‘Venetian origins of inventors’ rights’ (1960) *Journal of the Patent Office Society*, p.378-382, p.378.

¹⁸⁸ May/Sell, fn.121, p.59.

¹⁸⁹ Torremans P. *Holyoak and Torremans: Intellectual property law* (2001) London: Butterworths Tolley, p.6.

¹⁹⁰ Gerntholtz R.O.P., *Principles of South African Patent Law: and a comparative reference to German Patent Law* (1971) Wynberg, Juta & Co Limited, p.2.

¹⁹¹ Phillips J. “‘I wouldn’t want to be starting from here’”, or why isn’t intellectual property research better than it is?’ (2009) *World Intellectual Property Organisation Journal*, p.139-146, p.144.

¹⁹² May/Sell, fn.121, p.80.

¹⁹³ Phillips J. ‘The English patent as a reward for invention: The importation of an idea’ (1983) *European Intellectual Property Review*, p.41-44, p.41.

¹⁹⁴ Davies D.S. ‘The early history of the patent specification’ (1934) *Law Quarterly Review*, p.86-109, p.102. It is said guilds were in themselves monopolistic as they prevented non-members from practising in certain trades in designated regions although this system is said to have improved quality of goods and prices, but others hold this to be an erroneous assumption: Richardson G. ‘Guilds, laws

commanded respect that made parliament disregard these privileges and abuse of the royal prerogative, she was eventually pressured to issuing the Proclamation concerning Monopolies of 1601.¹⁹⁵ This instrument mainly sought to reform these grants which were causing public misgivings as by then some were to practices that were already practiced in the kingdom.¹⁹⁶ She retained powers to issue grants but they were subjected to judicial review when there were disputes. For example, in *Darcy v Allin*¹⁹⁷ it was decided that the monopolies granted by the Crown for inventions that were already known in the kingdom were illegal and contrary to the common law.

James I was not so discreet in granting his political creditors letters of patent for monopolies in trade.¹⁹⁸ Parliament sought to restrain this royal prerogative as invalid by promulgating the 1624 Statute of Monopolies.¹⁹⁹ It declared *inter alia* that grants of privileges and favours were void and of no effect with the exception of those for the working or making of new manufactures in the United Kingdom.²⁰⁰ In other words the Statute of Monopolies ‘had declared that legitimate patents of invention were not to be condemned as abuses of Crown prerogative.’²⁰¹

The Statute of Monopolies particularly declared that inventions shall be granted to the first and true inventor.²⁰² However, Hulme²⁰³ concludes that this statutory promulgation was nothing more than the declaration of common law on patentability

and markets for manufactured merchandise in late-medieval England’ (2004) *Explorations in Economic History*, p.1-25.

¹⁹⁵ The principle that monopolies should be granted only for new manufactures was propounded by Francis Bacon, speaking in the House of Lords in 1601: Fox H.G *Monopolies and patents* (1947) Toronto: University of Toronto Press, p.75.

¹⁹⁶ Dent argues that the patent was serving less sinister Crown policy goals than it is usually assumed, and was supported by other arms of the government: Dent C. “‘Generally inconvenient’: The 1624 Statute of Monopolies as a political compromise’ (2009) *Melbourne University Law Review*, p.415-453, p.418-420.

¹⁹⁷ *Darcy v Allin* 11 Coke 84b, 86a, 77Eng.Rep. 1260 (1602), it has been called the Case of Monopolies, where the court stated that the patent grant was ‘utterly void and that... it is a monopoly and against the common law’.

¹⁹⁸ Referred to as ‘odious monopolies’ by Holdsworth W. S. ‘The common debates 1621’ (1936) *Law Quarterly Review*, p.481-493, p.487.

¹⁹⁹ Statute of Monopolies 1623 c.3 21_Ja_1. It has been asserted that James I supported passage of the Bill: Kyle C.R. “‘But a New Button to an Old Coat’: The Enactment of the *Statute of Monopolies*, 21 James I Cap 3’ (1998) *Journal of Legal History*, p.203-223, p.218.

²⁰⁰ Statute of Monopolies, s.6.

²⁰¹ Fisher M. ‘Classical economics and philosophy of the patent system’ (2005) *Intellectual Property Quarterly*, p.1-26.

, p.17.

²⁰² Section 6.

²⁰³ Hulme E. W. ‘History of patent law’ (1902) *Law Quarterly Review*, p.280-288, p.280-281.

that was existing this far. He does this by considering that, then, the phraseology to invent also meant to be the first to bring into use, so the statute's first to invent included importers of the arts. 'The invention, i.e. the exercise of the inventive faculty; was not an essential qualification - institution of the manufacture, from whatever source derived, was a valid consideration of the patent grant under the statute.'²⁰⁴ Therefore the first and true inventor here is not referring exclusively to inventive activities.

Section 6 of the Statute of Monopolies defined the patentable invention as:

'the sole working or making of any manner of manufactures within this Realm.....which others at the time of the making of the such Letters Patents and Grants shall not use, so as also they be not contrary to the Law, nor mischievous to the State, by raising prices of commodities at home, or hurt of trade, or generally inconvenient.'

An element of this definition is that the working or use of the invention which qualified for protection must be within the United Kingdom. In other words that definition prescribed local use of the invention as a major patentability standard.²⁰⁵ The theme of local use survived up to the 1949 Patents Act where inventions would be protected as long as the patentee intended to 'make, use, exercise and vent the said invention...and to the end that the patentee may have and enjoy the sole use and exercises and full benefit of the said invention.'²⁰⁶ This statute was not concerned with protecting foreign inventors or their creations if they were not to be directly used in Britain.

Simultaneously in this definition, novelty as a patentability requirement was only limited and tied to the existence of the said invention in the United Kingdom.²⁰⁷

²⁰⁴ *Ibid.*

²⁰⁵ Hulme E.W. 'The history of the patent system under the prerogative and at common law: A sequel' (1990) *Law Quarterly Review*, p.44-56, p.55, asserts that although the consideration for the grant is not expressly stated in the statute unless the words 'for new manufactures' is expanded into 'for [introduction of] new manufactures', the case law of granted patents at that time attest to the implicit consideration that the patent grant is directed to importations into the Britain.

²⁰⁶ Schedule 4, under the 1949 Patents Act.

²⁰⁷ The novelty definition was recited in the patent grant, whereby the applicant affirmed that invention was not used by anyone else in the Kingdom: Hulme, fn.205, p.44-56, p.56.

Therefore foreign prior art had no bearing on UK patentability. Technologies that existed and were largely known abroad were patentable when imported to the United Kingdom.²⁰⁸ Commentators observe that ‘rather, there was an obligation on the patentee, expressed as a condition of the patent grant, to introduce and to work the invention in England.’²⁰⁹ Some even observe that in common law decisions before this statute, the applicant must have taken steps to introduce the art into British industry.²¹⁰ This custom then, not only seems like an economic model that promotes local industry empowerment, importation and assimilation of technology,²¹¹ but would now be viewed also as a kind of legalised piracy promoted by patent grants. The exploitation of foreign inventions, probably owned by someone else, shows how lax a standard the UK had in its formative years in order to attain patentability. For example, in 1667 *Howard and Watson Patent*, No. 154,²¹² an amendment extending the patent scope was allowed even though there was evidence that the invention existed abroad. It was declared that the invention was ‘a new manufacture, and the patentee the true and first inventors thereof, and that it was profitable to the Kingdom, and the privilege granted was a just and legal privilege fit to be cherished and preserved.’

This is in stark contrast with the principle of absolute novelty that now exist in the UK and also in South Africa where the monopoly is granted dependent on the newness of the invention regardless of place of its creation.²¹³ The advantage of this custom to Britain then, was that the local industry flourished as it absorbed foreign technology. It is upon this ground that it could be argued that developing countries should not be rushing to develop higher patentability standards if the plan is to advance local industries with having low patentability standards in place, as was demonstrated by Britain.²¹⁴

²⁰⁸ Hulme, fn.208, p.313-318. Also Terrell T. *Terrell on patents* (1991) Colorado: Fred B. Rothman and Co., p.7.

²⁰⁹ Brennan D.J. ‘The evolution of patent claims as property definers’ (2005) *Intellectual Property Quarterly*, p.361-399, p.363.

²¹⁰ Hulme, fn.203, p.280.

²¹¹ Torremans, fn.189, p.6.

²¹² Hulme E. W. ‘Privy Council law and practice of letters patent for invention from the Restoration to 1794’ (1917) *Law Quarterly Review*, p.63-75, p.68.

²¹³ Patents Act 1978, s.25 and Patents Act 1977, s.1(1)(a) and s.2.

²¹⁴ The background to the final consensus on TRIPS Art.1(1), prescribing only minimum levels of protection, was to the concern that higher patentability standards do not conclusively lead to automatic promotion of technological innovation and dissemination, the objective of TPIRS (TRIPS Art.7).

The patent gradually developed from being mere privileges, although the grants remained discretionary.²¹⁵ It is not clear as to when the lodging of the patent had to include a specification.²¹⁶ By 1663 patents were still being filed without a description; in 1663-4 *Garill's Applications*,²¹⁷ the petitioner refused to reveal his secret to the King and Council unless his patent was first sealed. In 1670 a Private Act was enacted that required the patentee to enter a description of their invention at the Court of Exchequer, although this was for the amendment of the patent a Private Act of which was previously rejected by the Commons in 1660.²¹⁸

Kingston states that 'beginning in 1712-1713 in England, patent applications have included a written description of an invention which should enable someone who is "skilled in the relevant art" to replicate it.'²¹⁹ One of the earlier cases where the specification was in issue was in *R v Arkwright*,²²⁰ and is indicative of a long existence of the specification custom, where Buller J. stated that:

'It is clearly settled at law that a man, to entitle himself to the benefit of a patent for a monopoly, must disclose his secret, and specify his invention in such a way that others may be taught by it to do the thing for which the patent is granted; for the end and meaning of the specification is, to teach the public, after the term for which the patent is granted, what the art is, and it must put the public in possession of the secret, *in as simple and beneficial a way as the patentee himself uses it*. This I take to be clear law, as far as it respects the specification.'

The specification is the basis of the justification of patentability standards as a public education tool, even though such specifications intended to disseminate technology to the public were very brief historically. A noteworthy boundary was that it should not

²¹⁵ MacQueen H., Waelde C. and Laurie G. *Contemporary intellectual property: Policy and law* (2008) Oxford: Oxford University Press, p.261.

²¹⁶ There are debates that it was on the insistence of the Crown, others saying it was by the applicants, that the specification custom developed, see Davies D.S. 'The early history of the patent specification' (1934) *Law Quarterly Review*, p.86-109.

²¹⁷ Hulme, fn.212, p.63-75, p.65-66.

²¹⁸ 1660 *Howard's Patent*, No. 130.

²¹⁹ Kingston, fn.2, p.350.

²²⁰ *R v Arkwright* (1785) 1 HPC 245.

mislead. In *R v Arkwright*, a patent at issue containing extra integers and claims, the court said ‘if those are of no use but are to be thrown merely to puzzle, I have no difficulty to say, upon that ground alone the patent is void.... If four only were necessary instead of ten, the specification does not contain a good account of the invention.’²²¹ The common practice then was that the patentee after grant would teach apprentices what is taught by the patent throughout its term. As such there was no particular emphasis on the specification as the master would generally impart the art and skill on his students practically.

A major patent statutory development after the Statues of Monopolies was in the form of the immensely debated Patent Law Amendment Act 1852.²²² From case law of this period, one could glean that the trend that was to follow is more or less similar in nature to the requirements of genuinely new inventions that have some usefulness. This was seen for instance in *Holmes v London & NW Rly Co*,²²³ where Jervis, C.J. said ‘the object of the condition in the patent requiring a specification is twofold; first that useful novelties should be given to the public...’. Novelty and usefulness were already being envisaged by the courts. The need for useful inventions in the patent system was expressed but not immediately thereafter realized by the enquiry into the operation of the patent system which observed that some patents are ‘practically useless, and are employed by patentees only to embarrass rival manufacturers.’²²⁴

The concern for examination of patent application as expressed in the reform commission was not addressed.²²⁵ As there continued to be no examination of patent applications, so did disputable patents continue to be registered²²⁶ especially if they existed abroad. In the same era in 1883 the Paris Union²²⁷ was being formed for the reciprocation of protection amongst member states. The patentability standards were largely raised through this Union as in theory it prevented the grant of parallel patents in member countries through the securing and recognition of foreign priority in local

²²¹ *R v Arkwright* (1785) 1 HPC 245.

²²² As a result of the 1851 Select Committee.

²²³ *Holmes v London & NW Rly Co* (1852) 6 HPC 501.

²²⁴ 1851 Select Committee, p.13.

²²⁵ Indeed, various witnesses before the 1851 Select Committee were of the view that examination was unnecessary.

²²⁶ Torremans, fn.189, p.7.

²²⁷ The 1883 Paris Convention for the Protection of Industrial Property.

patent applications. In other words this curtailed the ‘workings definition’ of the patentability standard that was generally accepted from the Statutes of Monopolies.

From 1864 to 1872, there was another thorough inquiry into the patent system.²²⁸ Afterwards, broad legislation was enacted in the Patents, Designs and Trademarks Act 1883 (1883 Act) which required for the first time that the patent specification should contain claims defining the scope of the monopoly sought by the individual.²²⁹ It has been observed that this requirement was accepted gradually by the judiciary.²³⁰

The 1883 Act also provided for applications to be deposited to the examiners in the Patent Office.²³¹ The examiners’ obligation was to report on whether the accompanying specifications contained fair description of the invention.²³² This was not substantive novelty examination. The 1883 statutory tool was, to a certain extent, used for judging whether the monopoly granted was appropriate for the invention made and did not prevent other local merchants from practising the trade they were already involved in.²³³ This evolution in patentability standards shows that economic necessities, as opposed to the initial crown control, were now the driving force for sustaining the patent system after these much debated legislative reforms.²³⁴

This 1883 Act purported to protect genuine inventions: ‘An application must contain a declaration to the effect that the applicant is in possession of an invention, whereof he...claims or claim to be the true and first inventor...’.²³⁵ The reasoning now was that ‘he is not called the inventor he who has in his closet invented it, but does not communicate it; the first person who discloses that invention to the public is

²²⁸ The 1872 Select Committee, records of which have been reproduced by academics Ford and Ford as a British Parliamentary Papers series: Ford P. and Ford G. *British Parliamentary Papers: Report from Commissioners and from Select Committees on letters patent with proceedings minutes of evidence, appendices and indices, 1864-72, Inventions-General 2*, (1970) Shannon: Irish University Press (hereafter, 1872 Select Committee).

²²⁹ Section 5(5) states that ‘a specification, whether provisional or complete, must commence with the title, and end with a distinct statement of the invention claimed.’

²³⁰ According to Lord Salmon in *Ethyl Corporation’s Patent* [1972] RPC 169, p.193-194.

²³¹ Section 5(1) ‘An application for a patent must be set made in the form set forth in the First Schedule...and must be left at, or sent by post to, the Patent Office in the prescribed manner.’

²³² Patents, Designs and Trademarks Act 1883, section 6.

²³³ Section 26(4)(e) allowed revocation on these grounds.

²³⁴ Torremans, fn.189, p. 7. However, according to section 12 (1) and (2), although the seal of the patent was of the Patent Office, its effect was to continue as if it were sealed with the Great Seal.

²³⁵ Section 5(2).

considered as the inventor.²³⁶ This therefore prevented what Lawson²³⁷ asserted then, which is that the phrase ‘true and first inventor’ as including the first importer besides the actual inventor is by what has been described as ‘a sort of anomalous decision which has acquired by time and recognition the force of law.’

An Act to consolidate the enactments relating to Patents for Inventions and the Registration of Designs and certain enactments relating to Trade Marks (so far as it relates to patents) was promulgated on 28 August 1907. Section 7(1) required novelty examination against descriptions in the UK patent records in the previous fifty years. That is to say that the novelty patentability standard was of limited term and was directed to internal prior art.

Legislative developments culminated in the Patents Act 1949 under which limited anticipation in a patent application was still only examined up to the previous fifty years.²³⁸ The 1949 Act provided for the revocation of patents that were considered obvious and not useful.²³⁹ The 1949 Act has been replaced by the current Patents Act 1977, which was designed to take into consideration the EPC and will be the primary statute under study in this thesis.

Summary

‘Clearly, when English Kings...granted patents to those who imported innovations that had been developed abroad they were not much concerned about the “natural rights” of the foreign inventor.’²⁴⁰ The historical examination shows a metamorphosis of the patent system from mere privileges and internal control of subjects and activities to being a tool accentuating inventions. Kingston states it this way:

²³⁶ *Househil Co. v Neilson*, 1 Webst, 719.

²³⁷ Lawson W.N. *The law and practice under the Patents, Designs and Trade Marks Acts, 1883 to 1888 with the practice in actions for infringement of patent, and an appendix of orders made in patent actions, and forms* (2nd ed) (1889) London: Butterworths, p.5.

²³⁸ Patents Act 1949, section 7(1) required prior art search to be done for anticipation by previous publication in UK patent applications in the previous fifty years and section 50(1) prevented invalidation of patents by prior art more than fifty years.

²³⁹ Patents Act 1949, section 32(f) and (g) respectively.

²⁴⁰ Drahos P. ‘Intellectual property and human rights’ (1999) *Intellectual Property Quarterly*, p.349-71, p.352.

‘The modern patent system with its quite different emphasis, is a creation of the nineteenth century. Because of its intellectual origins in the natural rights thinking ...it protects inventors—“those who find new things”-in contrast to the earlier system, which protected innovators- “those who get new things done”.’²⁴¹

That is to say the earlier system was more concerned with practical application of the inventions or refusing grants for abstract ideas that have not been applied practically rather than seeking to identify the deserving inventor.

2.3.2 The historical development of the South African patent

The formation of the Republic of South Africa has a long, somewhat convoluted history.²⁴² This thesis does not attempt to concern itself with much of this history.²⁴³ However, the historical excursion begins from where patent laws first appeared. It suffices to state there were four provinces, that were self-governing and also colonies of one imperial ruler or another at different times in their history. Hence, there are four legislative regions that however, have become of lesser significance than formerly with the advent of the new Constitution.²⁴⁴ Moreover, the current Patents Act 1978 transcends the divisions in provincial jurisdiction that still exist in some areas of law, and takes on a national jurisdiction.²⁴⁵

The colonies that formed South Africa are the Cape and Natal colonies, considered purely British colonies, and the former Boer Republics Transvaal and Orange Free State (OFS). The Cape was a British colony from 1806 and Natal formally annexed

²⁴¹ Kingston, fn.2, p.354.

²⁴² In 1961, the official name of what was then the Union of South Africa became the Republic of South Africa. Saidov, fn.65, provides an in-depth account of the origin of South Africa and legal system categorisation in the twentieth chapter.

²⁴³ There are relevant works in this regard. For example, du Plessis J. ‘*South Africa*’, in Smith, J.M. (ed) *Elgar encyclopedia of comparative law* 2006 Cheltenham: Edward Elgar Publishing Limited, provides a concise a history. Also Burrell T.D. *Burrell’s South African patent and design law, 3rd ed* (1999) Durban: Butterworths Publishers, p.6-8. [hereafter Burrell].

²⁴⁴ The South African Constitution chapter 1, defining South Africa as ‘one, sovereign, democratic state.’ An in-depth review of the Constitutional and legal developments in the history of South Africa and the relationship with the British Empire is provided by: Woolsey L.H. ‘A Comparative Study of the South African Constitution’ (1910) *The American Journal of International Law*, p.1-82.

²⁴⁵ Although the patent takes on a national character, there are still some aspects that are aligned to provisional practice customs, for instance Patent Act 1978 section 8.

in 1843 and became a separate colony in 1847. The OFS was declared by the Cape Governor and High Commissioner to be under British rule in 1848, later to be withdrawn in 1854. After the war in 1902, it became a British colony. The Transvaal, a South African Republic then, was annexed by the British in 1877 and liberated only to become a British colony again in 1902, after the war generally known as the Boer war and to the Afrikaner more as the Second War of Independence. The South Africa Act, 1909, created the Union of South Africa by uniting the four colonies to be headed by a British Governor-General and later granted independence in 1931 by the Statute of Westminster.

The seemingly somewhat arbitrary historical presentation is not at odds, or to deny the premise in this thesis that legal development should and/or does reflect the socio-economic environment. The repeated annexing and wars, brought about by *inter alia* political and social factors, occurred when this region was largely uninformed on the patent system or its utility. Patents were relatively merely imported into statutory books by imperial agents, with no significant application in local industry. The technical impetus to use the system then was also lacking. On another level, the long history of Roman-Dutch law, which was introduced before the English settlers and makes the South African system pluralist, offers only little insight into the operation of patents and is of limited use when applied to patents than in other areas of law.²⁴⁶ Customary law, which runs parallel with the hybrid system, is also of no relevance to the study of patents.²⁴⁷ Therefore the history of patent law as informed by socioeconomic activities can begin around or after this era when the British introduced patent law.²⁴⁸

²⁴⁶ Saidov fn.65, p.333. Cameron, fn.74, rejects Roman-Dutch law purists' notion of denying English law influence in South Africa and Fagan E., 'Roma-Dutch law in its South African historical context' in Zimmermann R. and Visser D. *Southern Cross: Civil Law and common law in South Africa* (1996) Oxford: Oxford University Press, suggests a narrow view of Roman-Dutch law in South Africa.

²⁴⁷ The large body of customary law has gained recognition with the advent of the new constitution, than formerly, but is abrogated where it is not consistent with it.

²⁴⁸ Sipa-Adjah Yankey G. *International patents and technology transfer to less developed countries: The case Ghana and Nigeria* (1987) Hants: Gower Publishing Company Limited, p.98, argues that the impact of patent laws of colonial masters was only felt twenty years later from implementation in the northern states of Africa.

Early patent laws in South Africa were framed upon those of the United Kingdom.²⁴⁹ For example, the Cape Parliament promulgated Act 17 of 1860, which was strongly fashioned after the UK's Patent Law Amendment Act 1852. The other British colonies that would later make up the Republic of South Africa would later adopt their own laws that closely followed the Cape Act,²⁵⁰ invariably all following UK statutory trend. Law 4 of 1870 was the first statute in Natal to deal with patents. In the Transvaal Province, Law 10 of 1887 was the first law to be promulgated that dealt with patents.

Importantly, the Cape 1860 Act was directed at giving patent protection to encourage useful invention. To emphasise this, the preamble of the 1860 Act stated that 'it is expedient that the making new and useful inventions should be encouraged by securing to their inventors for a limited time the exclusive enjoyment thereof.' South Africa emphasised rewarding inventors for inventive activities that resulted in new and useful inventions released to the public. This is opposite to the British statute which was not specifically clear on the underlying philosophy and purpose for securing patents. Only in case law are there pronouncements to this purpose. Notably therefore, the South Africa invoked the progress of the arts in its statutes as an inspiration for the patent system much earlier on in its development than the UK.

Furthermore, what is omitted from this UK derivative statute is the 'workings' clause that was key to the operation of the Statute of Monopolies. The UK statute covered situations both for the working and making of inventions while the South African view was directed only at the making of inventions. The workings clause covered situations where the 'communicator' of foreign inventions imported and worked them in the UK without some inventing, whereas in South Africa 'the object of the patent laws (was) to benefit the first inventor and only the first inventor'²⁵¹ in its literal sense as understood today.

²⁴⁹ Burrell T.D. *South African patent law* (1982) University of Witwatersrand: Unpublished thesis, p. 5. [hereafter, Burrell Thesis].

²⁵⁰ Slabbert C. *Non-obviousness as a requirement for patentability South Africa and in the United States of America- A comparative study* (1979) University of the Witwatersrand: Unpublished PhD thesis, p.45. Also, Burrell Thesis, p.6.

²⁵¹ *Veasey v Denver Rockdrill and Machinery Co. Ltd.* 1930 AD 243, p.270.

There was also a clause similar in the initial patent laws of the South African colonies to the effect that an invention is not a new invention if there is public use and exercise thereof. For example, Section 29(c) of Law No. 6, 1887 of Transvaal prevented a patent being granted or if granted be revoked if ‘the invention was not new, i.e. it was already published or applied in the State before the insurance of the letters patents.’²⁵² It is suggested in this thesis that the newness requirement applying only against prior art patents in the local state was influenced by the colonial British administrators’ desire for less burdensome novelty assessment rather than the intention to exploit foreign inventions as was the case within initial UK settings. A writer²⁵³ illustrates an instance where in 1862, the British Governor in Ghana, requiring assistance in the promulgation of patent legislation in the colony from the Secretary of State for Colonies in London, in consultation with the Controller-General of Patents, was given a copy of legislation of another colony modelled on existing British patent legislation to implement. The only change was that it no longer had the requirement that a person shall not receive a patent for an invention which had previously been patented ‘in Britain or any other country’ as, according to the Controller-General the cost of official novelty searches and administrative problems prevented any similar legislation in the colonies from being approved in Britain.

There was then a shift from local novelty into global novelty. Transvaal Law No. 12, 1897²⁵⁴ defined novelty without reference to where the invention was made or locality of the prior art. This trend was further developed by Proclamation No. 22 of 1902 which stated that an:

*‘invention means any new and useful art, process, machine manufacture or composition of matter or any new and useful improvement thereof capable of being used or applied in trade or industry and not known or used by others in this Colony and not patented or described in any printed publication in this Colony or any foreign country for more than two years prior to such application...’*²⁵⁵

²⁵² Similar to Orange Free State Patent Act of 1891, Section 29 (c).

²⁵³ Sipa-Adjah Yankey G. *International patents and technology transfer to less developed countries: The case Ghana and Nigeria* (1987) Hants: Gower Publishing Company Limited, p.99-102.

²⁵⁴ Transvaal Law that superseded Law No. 6, 1887.

²⁵⁵ Proclamation No. 22 of 1902, section 5.

The concept of statutory ‘local novelty’ was thus abandoned earlier on in South Africa (Law No. 12, 1897) than in the UK where it was only abolished in 1977.²⁵⁶

The purpose South Africa was issuing patents was more apparent in the earlier statutes and was linked to the prerequisite patentability standards being imposed. The 1902 OFS Patent Law stated that:

*‘Any person who makes a new invention, capable of being exploited in industry, shall have the exclusive right to exploit such invention to his own advantage for such a term and under such conditions as shall hereafter be determined.’*²⁵⁷

That is, the patent was issued for new inventions that are capable of industrial application and this was balanced against the monopoly for the inventor. The approach to novelty therefore seems to have been a combination of administrative convenience of the system and the need to use the system to encourage novel industrial activity.

A further condition for patentability that was emphasised within the colonies at the outset of the system was that the inventor had to be ‘the first and true inventor’²⁵⁸ indeed. This is a major difference between the UK and South African early patentability requirements. The UK would grant patents to importers of inventions and mainly concerned itself about use within their territories while South Africa offered protection to inventors in the true sense of the word.²⁵⁹ In this phrase the inventor was an individual entitled to the invention.

After the 1910 Union of the colonies, the patent laws were consolidated into the Patents, Designs, Trademarks and Copyright Act 9 of 1916. This law was also based

²⁵⁶ Grubb P.W. *Patents for chemicals, pharmaceuticals and biotechnology: Fundamentals of global law, practice and strategy* (2004) Oxford: Oxford University Press, at p. 58. According to Patents Act 1949, s32(e) an invention was revoked for lack of novelty if it was ‘not new having regard to what was known or used, before the priority date of the claim, in the United Kingdom.’

²⁵⁷ 1902 OFS Patent Law in *Law Book*, CXXII, section 1.

²⁵⁸ For example the Fifth Schedules of the Cape Act 17 of 1860 and Natal Law no. 4 of 1870.

²⁵⁹ Steyn J.R. *The significance in South African patent law of the claims in a patent specification* (1974) Unisa: Unpublished LLD Thesis, p.14.

on the UK's patent law, Patents Act of 1907.²⁶⁰ Act 9 of 1916 was repealed by the Patent Act 37 of 1952 (it too was based on the British Act of 1949), which was in turn was repealed by the current Patent Act 57 of 1978.

The 1916 Act continued to emphasise novelty as a pre-requisite for grant of the patent. Section 6 expressly excluded communicators of the invention from grant of the patent. It states that the “inventor” shall not include a person importing an invention from abroad.’ *Carnes v Maeder*²⁶¹ reiterated that a mere importer cannot be the first and true inventor in South African law. The major laws that subsequently developed in South Africa are the Patents Act of 1952 and the current Patents Act of 1978 which form the bedrock of this research.

Summary

Under colonial rule South Africa inherited UK laws, a majority of which may not necessarily have, or intended to progress the local industry, more than protect imperial interests or convenience. However, an interesting result has been that since Britain was ‘foreign’ it created laws that will protect the interests of other foreigners. Britain inevitably created and imposed a ‘national treatment’ principle, which recognises foreigners equally for patenting purposes. As South Africa weaned from British administration it continued to create laws to benefit invention, without discrimination as to place of invention. These are some of the principles underpinning the system that may not have necessarily revealed faults under the day-to-day British administration of the system, but are issues that become significant and have impact when there are reforms to be made as the local conditions keep on changing.²⁶² South Africa, after British rule, continued developing a system that incorporated the pillars of what constitutes a functional patent system that encouraged and protected inventions. This is not to detract advances made by the British in their own right within their local jurisdiction.

²⁶⁰ Burrell Thesis, p.8.

²⁶¹ 1939 WLD 207, p.214.

²⁶² Generally Dent C. ‘An exploration of the principles, precepts and purposes that provide structure to the patent system’ (2008) *Intellectual Property Quarterly*, p.456-477.

2.4 The emerging historical justifications of the patenting standards

There are at least four models for justifying the patent system that could be extracted from this discussion of the historical development of patents in the two jurisdictions.²⁶³ They exerted different influences in the conception and evolution of the patent system into what is now regarded as the modern patent system. Commentators point out that any serious scholar of IP can no longer avoid in-depth analysis of the economics underlying the patent system,²⁶⁴ a focus into their economic dimension which was largely absent at their origins. That is to say the legal justifications of patents now integrate economic principles in the justification of the patent system.²⁶⁵ These justifications now underlie global trade²⁶⁶ where South Africa and the UK are generally on opposite ends in terms of the objectives and implementation of the patent system.

Besides the economic considerations, these justifications also mainly revolve around the tension between private and public rights arguments.²⁶⁷ In pharmaceutical industries such tension is more pronounced. The inventors assert that the private right results in benefits accruing to the public. The public increasingly does not accept that individuals should have rights over inventions that are of benefit to public health.²⁶⁸ The human rights perspective is increasingly being integrated into these

²⁶³ More justifications exist, for example patents as commercialization prospecting device or as different categorization than the one adopted here. For example, see Duffy J.F 'Rethinking the prospect theory of patents' (2004) *University of Chicago Law Review*, p.439 and also chapter 2 Spence M. *Intellectual property* (2007) London: Oxford University Press or Spence M. 'Policy' in Roughton A, Cook T. and Spence M. (eds) *Modern Law of Patents* (2005) London: LexisNexis Butterworths, p.8-13, categorising them into economic and ethical justifications, respectively directed to encouraging invention and efficient exploitation of technology and to the treatment of the inventor equitably in view of their creative works.

²⁶⁴ Straus J. 'Impact of the new world order on economic development: The role of the intellectual property rights system' (2007) *European Review*, p.47-63.

²⁶⁵ May/Sell, fn.121, p.17. Lemley (Lemley M. 'Ex ante versus ex post justifications for intellectual property' (2004) *University of Chicago Law Review*, p.129-149) warns of the conflation of *ex ante* and *post ante* justifications of IP, with the former fitting the operation of patent frameworks whilst the latter, are not suited with the patent regime, such as those explained by Bentley and Sharman (Bentley L. And Sharman B. *Intellectual Property Law*, 3rd edn (2008) Oxford: Oxford University Press, chapter 14) concerned with the transformation of potentially valuable intangible artifacts into property rights to optimize use.

²⁶⁶ May/Sell, fn.121, p.20.

²⁶⁷ Spence, fn.263, p.63.

²⁶⁸ Adusei, fn.56, p.46.

discussions.²⁶⁹ As such, the classical justifications have to be modelled on modern realities if they can be sustained.

The thesis now turns to the examination of the individual justifications that develop from this historical analysis. They each received varying support and objection as a basis for the patent system. Despite the distinctions between the justifications, they may overlap in some contexts.²⁷⁰ The thesis argues that the individual justifications have vital roles to play in the attainment of optimal patentability standards.

2.4.1 Patents as natural rights to property

From the above historical account it is plausible to suggest that inspired by the need to move away from subjective grants, it was accepted that the patent grant determinant factor had to reside in an objective quality in the inventor or invention. This innate quality is one that could be applied consistently in all patent grants rather than the partiality that was occurring. It would be expected that there would have been the legislature's intervention in prescribing rules applicable equally to all knowledge producers '...a natural law, a non-arbitrary law grounded (if not ultimately grounded) in human nature' and 'not a law based on "utility", but it nonetheless serves the interests of all individuals.'²⁷¹ That is to advance the premise that positive patent statute-making must embrace the principles of natural law.

According to George²⁷² natural law or legal positivism are concepts that:

²⁶⁹ For instance commentators have noted that 'what had been essentially policy-based objections against minimum standards for pharmaceuticals during the negotiations started to be coined in human rights terminology after the TRIPS Agreement came into force' based on its adverse impact on some human rights guaranteeing accessibility of medicines, but as a counter argument 'more recently, other scholars have added that IP, too, is protected as a human right. Some have even ventured so far as to imply that the TRIPS Agreement itself is a human rights agreement.' Hestermeyer H. *Human Rights and the WTO: The case of patents and access to medicines* (2007) Oxford: Oxford University Press, p.76-78.

²⁷⁰ Ogoamanam C. 'Beyond theories: Intellectual property dynamics in the global knowledge economy' (2008) *Wake Forest Intellectual Property Law Journal*, p.104-154.

²⁷¹ Buckle S. *Natural law and the theory of property: Grotius to Hume* (1991) Oxford: Oxford University Press, p.146.

²⁷² George R.P. 'Natural law, the constitution, and the theory and practice of judicial review', in George R.P. (ed) *Natural law* (2003) Hants: Dartmouth Publishing Company, p.309.

'have no stable meaning in contemporary legal, political and philosophical discourse. It is therefore incumbent upon scholars who participate in discussions in which these terms are employed to attend carefully to the different meanings assigned to them by different writers or by a given writer in different contexts. The price of carelessness in this regard is error and confusion.'

For the purposes of this section it suffices to state that the interface between natural law and positivism is the view that the enactment and interpretation of positive law ideally ought to conform to natural law principles of human goods and moral requirements.²⁷³ The natural rights justification for the patenting system is viewed as introduced largely as a moral justification based upon the thesis that individuals have a natural property right in their original or inventive ideas.²⁷⁴ Therefore individuals have a right in the exclusive exploitation of these creations of their minds. It was contended that inventors or originators of scientific arts should have a natural right to their inventions in light of the labour to bring forth their inventions, the so-called Lockean Labour theory,²⁷⁵ under which we 'prioritise creative labour.'²⁷⁶ Their creations, therefore, gave rise to rights in property, albeit intangible, which non-originators should respect.²⁷⁷

The granted patents represented a natural private right conferred by the state to the patentee.²⁷⁸ As such the state was responsible for protecting those individual rights in common law. The creation of a patentable invention entails the granting of Crown privilege; privilege of use to the exclusion of others *and* privilege to exclude others from using it.²⁷⁹ Therefore the unauthorised or uncompensated exploitation of the

²⁷³ *Ibid*, p.62 states that 'commentators assumed that all good positive law 'grew out of' or were 'emanations' of the law of nature.'

²⁷⁴ Van Caenegem, fn.123.

²⁷⁵ Bainbridge, fn.179, p.270.

²⁷⁶ Merges R.P. *Justifying Intellectual Property* (2011) Massachusetts: Harvard University Press, p.289.

²⁷⁷ Generally, Moore A.D. 'Intellectual property: Theory, privilege and pragmatism' (2003) *Canadian Journal of Law and Jurisprudence*, p.191-209. Cf. Sherman B. and Bently L. *The making of modern intellectual property law: The British experience, 1760-1911* (1999) Cambridge: Oxford University Press, p.95-100, dispute this position suggesting instead that the recognition of mental labour is a more modern concept.

²⁷⁸ Brennan D.J. 'The evolution of the English patent claims as property definers' (2005) *Intellectual Property Quarterly*, p.361-399.

²⁷⁹ MacCormick N. 'On the very idea of intellectual property: an essay according to the institutionalist theory of law' (2002) *Intellectual Property Quarterly*, p.227-239, p.233-234. For example, UK Patent

ideas in the patents is a wrong to the individual. This justification however did not grow in popularity but it forms the basis of IP protection historically.²⁸⁰

It is unsurprising that this justification did not readily garner support in Britain, as some inventions were imported from abroad.²⁸¹ For instance, about half of witnesses before 1851 Select Committee thought it were expedient that patents should be granted to mere importers of foreign inventions.²⁸² Cornish more pointedly calls this practice theft of ideas.²⁸³ As such, in the UK, it can be argued that it was not necessarily the inventive ingenuity of the individual that was recognised in granting some patents, as it was perhaps someone else's property that was patented or more appropriately, misappropriated.

In European systems, especially in civilian systems, the natural rights justification was more readily accepted than in the UK. This may have had some influence on the UK though, as during statutory reform processes, the commissioners would enquire from witnesses what the practice was in other European counterparts, especially in France.²⁸⁴ The Venetian patent custom at around 1443 was said to be 'recognising the *right* of inventors' as 'in European practice this term had connotations of "basic right," especially in times and places where "basic rights," are given serious consideration'.²⁸⁵ The Venetian Act of 1474 desiring that 'men of great genius, apt to

Act 37 of 1952, s.32 conferred the right to use the invention, whilst the South African Patent Act 1978 s45(1) confers the right to exclude other from using. Tracing the evolution of the patent custom, commentators have stated that 'the patentee had complete control of the disposition of his invention. The basis(sic) of the patent system had altered completely, and the obligation to work the invention had been commuted into a duty to disclose its limits', a shift from the right to use to the right to exclude: Getz L. 'History of the patentee's obligations in Britain (1964) *Journal of the Patent Office Society*, p.62-81, p.80.

²⁸⁰ This justification is usually used in civilian systems and emphasizes the morality rights of the individual subsisting in the creation of new knowledge. Torremans, fn.189, p.23, calls it unfashionable justification. Milgate argues that although natural rights law was not the preoccupation of the English lawyer '[O]n the contrary, they seem to have accepted it as a component part of the laws of England. They did not regard it as an exotic import but rather as a legitimate source of English law', Milgate M. 'Human rights and natural law: From Bracton to Blackstone' (2006) *Legal History*, p.53-69, p.61.

²⁸¹ Cornish W. 'Secrecy and the evolution of the early patent system', in Pymont W.P.W., Adelman M.J., Brauneis R., Drexler J. and Nack R. (eds) *Patents and technological progress in a globalized world: Liber Amcorum Joseph Straus* (2008) Berlin: Springer.

²⁸² In response to question nine of the Report of the 1851 Select Committee, 'Do you think it is expedient that patent should be granted to importers of foreign inventions?', forty percent of witnesses were in agreement with patents for communicators of foreign art: 1851 Select Committee, p.178.

²⁸³ Cornish, fn.281.

²⁸⁴ This outlook was adopted in both the 1829 and 1851 patent law reforms consultations.

²⁸⁵ Mandich G. 'Venetian patents (1450-1550)' (1948) *Journal of the Patent Office Society*, p.166-224, p.169, original emphasis.

invent and discover ingenious devices.... so that others who may see them could not build them and take the inventor's honour away' provided that:

'every men who shall build any new and ingenious device...shall give notice of it ...[i]t being forbidden to every other person in any of our terrorise and towns to make any further device conforming with or similar.'

It has also been used in the French patent law of 1791, the preamble to which encapsulates the justification thus:

'That every novel idea whose realization or development can become useful to society belongs primarily to him who conceived it, and that it would be a violation of the rights of man in their very essence if an industrial invention were not regarded as the property of its creator.'

This establishes that historically there was some justification of the system on the basis that it was the application of the natural law principle of patents as property for the reward for creative labour,²⁸⁶ with some arguing that 'Locke's theory applies equally well, if not better to IP' than to real property.²⁸⁷ However, this standpoint attracted contemporary criticism and continues to do so in both jurisdictions. The epitome of the rejection of patents as natural rights to property in the UK historically was when it was stated that '[n]atural rights is simple nonsense: natural and imprescriptible rights, rhetorical nonsense- nonsense upon stilts.'²⁸⁸ Steyn, prior to the commencement of the current South Africa Patents Act, concluded that 'a patent right does not exist because of natural and basic "rights of man" as the inventor's natural right of property in the product of his creative mind, i.e. his invention.'²⁸⁹ Instead it was argued that the law in South Africa establishes there is no property right of the

²⁸⁶ Notably, the John Locke's labour theory of property. See Ostergard R. L. *The development dilemma- The political economy of intellectual property rights in the international system* (2003) New York: LFB Scholarly Publishing, p.11-13. Also see Machlup F. and Penrose E. 'The patent controversy in the nineteenth century' (1950) *Journal of Economic History*, p.1-29.

²⁸⁷ Merges, fn.276, p.32.

²⁸⁸ Davies claims that Bentham criticised this justification because he believed only the government had power to confer rights and there existed no absolute rights so it would be illogical to establish rights that could be upheld against the government: Davies A. 'Jeremy Bentham (1748-1832): The utilitarian foundations of collectivism' (1995) *Libertarian Heritage: Libertarian Alliance*.

<http://www.utilitarianism.com/jeremy-bentham/bentham.html>.

²⁸⁹ Steyn fn.259, p.102.

inventor, as ‘a patent right is not a property right of the inventor’ but a mere privilege²⁹⁰ As a consequence, depending on circumstances, it may require emphasis to be placed on one of the other functions of the patent system, with a result that sometimes the natural right of the inventor is disregarded. As a result, a radical call was made by Steyn of the appropriateness of granting patents sometimes even in the absence of a natural person as an inventor.²⁹¹ That means patents would have been granted without regard to the originator of the invention for administrative convenience or practical purposes.

This view, it is respectfully submitted, can no longer be good law in the modern patenting system, where there is recognition of patents as rights of the creator.²⁹² The UK Patents Act 1977 recognises that ‘any patent or application for a patent is personal property, and any patent or any such application and rights in or under it may be transferred, created or granted...’²⁹³ and ‘shall vest by the operation of law in the same way as any other personal property...’²⁹⁴ There is however no express provision in the current South African Patent Act 1978 that recognises the patent as personal property of the inventor. The South African Constitution though guarantees that ‘no one may be deprived of property,’²⁹⁵ which includes intangible property. The Constitutional Court has said that even though previously there may have been ‘judicial reluctance’, the constitutionally guaranteed right to property applies to IP albeit it being incorporeal and IP laws must be interpreted in a constitutionally tenable fashion including weighing up IP rights against other constitutionally guaranteed fundamental rights.²⁹⁶

Moreover, international instruments now recognise or create such natural rights in that ‘everyone has the right to the protection of the *moral* and material resulting from any

²⁹⁰ *Ibid.*

²⁹¹ *Ibid.*, p.103.

²⁹² Patents Act 1977, s.7 and Patents Act 1978, s.27 address the identity of the person who has the right to apply for a patent. Patents Act 1977, s.39 deals with employer-employee situations, which are prevalent in inventive activities: Giuri P., Mariani M. And Brusoni ‘Inventors and invention processes in Europe’ (2007) *Research Policy*, p.1107-1127. Patents Act 1978, s.59(2) bars contractual assignment of inventions made outside the course and scope of employment in order to protect employee interests.

²⁹³ Patents Act 1977, s.30(1).

²⁹⁴ Patents Act 1977, s.30(3).

²⁹⁵ South African Constitution Chapter 25(1).

²⁹⁶ *Laugh It Off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International and Freedom of Expression Institute* 2006 (1) SA 144(CC), para.17 and 18.

scientific, literary or artistic production of which he is the author.²⁹⁷ Furthermore, The United Nations Declaration on the Rights of Indigenous People has accentuated this right by declaring that indigenous peoples have rights over their knowledge or resources.²⁹⁸

Therefore, it could be said that an inventor or a group of inventors have a natural right in their creations which should be protected including through patents. Patents captured as a natural right does indeed reshape our approach to patentability from a purely utilitarian and economic balance between private and societal rights to a far more exacting approach of the indispensable right of the owners or originators of knowledge.²⁹⁹ This view can indeed reinforce the range of patentees that are admitted to protect their inventions through patents. Knowledge producers, including those who typically do not have large economic capabilities, for example one-time inventors and even traditional communities, would be guaranteed patent protection of their property through this right captured this way.

The main criticisms of natural rights as a justification for the patent system stems from the property's non-exhaustive character throughout the protection period.³⁰⁰ Thus, if property right in knowledge is a natural right, it seems illogical that it is limited as opposed to being perpetual.³⁰¹ That is to say that once an invention achieves the required patentability standard, it must remain valid for the rest of the life of the patentee,³⁰² as opposed to the reverting of the ownership to the public after a limited time.³⁰³

²⁹⁷ The Universal Declaration of Human Rights, Article 27(2); the same language was subsequently used in the International Covenant on Economic, Social and Cultural Rights Article 15(1)(c). The Constitution of South Africa, s.233 provides that the courts must interpret legislation with preference for reasonable interpretation that is consistent with international law over any alternative interpretation that is inconsistent with international law.

²⁹⁸ Art 31 (1) United Nations Declaration on the Rights of Indigenous People accepted by the General Assembly on 13 September 2007.

²⁹⁹ Chapman A.R. 'The Human Rights implications of intellectual property protection' (2002) *Journal of International Economic Law*, p.861-882, p.867. The goal of human rights subsisting in the IP regime is to improve human welfare in the social context rather than strict emphasis of the maximization of profits.

³⁰⁰ Spence, fn.263, p.46.

³⁰¹ Colston C. and Galloway J. *Modern Intellectual Property Law*, 3rd ed (2010) Oxon: Routledge, p.47.

³⁰² May/Sell, fn.121, p.18.

³⁰³ Steyn, fn.259, p.31.

Furthermore, it was suggested that the scope of the right awarded should be associated with actual effort, or degree of labour, exercised in creating the invention, with more time or effort deserving greater protection.³⁰⁴ This however, would unnecessarily concern itself with case-by-case-determination of the proportionality of the labour which brought about the invention, with the result that heavily invested inventions would get more protection than simple solutions to technical problems. Some have proposed conceptual proportionality models to account for this by interposing what is called ‘midlevel principles’ that prescribe that an inventor’s reward ought not to be out of proportion to the effort that went into the invention.³⁰⁵

It is unsurprising that this theory viewed this way would find little support in modern patenting industries. The thesis suggests that the patentability standard should be set at a constant threshold whereby the rights to the invention are enjoyed irrespective of the actual effort of the inventor but be based on the quality of the resultant invention, as determined by meeting the pre-determined patentability standards by the originator. It is irrelevant that this standard is arbitrary or artificial, as it is an agreed standard and objective benchmark that once patentees’ inventions attain, they are free to do with the protection as they deem fit within that time. Whether or not market forces accept the invention becomes irrelevant in determining the grant of this right. This eliminates subjectivity in patentability assessment that is introduced by focusing on events after grant.

Other pragmatic mechanisms of the patent system seeking to identify the inventor are compatible with the natural rights theory captured this way, particularly in an era where there are more patent stakeholders beyond borders. The first-to-file mechanism where the system rewards the one who reaches the patent office first is not contrary to natural rights principles because the one who reaches the patent office first still has to show entitlement to the invention. It is also for that reason that the grace period features are in place as they allow the one entitled to the invention to approach the patent offices even after the public disclosure or unauthorised disclosure of the invention.

³⁰⁴ Fisher, fn.201, p.8.

³⁰⁵ Merges, fn.276, p.160-162.

Anti-patent lobbyists formed commendable alliances to influence what is identified by commentators as the crucial legislative intervention to cast patents as a political and civic issue beyond the traditional legal and administrative stakeholders.³⁰⁶ However it remained public opinion that although the system was not totally efficient it was not to be abolished, but reformed.³⁰⁷ In the end there was divided opinion on how it was to be reformed and therefore there were modest reform proposals made.³⁰⁸ Tension between the Crown and Parliament had begun with the Statute of Monopolies where many compromises were made. It seems a likely explanation for the reticence to debate on the natural right justification lay in the close association that the patent granting procedures maintained with the monarch at that time. In South Africa, the influence of British royal authority was extended by the granting of these privileges through the Crown-appointment of British Governor-General.

An aspect that was not settled historically and continues to be widely debated is how strict the standard should be. In the past, inventions were clearly distinct, such that new knowledge and ideas were easily distinguishable from the works of others.³⁰⁹ This is contrasted to present circumstances, where there is integration and multi-disciplinary of industries and knowledge-generation activities. The consequences is that the natural rights justification has limitations by virtue of the fact that although the individual may come up with the patentable idea, that knowledge is always based on existing knowledge or the work of others which may themselves be just be a little short of the patentability standard. The standard set by patent law should encourage creators of knowledge to improve on the knowledge they have for the betterment of society. That is to say then society places an obligation on the person soliciting a patent to make full disclosure of his invention and usable idea to the public which

³⁰⁶ Generally in Schneider I. 'Can patent legislation make a difference? Bringing Parliaments and civic society into patent governance', in Hauss S. and Shadlen K.C. *Politics of intellectual property: Contestation over the ownership, use and control of knowledge and information* (2009) Cheltenham: Edward Elgar Publishing Limited.

³⁰⁷ May/Sell, fn.121, p.97.

³⁰⁸ For instance, the 1872 Select Committee report by the chairman, indicates that the committee only made recommendations and could not find a solution for statutory promulgation, hence the decision to even publish the minutes of the consultations: 1872 Select committee, p.13-17.

³⁰⁹ Patent law is said to have embraced more of what is generally referred to as pioneer or ground-breaking inventions, which are claimed to be the foundation of much of modern technology, but such views of the inventions have been doubted as overstated and 'resulted more from their superior marketing and political acumen than technological merit or foresight': Love B.J. 'Interring the pioneer invention' (2012) *North Carolina Law Review*, p.379-459.

meets the set patentability standard to be granted protection.³¹⁰ This demonstrates the importance of the system setting the appropriate patentability standards, which as was said in *Veasey v Denver Rockdrill and Machinery Company Ltd*, ‘will reward those who make substantial discovery or invention which adds to our knowledge and makes a step in advance in the useful arts.’³¹¹ People who derive and possess such level of knowledge are therefore entitled to patents if they use their right to that knowledge and forgo their secret to the public.

Patents seen as rights have consequences that are absent when it is seen as privilege. A privilege conveys the impression that it is more of a favour that can be withdrawn at any time or for any reason. What is often overlooked, especially in the context of policy flexibilities within the system, is that although rights may be curtailed, there has to be specific pre-conditions for such curtailment. In such a rights model, a patentee would be certain that his rights within the protection term can only be disturbed if it surfaces that it suffers an objective and reasonable pre-stated defect or only in the case of recognized extraordinary circumstances.

The viewing of patents as more than mere privileges also finds support in a commentary that asserts that patents suffer incorrect categorization as special legal privileges rather than natural rights because they are only largely viewed through a historical error perpetuated by misreading of history by legal historians and then compounded by legal scholars reciting that information without question as to the entirety or holistic accuracy of historical record relied on.³¹² Contending that the labour theory of property and social contract doctrine of natural rights was established and functional at the conception of patents, the commentator disputes the accepted line of thought that patents were merely viewed as special privileges then. He asserts that the interpretation of history ‘from today’s positivist, utilitarian world to the natural rights world of the eighteenth and early nineteenth century’ is negatively affected by the different cultural and social concepts and connotations of the legal

³¹⁰ Testimony of Aikin before the 1829 Select Committee, p.41.

³¹¹ *Veasey v Denver Rockdrill and Machinery Company. Ltd* 1930 AD 243, p.270.

³¹² Mossoff A. ‘Who cares what Thomas Jefferson thought about patents? Reevaluating the patent ‘privilege’ in historical context’ (2006) *Cornell Law Review*, p.953-1012.

term of art ‘privilege’ such that there is no appreciation of the fact that privilege consisted of natural rights and even fundamental rights.³¹³

A suggestion that an error could occur through the narrow reading of history is demonstrable in the fact that the underpinnings of the concept of novelty cannot be identical if the patent was both for importation and for true invention. Patents resulting from mere importation are likely to be based on different grounds from those of genuine invention. The justification for mere importation patents bears more roots in utilitarian foundations, whilst true inventor patents have, in addition, to do with rights conferred on inventor. And this plurality of foundation, it is suggested here, could be one overlooked or at least one alternative basis of patents as natural rights. Indeed some medieval scholars dispute the accounts conveying the impression that historically, society ‘did not think of individuals as possessing inalienable rights to anything.’³¹⁴ It is on this ambivalent historical basis of the operation of the newness criteria in the patent system, or at least plurality of history, that the pejorative view of patents as natural rights by scholars, using a narrow interpretation of history to criticize what is perceived as expansion of patents in contemporary discussion, is discouraged.³¹⁵

2.4.2 Patents as reward by monopoly

Lord Blackburn in *Bailey v Roberton*³¹⁶ stated that ‘patent law, dating from the time of James, gave a monopoly to the invention of the first inventor’, highlighting that patents have for a long time been viewed as monopolies. ‘Just like the natural-law theory, the reward theory is premised on the idea that the individual should be rewarded for his labour and effort, but the reward theory specifically takes into account the benefit to society in general which flows from the individual’s effort.’³¹⁷ As opposed to the natural right theory, the reward by monopoly thesis advocates for

³¹³ *Ibid*, p.958.

³¹⁴ Tierney B. ‘Natural rights in the thirteen century: A *quaestio* of Hendry of Ghent’ (1992) *Speculum*, p.58-68, p.58.

³¹⁵ Mossoff, fn.312, p.956 and 1011.

³¹⁶ (1878) 10 HPC 359.

³¹⁷ Mostert F. ‘The development of the natural-law principle as recognition of intellectual property: A survey from Roman law to modern-day law’ (1987) *South African Law Journal*, p.480-501, p.500.

protection on the demands of justice or fairness grounds as opposed to moral obligations. It was thought that it was ‘just and right that some reward should attach to inventors’³¹⁸ for the usefulness of the invention to society. That means that the patent system is established on a *quid pro quo* between the inventor and the public represented by the state. The consideration in this exchange was the temporal monopoly that the patentee enjoyed for making the invention.³¹⁹ This reasoning as such relates the patentability standard which inventions have to attain in order to be patentable to the value of the monopoly for the invention made.

It was believed that the provision of a temporary monopoly was a suitable mechanism the state could use to remunerate the patentee as ‘commercial ventures were attended with great risk, both to life and capital, due to the unsettled conditions of the times.’³²⁰ State intervention through the provision of temporary monopoly was warranted as the reward could not be guaranteed by ordinary market forces. Other rewards, for example monetary ones,³²¹ would be difficult to make proportional to the merit of the invention. The grant of such a monopoly was harmless to society as the consideration for the monopoly granted was considered adequate as the invention would benefit the public interest.

The reward by monopoly theory was not without difficulties. The basis of rewarding the inventors with monopolies for making an invention were not entirely clear, as initially, many patents were granted as special patriotic distinction, for example to those who made the voyage beyond the sea where they imported technologies from abroad.³²² As such, there was a long-standing association of patents with Crown privilege engraved in society’s psyche as writers have observed that the patent was the Crown’s central tool in furtherance of royal policies.³²³ There was no clear corresponding basis for awarding those who made inventions locally. A reasoning advanced to justify granting monopolies for inventions that meet the patentability

³¹⁸ Taylor, witnessing before 1829 Select Committee on Letters Patent, p.5.

³¹⁹ *R. v Arkwright* (1785) 1 W.P.C 64, p.66.

³²⁰ Federico, fn.181, p.292.

³²¹ Mandich, fn.187, p.380, for instance identifies a Venetian Law of 1474 to confer monetary rewards to those who proposed new things.

³²² Federico, fn.181, p.292-293. For example, in *Mansell’s Patent* (1624) 1 WPC 17 and *Barker’s Smalt Patent* (1606-19) 1 HPC 41, in issue, were imported inventions.

³²³ Mossoff A. ‘Rethinking the development of patents: An intellectual history, 1550-1800’ (2001) *Hastings Law Journal*, p.1255-1322, p.1259.

standard is that there is some labour involved in working the invention to perfect it for introduction to the general public.³²⁴ Therefore the ultimate reasoning was that the provision of a temporal monopoly was so that others but the patentee should be excluded from practising the invention for a while.

However, this accepted view, that the inventor deserved reward through a monopoly did not seem satisfactory in view of the value of the inventor's contribution to the progression of human knowledge. The criticism of patents as reward is based on the notion that the contribution of any one individual is infinitesimal to deserve a monopoly reward.³²⁵ Commentators believed that virtually all useful inventions could not be attributed to individual contribution but rather on society as a whole.³²⁶ As such, there is no compelling reason to reward the one who made a technological breakthrough before everyone else.³²⁷ This criticism, it is observed, suggests that inventions are an inevitable result of industrial activities or dynamism of knowledge; therefore any person, without effort could just stumble upon them.

At the same time this criticism further manifests the need for exacting patentability standards that can accurately measure this supposedly infinitesimal addition which has no guarantee to be made. It could be said such view fails to acknowledge that in the knowledge economy where there is abundance of information, it may take a lot of labour and time to reach a known or desired goal, which in hindsight looks very simple. In fact, sometimes in pharmaceutical discovery, the ultimate result that is desired can be known but impossible to practically reach even over decades, which after the fact does not look like a medical breakthrough.³²⁸ In such fields therefore, there needs to be a mechanism that would reward those who engage in such activities that do not always have an achievable or predictable outcome.

³²⁴ *Ibid*, this has roots in the Lockean theory.

³²⁵ Kamppa K.K. *Problems with the justifications of intellectual property rights* (2007) Turku: University of Turku, Finland, p.35.

³²⁶ Machlup/Penrose, fn.286, p.18. Also see Nelson R.R. 'What is "commercial" and what is "public" about technology and what should be', in Rosenberg N., Landau R. and Mowery D.C. (eds) *Technology and the wealth of nations* (1992) Stanford: Stanford University Press, p.52.

³²⁷ Machlup/Penrose, fn.286, p.18.

³²⁸ Pharmaceutical and medicinal chemistry experts, suggests that a solution may be sought for thirty years but with no solution found: Cockburn M.I. 'The changing structure of the pharmaceutical industry' (2004) *Health Affairs*, p.10-22.

Other opponents of the rewards theory accepted that inventors had the right to be rewarded for their effort.³²⁹ However, they thought this reward would derive naturally in the market forces without the need for legal intervention. They reasoned that the head-start the first user of an invention gained within the market would, as a general rule, provide sufficient reward for the inventor.³³⁰ In today's market economies in the fields of pharmaceuticals, biotechnology, genetic engineering and others, the lead time would be insignificant without such protection,³³¹ because of the channels of rapid dissemination of knowledge, ease of copying and bureaucracy before practice of the said inventions. Therefore, as some industrialists believed historically, the patent monopoly is essential security for maintaining the first-mover advantage in fields where none is ordinarily possible.³³²

Regulators, persuaded by activists for cheaper new medicines access in South Africa, have persisted in viewing the pharmaceutical industry as one that exercises significant monopoly at unwarranted social cost.³³³ Such monopoly costs have been doubted by analysts and empirical evidence advanced that does not support such view.³³⁴ Djolov argues that '[t]he reward for being first to market with new products is the so-called "monopoly" price, which is temporary precisely because its very existence attracts new entry, and which must both cover the current R&D costs and generate profits that pay for the profits of tomorrow.'³³⁵ He concludes that 'the cost of the patent system to the South African public is... a minuscule price to pay for access to the advances in medicinal treatment, innovation and the concomitant assurance of choice when it

³²⁹ Fisher, fn.201, p.10-11.

³³⁰ Torremans, fn.189.

³³¹ Bedsted B. *Recommendation for a patent system of the future: Report by a working group under the Danish Board of Technology, revised edn* (2007) The Danish Board of Technology: Copenhagen, p.34. Also, there are additional registration requirements that make it impossible to competitively release pharmaceuticals to the public, without competitors easily anticipating or catching-up.

³³² Spear B. 'James Watt: The steam engine and the commercialisation of patents' (2008) *World Patent Information*, p.53-58 p.56.

³³³ *Report 6: Report on the propriety of the conduct of members of the Ministry and Department of Health Relating to statements in connection with the prices of medicines and utilisation of generic medicines in South Africa* 1997 Pretoria: The Public Protector, p.14. The regulatory price control of pharmaceuticals, for instance, is made under the single-exit price mechanism and such 'price shall be the only price at which manufacturers shall sell medicines': section 22G of the Medicines and Scheduled Substances Act 101 of 1965.

³³⁴ Djolov G.G. 'Market power and the pharmaceutical industry' (2004) *Economic Affairs*, p.47-51. Also, Djolov, fn.155, p.612 differentiates between a monopoly and a monopolistic competition, with patents falling under the latter as they have limitations on supernormal prices that could be charged by a true monopoly because of ease of new entrants or substitute of patented products with improved products by competitors more likely also patented or invented around original patent.

³³⁵ Djolov, fn.334, p.49.

comes to product variety.³³⁶ It is therefore doubtful that the social costs are disproportionately high when viewed in light of the input costs that have to be paid by the inventor.

Undeniable is the opinion that the open market could not always be useful to the inventor 'to receive an adequate recompense for his labour, expense and time.'³³⁷ To illustrate this reality is the practice that was developed both in the UK and South Africa where patent terms were extendable based on whether there had been profits made from the invention at the expiry of the initial term.³³⁸ This, at least to some extent, confirms that standardised patents monopoly terms are hardly in proportion to their contribution to the state of the art.³³⁹ It is observed here that the monopoly rewards argument is a useful mechanism to assist inventors to reap their just rewards by preventing adverse competition which would occur in open markets.

At a glance, this justification thus has little bearing on the imposition of patentability requirements for inventions. Patentability is independent of the market response to the invention, even though sometimes market success could be an indicator of the usefulness of the invention. It would not be practical to examine and determine how much time-limited monopoly reward should be granted for patents that are just a little above the patentability standard as opposed to those that are far above. Breakthrough inventions would probably deserve more time rewards. The proportionality of the monopoly reward seems undeterminable, except on a case-by-case basis which would be cumbersome and undesirable for administrators of the system.³⁴⁰ Hence, the rewards justification, although arbitrary, serves the purpose of rewarding inventors with the monopoly which can only exist with the time-limited exclusion of others. In an industry where rivalry is driven by competition, in order to be fair and meet the

³³⁶ *Ibid*, p.50.

³³⁷ *Liardet v Johnson* (1778) 1 WPC 52.

³³⁸ The practice of extending patent terms was the norm in South Africa until the Patents Act 1978 which has no provision for such. Patents Act 1977, section 128B provides for supplementary protection certificates which extend the monopoly for pharmaceutical products in the UK.

³³⁹ Ensuring that the scope of the patent matches the extent of the invention has been seen as allowing the balance between the interests of the public and private actors: Christie A. and Rotstein F. 'Duration of patent protection: does one size fit all?' (2008) *Journal of Intellectual Property Law & Practice*, p.402-408.

³⁴⁰ Moe T. 'The New Economics of Organization'(1984) *American Journal of Political Science*, p.739-777.

demands of justice, the law can only set an artificial standard, after which it is incumbent upon the patentee to utilise the monopoly granted.

2.4.3 Patents as incentive to invent and innovate

The incentive justification for patents principally has utilitarian roots. It is not concerned with moral arguments or whether justice for individuals calls for inventors to be rewarded. It was thought that under the patent system, ‘gratitude toward the inventor is only of secondary importance’³⁴¹ to the need to incentivise innovation and inventive development. In *Liardet v Johnson*,³⁴² the specification was framed in the words ‘His said Majesty, being willing to give encouragement to all arts and inventions which might be for the public good...’ highlighting the fact that invention and innovation inducement by the patent was assumed.

The incentive theory although sometimes criticized is offered as a mainstream justification underpinning the system in market economies whereby the firm sees the patent as an incentive that safeguards returns on investment of resources in its inventive activities.³⁴³ Despite having been criticised as an overly simplistic analysis as far as the modern economics of the patent system is concerned,³⁴⁴ it is an argument that is still routinely utilised to justify the system today even though the incentive is one amongst many that have to be considered by the inventor.

The historical study of patents is usually associated with the industrial progression of Britain. The industrial policy of generating and assimilating technology is usually attributed to the existence of the patent system. Thus writers alluded that the protection policy had, despite its problems, produced a ‘system of patents for the effective *encouragement* of invention’.³⁴⁵ Countries that were ambitious to prosper modelled their policies in line with what they perceived as the key to the successes of

³⁴¹ Torremans, fn.189, p.6.

³⁴² (1778) 1 CPC 35.

³⁴³ Taylor C.T. and Silberston Z.A. *The economic impact of the patent system: A study of the British experience* (1973) Cambridge: Cambridge University Press, p.25.

³⁴⁴ Scotchmer S. ‘Standing on the shoulders of giants: Cumulative research and patent law’ (1991) *Journal of Economic Perspectives*, p.29-41, p.29.

³⁴⁵ Fisher, fn.201, p.13.

Britain. For example the Japanese proclaimed that ‘we looked about us to see what nations are the greatest, so that we can be like them ... we investigated and found that it was patents, and we shall have patents.’³⁴⁶

What this justification raises is that developing countries, which have been typically identified as offering no or little patent protection historically, could use the patenting system to foster development and industrialisation. This is in spite of the lack of solid and conclusive evidence that indeed the historical development of the UK was integral with patents. At least there is some correlation, although the extent of the incentives’ effect is not entirely known.³⁴⁷ South Africa’s first patents were in the mining industry.³⁴⁸ It is likely that that its prominence in the mining trade, over its neighbours who also had significant resources but introduced the patent much later on, could be a result of the patent, but this cannot be conclusive.

Historically, observers could not easily accept that there was any intervention necessary to induce invention and innovation. It was assumed that the inventive activities were natural processes that were embedded in industrial culture.³⁴⁹ As such, the patent was not necessary; self-promotion in the trades and guilds would be adequate for optimal invention and innovation.³⁵⁰ This was a view shared by industrialists who thought the patent was not integral to the functioning of industry, stating ‘people will always invent anything that is useful and good, if it will answer their purpose to do so, even without reference to a patent.’³⁵¹

Views against the incentive theory seemed inadequate. The main thrust of opposition is the argument that scientists do not need patent incentives to carry out their activities. This argument seems resonant with our modern realities, where for

³⁴⁶ Fisher M. ‘Growth of the Japanese patent system: A lesson for us all’ (2004) *Intellectual Property Quarterly*, p.85-113, p.85.

³⁴⁷ Maskus K.E. ‘The role of intellectual property rights in encouraging foreign direct investment and technology transfer’ (1998) *Duke Journal of Comparative and International Law*, p.109-161.

³⁴⁸ Van Rooy W.A. ‘History of the Kisch family and DM Kisch Incorporated’, in Van Der Merve A. *Looking back fifty years after the establishment of the Institute* (2004) South African Institute of Intellectual Property Law Special Newsletter, Pretoria, at p. 4. *Hay v African Gold Recovery Co* (1896) 3 Officiele Rapporten 338, was the first litigated patent case.

³⁴⁹ Witness testimony before 1851 Select Committee, p.56.

³⁵⁰ Vincent D. ‘The culture of secrecy: Britain 1831-1998’ (1998) Oxford: Oxford University Press, at p.110, talks of the ingenious artisans’ culture of innovation that is associated with the pride of belonging to the society of skilled trade and apprenticeship.

³⁵¹ Report of the 1851 Select Committee, p.456.

example, university research output is a result of the primary quest to improve knowledge, rather than inventing or innovation. Nonetheless, individuals involved in inventing could hardly be said to be doing this only out of pleasure. It is not satisfactory that basic research be merely carried out with no particular purpose as, although valuable, is of little use to the public. The ‘law looks to the inventor or discoverer who finds out and introduces a manufacture’ that could be a ‘little more than the ornament of a museum.’³⁵² There has to be application of that research in practice, hence one plausible reason patents are not granted for mere scientific principles and theories as will be seen in chapter four. The sprouting of commercial R&D divisions is a testament to the need for inventing more useful inventions that can be pursued to commercialisation,³⁵³ as opposed to basic or primary knowledge that remains stagnant in scientific journals and libraries.

It may perhaps be strained logic to make a correlation between patents and the incentive to innovate and invent in all industries. That, however, does not preclude the conclusion that it may be possible for patents to induce inventive activity in some fields of technology. It is sensible to assert that although patents have their shortcomings in some fields, the benefit that they provide generally outweighs any such considerations; the so-called patent cost-benefit analysis of the system.³⁵⁴ One witness before the 1851 Select Committee conveyed the impression that workers were restricted only to routine work if they were to avoid infringement of patents.³⁵⁵ Indeed, one industrialist gave examples of how his own patents could prevent him from making improvements.³⁵⁶ More concerning is the opinion that in the contemplation of the patent, the application and grant process stopped scientists from practice, destroy models or any vestige of them remaining or even send workmen on distant missions, to prevent leaking of technical details of the invention to

³⁵² *Young v Fernie* (1863-6) 8 HPC 395.

³⁵³ For example academia now has spin-off technological companies or technology-transfer units concentrating on commercialization of new knowledge. PCT most frequent users of the system have a considerable number of academic institutes than formerly, see PCT Newsletter, No. 04/2006, April 2006, World Intellectual Property Organization, Geneva, Switzerland. Also, Stuart T.E. and Ding W.W. ‘When do scientists become entrepreneurs? The social structural antecedents of commercial activity in the academic life sciences (2006) *American Journal of Sociology*, p.97-144.

³⁵⁴ Taylor C.T. and Silberston Z.A *The economic impact of the patent system* (1973) London: Cambridge University Press, p.49.

³⁵⁵ 1851 Select Committee, p.161.

³⁵⁶ Brunel testimony, 1851 Select Committee, p.248.

competitors.³⁵⁷ The patent system, the abolitionists opined, served to rob inventors of the opportunity to evolve and improve upon inventions. This concern thus requires the setting of the system such that continuous improvements are not blocked by the system. As is common in the sciences that more than one inventor may have been working towards the same or similar goal, the system also has to guard against the dispiriting influence of the first-to-file system that does not acknowledge the other active inventors who came close to the patented invention. Therefore the system must guard against the discouraging of ‘near-patentees.’

2.4.4 Patents as an information system

Patents represent a *quid pro quo* between the state and the inventor.³⁵⁸ The *quid* is the monopoly conferred on the patentee and the *quo* is the new knowledge entering the public domain through the invention. In other words, the consideration in this contract is the disclosure of previously unknown knowledge into the public domain by the patentee in light of the state’s protection.³⁵⁹ In *Miller v Boxes & Shooks (Pty) Ltd*,³⁶⁰ it was established that it is in the public interest that persons with inventive minds should be encouraged to disclose the results of their efforts to the public.

The concept of such a bargain gathered eminence from the emergence of the patent specification.³⁶¹ The public might temporarily have been limited in utilising information contained in the specification, but this was in return for the disclosure made by the patentee. In *Walton v Potter*³⁶² the court held that the ‘specification is the price paid by the inventor for the patent he obtains.’ Consent for this exchange was deemed to exist because of the benefits accruing to society from the publication of the

³⁵⁷ 1851 Select Committee at p. 18, witness who was a routine or habitual inventor.

³⁵⁸ *Letraset Limited v Helios Ltd*. 1972(3) SA 245 (AD), p.249E-F and 1972 BP 243(A) at 246D-E.

³⁵⁹ *Liardet v Johnson* (1778) 1 CPC 35, p.37. Also, in *John Waddington Ltd v Arthur E Harris (Pty) Ltd* 1968(3) SA 405(T) the court stated that the invention passes into the public domain at the expiration of the patent.

³⁶⁰ 1945 AD 56, p.568 and 578.

³⁶¹ Pila J. ‘Inherent patentability in Anglo-Australian law: A history’ (2003) *Australian Intellectual Property Journal*, p. 109-125, p.113. Coulter M. *Property in ideas: The patent question in the Mid-Victorian Britain* (1991) Kirksville: Thomas Jefferson University Press, p.27, observes that many applicants chose to be deliberately vague and general but the courts would increasingly void patents whose specifications were deemed inadequate to the claims for the invention.

³⁶² (1841) 3 HPC 859; 1 *Web*. P. C. 595.

invention where it might have remained secret.³⁶³ This has origins in the case of *Cartwright v Eamer*³⁶⁴ in which Lord Eldon C.J. opined that the patent grant should not be considered ‘in the light of a monopoly, as it had before been put by the judges, but as a bargain with the public.’ A qualification to the identity of the public was clarified in *Bichfird v Skewew*³⁶⁵ where it was held that the ‘specification is addressed, not to persons entirely ignorant of the subject-matter, but to artists of competent skill in the branch of manufactures to which it relates.’ It is deducible that the patentability standard that is set should be one that guarantees that a granted patent gives detailed information and knowledge to the public that is valuable and can be put into use by appropriate scientists.

For a long time after the enactment of the Statute of Monopolies, there existed no general, formalised requirement to furnish a detailed specification that set out precisely what the invention was. This would cast some doubt on the justification of the patent on the public education premise. It is asserted that this justification may be viewed more as an adaptation of the patent system to changing times and evolving demands of industry practices.³⁶⁶ Hulme suggested that with the introduction of the specification ‘the doctrine of the instruction of the public by means of the personal efforts and supervision of the grantee was definitely and finally laid aside in favour of the novel theory that this function belongs to the patent specification.’³⁶⁷ That is not to say the other justifications were to be obsolete, but the public education premise was becoming more relevant with the times and in practice.

The specification had other functions that it came to fulfil besides the public disclosure function. In *Holmes v London & NW Rly Co*,³⁶⁸ the court said ‘the object of the condition in the patent requiring the specification is twofold; first, that useful novelties should be given to the public,... and, secondly, that no person should inadvertently infringe the rights of the patentee.’ Contemporary, in *Kirin-Amgen v*

³⁶³ Generally Davies D. ‘The early history of the patent specification’ (1934) *Law Quarterly Review*, p.86-109.

³⁶⁴ (1800) G112 (LC), p.112.

³⁶⁵ (1837-41) 3 HPC 233.

³⁶⁶ Walker R.D. *Patents as scientific and technical literature* (1995) London: Scarecrow Press, Inc., p.40-59, arguing that patents are no longer the ‘forgotten literature of science’, traces the evolving use of the patents as information source.

³⁶⁷ Hulme, fn.208, p.317-318.

³⁶⁸ (1852) 6 HPC 501.

Hoechst Marion Roussel,³⁶⁹ Lord Hoffmann acknowledged that ‘during the course of the 18th and 19th centuries, practice and common law had come to distinguish between the part of the specification in which the patentee discharged his duty to disclose... and the section which delimited the scope of the monopoly which he claimed.’ This supports the view that patents were granted partly for imparting knowledge to the public on how to perform the invention, in addition to their monopoly-claiming function. In other words, this justification has fundamentals in the exchange of secrets with the public through the specification. In South Africa, it was acknowledged by the Appellate Division in *Anglo American Corp. v Osterreichische Eisen und Stahlwerke A.G.*,³⁷⁰ that ‘amongst the benefits conferred by the patentee on the public must be counted the benefit which he conferred by the disclosure of a valuable invention.’ Moreover, the patentee was under the duty to disclose the best method of carrying out the invention,³⁷¹ with this confirming useful knowledge given to the public as a standard for patentability.

The principle that was brought by the patent specification is that it accentuates the need to make a public disclosure, as the patentee may only claim protection for what he has actually created and fully disclosed to the public. As an ideology, the justification therefore fits with the model that promotes dissemination of technology more than only giving an incentive to create pioneer inventions. When setting the patentability standards it should be borne in mind that the exchange price should not be too high to an extent that they discourage disclosure as an option to all kinds of knowledge producers, holders and improvers.³⁷²

The information disclosure argument did not proceed unchallenged over the years. Observers doubted that the technological progress of the state would be at all harmed if inventors were not encouraged to disclose their inventions as ‘nearly all useful inventions depend less on any individual than on the progress of society.’³⁷³ It is

³⁶⁹ [2005] 1 All E.R. 667, p.677 citing Fletcher-Moulton L.J. in *British United Shoe Machinery v A. Fussell & Sons* (1908) 25 RPC 631, p.650.

³⁷⁰ 1967(4) SA 332(AD), p.331D and 333D.

³⁷¹ In South Africa, the repealed 1952 Patents Act, s.10(3)(a) and 23(1)(f).

³⁷² It has been suggested that even in developing countries the patent plays a role as a source of information of diverse research and inventive activities: Pretnar P. ‘Patent applications as an information source for managing exports in less-developed countries’ (1990) *World Patent Information*, p.216-221.

³⁷³ Machlup/Penrose, fn.286, p.27.

inevitable that when keeping inventions secret someone else will make the discovery with the willingness to bring it to the general public.³⁷⁴ Such an argument is less convincing when viewed under this justification of the patent. It assumes that an alternative scientist in the invention chain will have the same patentable idea and will choose to disclose or inadvertently have the invention leaked to the public. To prove a point, trade secrets are still a major practice in industry and some have successfully been long standing.³⁷⁵ Phillips riposting a contention that trade secrets may be exaggerated pointed out that the fact that they are intrinsically secret makes quantification of their use or value challenging.³⁷⁶

There were also views that questioned the granting of a patent to an inventor because knowledge is cumulative and why one should be granted protection for this relatively minute knowledge he adds to the large store of human knowledge under the guise of incentive to disclose.³⁷⁷ This view seems to fail to acknowledge incremental inventions, which if disclosed, can have enormous effects in putting some idle historical information or knowledge into a useful practical application. There are situations where there may have existed technical problems before which could not be solved but by the seemingly minor inventive idea of latter disclosures. The case in point is cases where there is a lot of work done on a disease, the target solution of which is known or a mechanism of the disease is known, but no solution found for a long time. It may turn out to be a simple disclosure that triggers a solution to the stagnancy. The non-obviousness of that disclosure has to be accounted for within the patentability system. Therefore current patentability standards should recognise the importance of disclosures by incremental innovators, who are the cornerstone of today's industrial creativity.

³⁷⁴ Schachman H.K. 'From "publish or perish" to "patent and prosper"' (2006) *Journal of Biological Chemistry*, p.6889-6903.

³⁷⁵ Phillips insightfully proposed that the reason such pronouncements cannot be substantiated or quantified is because of the very reason of secrecy: Phillips J. 'Protection of trade secrets: a property right, equitable right or contractual obligation? Does it matter?' Lovell Seminar, 14 December 2009. Studies have analysed how firms leverage non-patented inventions without the risk of imitation: Coff, R.W., Coff, D.C. and Eastvold R. 'The knowledge-leveraging paradox: how to achieve scale without making knowledge imitable' (2006) *Academy of Management Review*, p.452-465.

³⁷⁶ Phillips J. 'Protection of trade secrets: a property right, equitable right or contractual obligation? Does it matter?' Lovell Seminar, 14 December 2009.

³⁷⁷ Spence, fn.263, p.46.

As consequence of the need to keep an invention secret before a patent application was granted,³⁷⁸ there were arguments that the system was actually encouraging secrecy. Commentators stated that, in the absence of a patent system, ‘secret and isolated work would cease and its place would be taken by a cooperation of all qualified talent.’³⁷⁹ Interestingly, the model of scientific research advocated closely resembles the corporate-led research efforts of the present day.³⁸⁰ Even where there is industrial cooperation and partnerships, parties still keep some information secret, hence this argument does not hold.³⁸¹ Moreover, the keeping of inventions secret is only temporary until the patent has been applied for, whereby all the information is disclosed to the public systematically. Systematic disclosure of knowledge is therefore a justification of the patent system.

2.5 The historical justification model advancing adequate patentability standards

Various models have been proposed that justify IP. One such model useful in concrete IP policy formulation, is centred on ‘midlevel principles’ of proportionality, non-removal from the public domain, efficiency and dignity, which are generalised and informed by specific doctrine, practice and operational detail on the lower level and, at the high-level, are an embodiment of broader normative principles corresponding to deep ethical or foundational values and, more significantly, such model enables debates on IP regardless of one’s normative commitment.³⁸² Cognisant of this model, this thesis suggests, for patents specifically, a more balanced model of all the justifications without ranking them and retracts the dominant utilitarian view from supremacy. An optimal overall justification is achievable this way as it has been noted

³⁷⁸ For instance, Nasmith, an industrialist who refused to disclose his invention until the Office of the Attorney General granted him the patent, Davies D.S. ‘The early history of the patent specification’ (1934) *Law Quarterly Review*, p.86-109, p.87-88.

³⁷⁹ Machlup/Penrose, fn.286, p.28.

³⁸⁰ Dutfield G.M. and Suthersanen U. ‘The innovation dilemma: Intellectual property and the historical legacy of cumulative creativity’ (2004) *Intellectual Property Quarterly*, p.379-421.

³⁸¹ See generally Hagedoorn J. ‘Sharing intellectual property rights – an exploratory study of joint patenting amongst companies’ (2003) *Industrial and Corporate Change*, p.1035-1050.

³⁸² Merges, fn.276, p.304-305. Also, Paine suggests two levels of justification, with one dealing with the objectives, purposes and explanations of practice or an IP institution and the other linking those objectives to our most basic legitimising ideas for IP such as common good: Paine L.S. ‘Trade secrets and the justification of intellectual property’ (1991) *Philosophy and Public Affairs*, p. 247-263, p.249.

that ‘as applied to IP law, utilitarian theory could not bear the load that has been assigned to it.’³⁸³

Focus now turns to how the modified and balanced classical justification model could be viewed from different perspectives, namely from the policy-making perspective, from industry perspective and the courts. A limitation to be mindful of in the creation of models is that they could be grounded on unique rules and practice in one jurisdiction and have an uneasy fit when attempting to apply into a different jurisdiction.³⁸⁴

2.5.1 At policy level

At the dawn of a new epoch in patentability laws where a lot of effort and consensus is sought for the reform of the patent system, it is prudent to consider whether any proposed change will improve the purpose and function of the system. It is important to understand the strength and weakness of the justifications in order to assess whether a particular proposed approach to patentability minimises the weaknesses and optimises the strengths of the system.

The justifications that were utilised throughout history may reveal useful characteristics of the patent which may be used to model a patenting system that is effective in encouraging and protecting inventions.³⁸⁵ This is not to say the patent justifications are to be utilised in their historical context, but should offer an inspiration and a nudge forward to make the system work to higher efficiencies. It would be detrimental to inventive activity if they were to be completely ignored by contemporary policy and law makers. The policymakers under pressure for good public perceptions in handling public health problems have sometimes made adverse regulatory changes even if expert findings for instance ‘indicate that the total profits

³⁸³ Merges, fn.276, p.305.

³⁸⁴ Merges, f.276, p.143-144.

³⁸⁵ This modeling is what writers have called social-scientific prognostication—a history of the future—which is methodologically rigorous and informative, allowing one to depict a number of plausible alternative and empirically-grounded scenarios that may develop in the future, as differentiated from mere predictions which are a ‘little more than extrapolations from present trends or imaginative projections of hopes or fears, and in either case are consequently doomed to fail’: Fay B. ‘Unconventional History’ (2002) *History and Theory*, p.1-6.

made on pharmaceuticals are not exorbitant.³⁸⁶ As such, a balanced and integrated justification model, which is explained below, is proposed.

Although the natural rights justification is rarely relied on, it appears to offer a balancing function to the whole patenting regime. It reiterates that patents are rights. Individuals come up with the inventions. The inventors overcome the barrier in the state of the art and come up with new and non-obvious inventions. This justification demands an exacting patentability standard to be set, both to qualify for the right and also how far the right should extend and the circumstances in which the right should be curtailed or denied. In contentious cases, it seems to be a good candidate in justifying the setting of patentability standards that seek to identify the true and deserving inventor. Rules of newness and priority crystallize upon the identity of the source or origin of the invention. The natural rights justification, for example, appears to offer the critical ingredient to transform patentees from previously disadvantaged groups mainly located in the developing world into the mainstream patenting field through the recognition of these participants as the natural private right holders of patentable subject-matter, if patenting is their option chosen. Conversely, it offers the rationale for rejecting some technologies or patentees from the patenting arena. Animals or plants, for example, are hardly classifiable as falling within the control of an individual to be patentable.³⁸⁷

There may be some unease on the adequacy of the monopoly reward justification for setting optimal patentability standards. It may not be adequate or appropriate across all fields of technology, but it is constant amongst competitors within the same fields of technology. Some inventions are stumbled upon without much thought or have short investment return periods but still get the same terms of protection as laborious and complex breakthrough inventions that may have longer return-on-investment periods. However, it is agreeable that time-limited monopolies are a form of reward

³⁸⁶ *Browne Report: Fifth Interim Report of the Commission of Inquiry into Health Services -Interim report on pharmaceutical services*, 1985 Pretoria: The Government Printer.

³⁸⁷ For instance, TRIPS Art 27(3)(b), South African Patent Act 1978 s.25(4). The degree of modification in genetically modified animals in order to be patentable has been difficult to resolve and continues to be debated, with many models for the demarcation being suggested; for instance Safrin S. 'Chain reaction: How property begets property' (2007) *Notre Dame Law Review*, p.1917-1969, suggests a chain reaction theory whereby the granting of private property evolves into unanticipated second generation rights encroaching on the public domain over time.

that is practicable and suitable; it is then the patentee's burden to make the most out of this monopoly reward for inventions meeting the required patentability standard.

The incentive to invent or innovate encourages the practical exploitation of knowledge through activities that prioritises inventing solutions to problems.³⁸⁸ The reality is that for the inventive process to sustain development and improvement of the state of the art beyond mere discovery of fascinating scientific principles and knowledge, it has to be applied, often with costly activities carried out. It is recognised that there are 'hobby inventors', but most industrially useful inventions can only be sustained with considerable economic investment.³⁸⁹ Scholars observe that the system has to 'induce risk-takers, whether they are researchers or investors, to search for novel ideas that are capable of becoming marketable innovations.'³⁹⁰ In other words this justification acknowledges the practical advantage that the invention possesses as evidenced by the willingness to make actual, often strategic, investment input into the invention.³⁹¹

In return, society enjoys the inventive and innovative advances that are perfected in practice from this inducement. The policy makers should not assume it is an automatic process or perceive the return of that investment in bad light, for instance in perpetuating historically incorrect opinions about the inventive processes of the industry even though, for instance, empirical 'investigation do not support the view that the pharmaceutical industry in South Africa is, as a whole, earning excessive profits, particularly if the risks are borne in mind.'³⁹² Hence, contemporary patentability standards must be set at a level where inventors are inspired and encouraged to make useful and practical inventions to qualify for a patent.

The information disclosure or public education justification brings the patentability standards to levels where protection is offered if and only if the patent will teach the

³⁸⁸ Kitch E. 'An economic review of the patent system' (1977) *Journal of Law and Economics*, p.265-302.

³⁸⁹ von Hippel E. 'People don't need a profit motive to innovate' (2011) *Harvard Business Review*, p.36-37.

³⁹⁰ Cornish, fn.281, p.751.

³⁹¹ Van Caenegem, fn.123, p.250.

³⁹² Steenkamp Report: *Report of the Commission of Inquiry into the pharmaceutical industry*, 1978 Pretoria: The Government Printer.

public something new and valuable which could otherwise be kept out of the public domain. This disclosure element of the patent grant has strengthened significantly since the Elizabethan era. As such it should not just be seen as a late-comer in the patenting field, but more as a critical element which is undoubtedly a valuable consideration for patent protection in contemporary knowledge economies.

Generally, the natural rights and monopolies justifications could be viewed as geared up more for the benefit of the knowledge producers in the system. The incentive and public disclosure justifications are more of public policy levers to the system. Some suggest that although there is close relationship between them, ‘the difference between them lies in the relative value placed on the individual or societal interest.’³⁹³ It is therefore these competing perspectives that have to be balanced if the system is to attain an optimal level of encouraging invention and innovation and offering reasonable protection for the resulting inventions.

This leads to a caution in the balancing of the justifications in the design of the patentability standards. It is easy to assume that the public or policy inspired justifications override those of industry or private interest. Mainly, this is because policy can be set without consensus with industry players.³⁹⁴ In such a situation industry would have to go through a metamorphosis to survive and adapt to the changes thrust upon it.³⁹⁵ However, this does not necessarily mean the resultant system would be optimal. A desirable view is one that recognises that creator-centred justifications are also essential³⁹⁶ for the system to work and so there always has to be a balanced view of the justifications which accommodates the private interests. The

³⁹³ Mostert F. ‘The development of the natural-law principle as recognition of intellectual property: A survey from Roman law to modern-day law’ (1987), *South African Law Journal*, p.480-501, p.500.

³⁹⁴ Approaches to IP policy-making have been expanded from the traditional social or welfare view focusing on the balancing of IP benefits and costs to society to include, as equally important, the industrial dimension viewing knowledge, information and intellectual creations as assets of strategic economic importance, the creation and exploitation of which should be boosted by the formulated IP policy and recognising that such industry or business considerations in policy formulations are vulnerable to unreasoned political pressures and compromises that may undermine their entire rationale: Pugatch M.P. ‘The process of intellectual property policy-making in the 21st century- shifting from general welfare model to a multi-dimensional one’ (2009) *European Intellectual Property Review*, p.307-315.

³⁹⁵ Wertheimer A. and Santella T. ‘History and economics of the pharmaceutical patents’, in Farquhar I., Summers K.H. and Sorkin A.(eds), *Research in Human Capital and Development*, Bingley: Emerald Group Publishing, p.101-119.

³⁹⁶ Spence, fn.263, p.45-46.

beneficial outcome of fulfilling the creator interests are bestowed onto the public via the advance in the state of the art or the exploitation of the inventions.

Complementary to a necessary balanced view of the justifications, one theme resonates in all the justifications outlined above: they all have a vital contribution to make in setting the appropriate patentability standards. That is to say the system properly operates on an integrated view of the justifications. It does not matter whether they were deployed later on in the patent debate such as the public education justification³⁹⁷ or they have dropped off along the way as unfashionable such as the natural rights justification. If the patenting system is to be properly understood, retained, refined, and harmonised, it would be worthwhile to carefully deploy all of these classical justifications. It is proposed that when setting policy or making assessment of whether an invention meets the patentability standards, regard should be taken of all of them. Even at the international level, there is the recognition of the natural rights justification, which was overlooked when the other justifications were well-accepted and deployed. This puts this justification at par with the other classical justifications³⁹⁸ and brings it to the fore of the reform discussions. That is to say they each contribute without the exclusion of the others.

The integrated view of the justifications can be attained by way of not ranking or prioritising some the justifications when formulating the appropriate patentability standard. Ranking is unhelpful and distorts their historical function or uses within the system. What would be low-ranked justification is essential to the system as a whole in achieving equilibrium. For instance the late-comer public education premise cannot be relegated, certainly not eliminated. A societal or public focused policy cannot properly function when a pejorative view is held of private rights. The devastating effects of such a negative view may not be manifested instantaneously, but could be long-term and long-lasting, when the private actors in the systems start to shun the system in preference to other modes of invention protection, even if less secure or less optimal than the patent system.

³⁹⁷ Cornish suggests that the role of advancing public knowledge, although important, was nonetheless secondary: Cornish, fn.281, p.751.

³⁹⁸ Mossoff, fn.323.

Such a non-ranking approach keeps in check a populist or even sensationalist or alarmist public policy in the patent administrative and legislative forums.³⁹⁹ A position of this kind is susceptible to manipulation by media and politicking rather than well-reasoned long-term principles to optimise the system.⁴⁰⁰ For example, the monopolistic justification is easily cast in unfavourable light. The danger of an emotive approach, both in setting the patentability standards and assessing whether the standards have been met, rather than one that uses pre-ordained triggers for disturbing patentability standards is evident.

2.5.2 In industry

The justifications as a whole also have to be appreciative of the reality of the pharmaceutical industry, from conception of the idea to engage in these activities to the daily operations and decisions that confront practitioners and also of the need for constant re-evaluation of remaining in the pharmaceutical industry. This need is critical in Africa which is historically a neglected market compared to other markets perceived to have significant buying power or at least being larger non-segmented jurisdictions.⁴⁰¹ Therefore a patent system must exist that comports with the practical realities of a pharmaceutical industry.

There are some indications that the industry could be consolidated in emerging markets. Some observers even suggest that with the rapid industrialisation and improvement of the standard of living in India and the Far East, there may be the diminishing advantages of cheaper labour that, *inter alia*, initially attracted pharmaceutical companies to these regions, and they may in turn consider more investment in Africa that was historically neglected.⁴⁰² This trend of setting up more

³⁹⁹ For instance, some organisations and advocacy groups can generally be anti-patent and alarmist in IP issues: Ghafele R. 'Of war and peace: analyzing the international discourse on intellectual property law' (2010) *Intellectual Property Quarterly*, p.237-255, particularly at p.249-250.

⁴⁰⁰ It has been cautioned that 'the public is the whole community- which at times may not be represented by the majority or the media', Justice Susan Kenny 'Maintaining public confidence in the judiciary: A precarious equilibrium' (1999) *Monash University Law Review*, p.209-224.

⁴⁰¹ Market reforms to address healthcare institutions and infrastructure more than just healthcare products such as pharmaceuticals have been identified as crucial in addressing disease eradication in developing countries: Callahan D. and Wasunna A.A. *Medicine and the market: Equity v choice* (2006) Baltimore: The John Hopkins University, p.116-117.

⁴⁰² Aldridge S. 'Is Pharma moving to Africa' *Pharmaceutical Technology Europe*, December 2007, Advanstar Communications Inc, p.15.

pharmaceutical plants locally is of benefit in fighting diseases within Africa. For instance, commentators have noted that the pharmaceutical industry in South Africa in one particular area of treatment or disease, for instance Galderma Pharmaceuticals focuses on African dermatology because ‘there is little research on African skins worldwide.’⁴⁰³ Regulation must be with the intent of encouraging localised pharmaceutical research. Therefore setting a policy underlined by patentability laws that recognise this industry reality is imperative.

Considering the justifications, it can be said that the natural rights doctrine could confer confidence in firms that they will be entitled to the rights arising from their invention in the previously ignored medical fields. Most of the inventive stages in the pharmaceutical process are indeed laborious and require a considered choice to be made to follow that line of research. This will often take years and a lot of investment. Therefore the monopoly reward will act as security for making the decision that has no guarantees of success.⁴⁰⁴ The incentive justification is especially important for inducing firms into research areas that are neglected. It would be unwise to assume that an inventor would pursue research in an area without any incentive to do so.⁴⁰⁵ The disclosure justification is perhaps less attractive to industry because secret information the firms hold usually represents competitive advantage. The disclosure requirement must be such that it is nevertheless viewed as a worthwhile business exchange of secrets.

2.5.3 In court

It is submitted that the classical justifications are essential in explaining the stipulated patentability standards or why particular tests are applied or particular questions are asked as part of patentability assessment. The patentability assessment questions or tests customarily used in court are a summary of the applicable law. Arguably, the tests or questions could work even if the one making the patentability decision has no

⁴⁰³ (Unkown) ‘Carving out a space- niche players in South Africa’ *Pharmaceutical Technology Europe*, May 2009, Advanstar Communications Inc, p.44.

⁴⁰⁴ Grabowski, H.G.,*et al* ‘Returns on Research and Development for 1990s new drug introductions’ (2007) *Pharmacoeconomics*, p.11-29.

⁴⁰⁵ Sonderholm J. ‘A reform proposal in need of reform: A critique of Thomas Pogge’s proposal for how to incentivize research and development of essential drugs’ (2010) *Public Health Ethics*, p.167-177.

thorough knowledge of the underlying justifications, but follows them carefully. However in some borderline cases, following these without understanding their origin could lead to incorrect decisions.⁴⁰⁶ It is in these circumstances that the use of the classical justifications becomes particularly valuable.

As a result of asking the patentability questions against the background of the justifications, it is suggested that this would prevent the questions or assessment becoming merely mechanistic, especially if the tests seem to work in the majority of cases in practice without the need of reverting to exhaustive examination of why a particular patentability criterion exists. This is to say that although the final assessment tool may be a practical shortcut to answering why a particular invention is deemed patentable, this practice has to correspond with the underlying reason for making that choice,⁴⁰⁷ even though one does not necessarily have to investigate this in all cases when judging patentability. Moreover, the justifications could explain why even a particular patentability assessment approach is preferable over another.

Formulating the justifications as an aid to interpretation of the patentability questions or approach has its advantages. This is significant when the justifications are considered by academics and legal history scholars as contrasted with practitioners mainly due to their different approaches to the analysis and use of the law.⁴⁰⁸ Due to the tensions between the classical justifications and the need to choose the best one to

⁴⁰⁶ To improve on fact-specific patentability judgments, policy-based decision-making has been identified as a viable approach: Rai A.K 'Engaging facts and policy: A multi-institutional approach to patent system reform' (2003) *Columbia Law Review*, p.1035-1135, generally and particularly, p.1101-1103.

⁴⁰⁷ One view is that legal argument and judicial decision-making must be grounded in philosophy and reasoning and be structured and unified, even though there may be practical limitations on judges, but 'any practical difficulties would not exclude such a philosophical goal from at least informing legal argument and it could be argued that those who supported principled reasoning certainly seems to have such a goal and to seek to see law displaying a character which is logical and rational. This would suggest judges and philosophers have similar roles and goals': Malloch, V.A. *Persuasion : a historical-comparative study of the role of persuasion within the judicial decision-making process.*(2002) University of Glasgow: Unpublished PhD thesis, p.239-240.

⁴⁰⁸ Some analysts have criticised the overall disjunction between the academia and practitioners as a result of the growing divergence amongst academics, with one group being seen as 'impractical' scholars who produce abstract scholarship that has no regard for legal doctrine that may constrain or guide the practitioner and has little relevance to concrete issues to the practitioner and the 'practical' scholar who 'gives due weight to cases, statutes and other authoritative texts, but also employs theory to criticize doctrine, to resolve problems that doctrine leaves open, and to propose changes in the law or in systems of justice. Ideally, the "practical" scholar always integrates theory with doctrine.' Edwards H.T. 'The growing disjunction between legal education and the legal profession' (1992) *Michigan Law Review*, p.34-78, p.35.

explain their position in court, legal practitioners have usually sought to present their preferred justification as the best view supporting or sustaining the patent system. A shortfall of this analysis is that this can be done at the expense of the other justifications whereas, on the other hand, the academics or scholars present the justifications as a balance of possibilities in explaining the patent system. This may lead to different conclusions.

To elucidate this point of how interpretation could be different between these groups, Webber states that the interpretation of law from the academic or legal historical perspective adopts what has been called an external approach which focuses on the historical and sociological account of the law and addresses the same phenomenon, but for different reasons as the internal approach which focuses on how arguments are fashioned and deployed within legal practice to make decisions, although it is common to rely on both kinds of explanations to understand legal development.⁴⁰⁹ He argues that the law therefore exists in two distinct modes, on the one hand being the descriptive mode which encompasses good legal history and seeks to describe the legal order in effect in a particular society and particular time and examines a range of possible arguments and as a result is inevitably plural as its conclusions are imperfectly rationalised as there remains as yet unresolved controversies.⁴¹⁰ On the other hand, operating in the exhortative mode, legal practitioners seek to eliminate the normative range of possibilities and establish a common and best procedural mechanism that is peremptory and ‘assist in the process of winnowing normative controversy and determining a single, authoritative interpretation’ although the underlying controversies remain and may appear in future appear.⁴¹¹ In the exhortative mode the practitioners are supporting one specific outcome, the best interpretation and not necessarily dictated by the raw or historical material to form that particular best outcome.⁴¹²

⁴⁰⁹ Webber, fn.120, p.2.

⁴¹⁰ Webber, fn.120, p.6. There is opinion that the development of the law is enhanced if there is plurality of opinion in judgement rather than reaching a final conclusion prematurely, even though this may lead to some uncertainty: Lord Reid, *The Judge as Lawmaker* (1972) *Journal of the Society of Public Teachers of Law*, p.28–39, p.28.

⁴¹¹ Webber, fn.120, p.6-7. Lord Hope is of the view that a judgment style could be a declaratory type, bringing finality to a matter or an exploratory type, where the judge sets out to persuade the reader by debate: Lord Hope *Writing judgments: Annual Lecture 2005* (2005) Judicial Studies Board, London, p.7.

⁴¹² Webber, fn.120, p.7.

Such an approach to patentability interpretation illustrates the plurality of the law that can result as the descriptive and exhortative modes are not independent.⁴¹³ The justifications represent the descriptive mode where the source, origin and rationale for the patentability decision is based and on the other hand the patentability assessment questions represent the exhortative mode where the arguments in practice are presented by the respective parties in dispute only to achieve their preferred outcome. The implication for viewing the law of patentability standards in both modes is that it can be used to resolve dissonance in cases where there is difference of opinion in the development of case law. For instance, Burrell argues that the latest South African Court of Appeals authority on the assessment of non-obviousness is incorrect and is not the law operative in South Africa, preferring instead the approach that was previously formulated by the Court of Appeals under the first patent statute after British rule.⁴¹⁴ One notices that the Court of Appeals is operating in the exhortative mode, simply stating the questions that have to be answered pragmatically to get to the answer whilst Burrell seem to be relying on the descriptive mode relying on the history and incorporating the classical justifications in his analysis. As these approaches can lead to different outcomes, it is preferable therefore that the exhortative mode incorporates elements from the descriptive mode and hence the suggestion that patentability assessment tests or questions be informed and aligned with the classical justifications. Noting the difference between the two modes of looking at the law has the implication that ‘it can prevent us from writing history that is entirely divorced from the law as it was lived and experienced.’⁴¹⁵

Formulating the model in this way not only exposes the disjoint that could occur in the historical study of patentability in practice, but could also highlight the limitations of comparative law. The comparative element imports into this discussion concepts that may seem identical in different jurisdictions but are not, more especially in a globalised world. Arguments may be perpetuated that are founded on assumed facts which have a different meaning in another jurisdiction or society as seen with regards to the history of the patent custom in the two jurisdictions compared in this thesis. To

⁴¹³ Webber, fn.120, p.4.

⁴¹⁴ *Ensign-Bickford (South Africa) (Pty) Ltd and Other v AECl Explosives and Chemicals* 1998 BIP 271 (SCA); Burrell, p.158.

⁴¹⁵ Webber, fn.120, p.9.

remedy this, we have to constantly re-define what the basic meaning of these concepts as applying to current conditions is. That is not to eliminate the individual history of the converging societies or the case law thereof, but it is to develop a tool that could resolve some of the borderline issues that confront a patent practitioner in a world of diminishing borders in which the pharmaceutical activities are typically carried out. Retaining previous local customs may not be helpful when other jurisdictions align themselves with an emerging internationalised justification for the patent system.

In this comparative context South Africa is at the risk of appearing as a jurisdiction which easily curtails pharmaceutical patent rights, mostly because of the challenges it faces not only in trying to develop an internal pharmaceutical industry, but at the same time appease advocates against the patent regime in the arena of pharmaceutical patenting. The UK challenges lies in its position as a long time dispenser of the law and originator of the Commonwealth case law. With increasing growth of the pharmaceutical industry activity occurring outside of the UK and the mobility of the pharmaceutical firm, the emerging influence of the patent justifications from other jurisdictions may take pre-eminence. The relevance of the historical context of the English judgements may become doubted over time.⁴¹⁶ As authors note, ‘the key issue we take from this pluralized historical context, however, is that any particular settlement can never be the *final* political economic settlement for IP, its protection, and enforcement.’⁴¹⁷ The preferable position is one where a converging view of the justifications is achieved relative to other jurisdictions. It is easier to set and make patentability decisions when there are closely approximated justifications for the patent between different jurisdictions. This is manifest in borderline cases where reliance on a particular justification could prove decisive in one jurisdiction where it would be opposite in another when the justifications are viewed differently.

2.6 Conclusion

From this exploration, the thesis forms the central argument that the historical justifications are all important in shaping a system that meets today’s challenges in

⁴¹⁶ Mustill LJ in *Genentech Inc's Patent (Human Growth Hormone)* [1989] RPC 147 stated that the UK has a rich history of case law and patentability principles, but warned that it should not be applied without regard to new and contemporary law.

⁴¹⁷ May/Sell, fn.121, p.27.

the pharmaceutical industry and serves to direct the making of enhanced patentability decisions. In pursuance of this argument, it has been suggested a conceptual framework under which to formulate an optimal contemporary patentability standard importing rationales from the history of the system.

One of the fundamental qualities of the desirable patentability standard under the suggested conceptual framework is that anyone who has created an idea has a right to apply for, and be granted, protection for their creations, local or foreign, as long as it meets certain objective and universal criteria. Whilst Britain was free to formulate its own practices and implement an invention and innovation policy that exclusively benefited its population, this may not be feasible today. Then, there was no external agenda to contend with, no pressure on the local system for conformity to an international level.⁴¹⁸ Thus, one way to promote and protect inventions now is by establishing a local patentability model that resonates with all types of patentees at a cross-jurisdictional level. South Africa is in a delicate position, as there are international treaties to take into consideration when tweaking the local patent system. International trade would be hurt by patent regimes not complying with international treaties⁴¹⁹ that restrict national favourism policies that existed historically.

The examination of the patentability history through the lens of what can be viewed a prosecutorial spirit for the ills and compensations for the past runs the risk of reducing patentability discussions and philosophy into mere politics of the direction the law is to develop. In such an environment, the merits of the historical justifications of the patent system may be lost. To prevent retrogression of the system, it is therefore concluded that the present patentability standards need to be developed in ways that recognise the interconnectivity, cumulative and global nature of most inventions and innovations. This has to be done while ensuring that patent holders, irrespective of origin, size or type, have, in the patent system, access and the opportunity to secure a reasonable return on their investment in producing inventions and are incentivised in bringing them to the public.

⁴¹⁸ Fisher, fn.346, p.92.

⁴¹⁹ TRIPS Art 3 in particular requiring treatment of all patentees as equal.

CHAPTER 3

THE INTERNATIONAL PATENTABILITY DIMENSION

3.1 Introduction

Integration and harmonisation of patentability laws is a continual process in the international arena. The cumulative convergence of international legal obligations restricts the domestic law-making process to narrower confines than what legislators are accustomed to.⁴²⁰ In the previous chapter it was established that historically, the UK and South Africa, were at liberty to develop their laws and patentability was decided domestically. There is now progressively less freedom for internal patent law-making and the international and regional dimension of patentability takes more prominence in both the UK and South Africa.

Numerous models are proposed that seek to attain the goal of a 'global' patent. A growing consensus on appropriate international and regional instruments emerges, albeit slowly. Informal forums are increasingly used as stepping-stones to fully-fledged binding legal instruments that both directly and indirectly determine the patentability standard.⁴²¹ Nonetheless, shortfalls are apparent in most of the reforms suggested in the negotiations that have virtually divided developed and developing nations, North-South divide where the UK and South Africa usually find themselves on opposite ends. If a lasting or satisfactory solution of the appropriate legal standard is to be attained, the international instruments being formulated could seek to understand and incorporate the viewpoints, perspective and priorities of stakeholders in local jurisdictions where it is to be ultimately implemented. At the same time, the resultant harmonisation of laws should allow for the patentability standards to be compatible with industry practices and technological development and exploitation,

⁴²⁰ *Bilateralism in Intellectual Property* (2001) A Paper Prepared for Oxfam by Peter Drahos, Herchel Smith Senior Fellow in Intellectual Property, Queen Mary College, University of London, p.14.

⁴²¹ Informal discussion on patentability requirements are for example the WIPO SPLT informal Casablanca talks convened by WIPO director-General to 'recommend future course of action for WIPO work program' http://www.wipo.int/edocs/prdocs/en/2005/wipo_upd_2005_241.html or USPTO informal talks with partner offices on driving substantive patentability harmonization initiative: USPTO David Kappos transcript of speech at an event entitled 'A Dialogue with David Kappos, Director of the US Patent & Trademark Office', <http://www.directorsroundtable.com/pdf/London%20Patent%20Program%204-4-11.pdf>.

otherwise the laws would be ineffective in encouraging and protecting inventive activities.

In recent times, there increasingly have been arguments that South Africa and developing countries generally have not benefited from high patentability standards or the patent system generally, especially in the area of public health and technology transfer.⁴²² Despite the different underpinnings of the North-South patenting systems, it is suggested in this thesis that patentability should be universal for identical inventions, mainly due to globalized nature of the scientific world and uniformity in knowledge generation and utilization and trade practices.⁴²³ Despite the historically different patentability law development of the South African and UK jurisdictions, it is desirable that the protection of an identical invention should yield the same result, irrespective of the type, size or domicile of the patentee. That is to say any aspect of knowledge or invention, regardless of the beholder, should be protected similarly if it possesses similar predetermined characteristics. Indeed, it has been said that '[a]ny science, theoretical or applied, that would limit itself to one nation would be

⁴²² Tensions include the realization that the benefits from TRIPS may have been over-estimated and from generally viewing IP as unsuitable to developing country's technological realities to arguments that higher patent requirements cannot suit developing countries' access to medicine needs. For instance some have stated that 'developing countries that used to have low patent protection standards...enjoyed a strong flow of information and technological development' and developed strong generic-based pharmaceutical industries and competitive markets. Pharmaceutical patenting both in developing countries and least-developing countries will negatively affect access to treatment: Wanis H. 'Agreement on Trade-Related Aspects of Intellectual Property Rights and access to medication: Does Egypt have sufficient safeguards against potential public health implications of the agreement' (2010) *The Journal of World Intellectual Property*, p.24-46. Some assert that developing countries sign TRIPS-plus deals as a way of competing for foreign direct investment (FDI) when they were united in resisting TRIPS which only has minimum standards: Bernieri R.C. 'Intellectual property rights in bilateral investment treaties and access to medicine: The case of Latin America' (2006) *Journal of World Intellectual Property*, p.548-572, p.560. Some have asserted that high IP standards from TRIPS-Plus agreements have negative impact on developing countries, especially access to medicine whereby the 'companies are pursuing the higher level of protection, not to increase R&D, but to limit generic competition', Kuanpoth J. 'TRIPS-Plus intellectual property rules: Impact on Thailand's public health' (2006) *The Journal of World Intellectual Property*, p.573-591, p.589. There has been concern that the balance between IPR holders interests and technological achievement has not been achieved, para.3(ii) WT/WGTTT/W/6, p.7.

⁴²³ Merton R.K. *Social theory and social structure* (1957) New York: Free Press, provides a doctrinal perspective positing that the behaviour and action of scientists is controlled by adherence to a set of universal norm of universalism, communism, disinterestedness, organised scepticism originality and autonomy and good science is argued to transcend cultural or geographical boundaries: Corbern W.W. and Loving C.C. 'Defining science in a multicultural world' in Murphy P (ed) *Reconsidering science learning* (2004) London: Routledge. Rimmer D 'Learning about economic development from Africa' (2003) *African Affairs*, p.469-491 examines the causes of the differences in realities for the science human capital in national development and technology settings for developing countries.

laughable.’⁴²⁴ This section of the thesis therefore argues for a universal but realistic patentability standard from this continuous international harmonization of patentability laws. This proposition is dual in nature. Firstly, it addresses the desirability of universal patentability standards, at least within the same fields of technologies.⁴²⁵ At the same time it is equally mindful and appreciative of the industrial realities and the possible effects of the history and technological developmental stages of different nations and trading regions seeking to attain a harmonized patent standard.⁴²⁶

Such a standpoint seems appropriate for pharmaceutical activities. On one level, the universality of patentability standards at the global level puts an emphasis on the harmonisation and coordination of patentability laws. This is a complex task involving stakeholder consensus and agreement on the appropriate framework and often persuaded by an array of interests beyond the patentability standard, although the patentee and invention commercialisation maximization are the major beneficiaries. On another level, the realities of the implementation of those internationally negotiated instruments is an endeavour that requires careful thought and manoeuvring if it is to be successful practically and at industry level. Misunderstandings in the harmonisation process causes misapplication of the instruments and actions that undermine patentability standards and indeed abandoning of the regime by industrial players.⁴²⁷ To avoid not achieving the desired standard, it

⁴²⁴ Kozyris P.J. ‘Comparative law for the twenty-first century: New horizons and new technologies’ (1994) *Tulane Law Review*, p.165-179. Cf Marković S.M. ‘The patent system- Not more than an instrument of public policy’ in Pyrmont et al, fn.281, p.829, although acknowledging the desirability of uniformity, comments about the suboptimal value of patents in some geographical and social environments, which in order to be optimal would have to be directed at the use of the knowledge rather than its intrinsic qualities.

⁴²⁵ There are views that patentability requirements in practice shift toward being technology-specific. See Burk D.L and Lemley M.A. ‘Is patent law technology-specific’, University of California School of Law Public Law and Legal Theory Research Paper Series, 2002, Research Paper No. 106, p.1-65 available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=349761.

⁴²⁶ A spectrum of views are expressed in this regard; some insist that developing countries should strictly comply with international patent instruments as they already serve their benefit (Straus, fn.264, p.47-63), some suggest that it is plausible that developing countries could use patents to their advantage as a transition tool in industrial development (Matthews D. *Patents in the global economy: A Report to the Strategic Advisory Board for Intellectual Property Policy (SABIP)*, 2010, UKIPO, p.11-14, p.26 and also, Maskus K.E. ‘Intellectual property challenges for developing countries’ (2001) *University of Illinois Law Review*, p.457-473) whilst others are of the view that patents are irreconcilable with developing nations’ economies (Adusei, fn.56).

⁴²⁷ Commentators assert that for inventive pharmaceutical processes, inventors are often faced with the dilemma of whether to patent them or keep them as trade secrets, a choice swayed by their perception

therefore requires a study of how the harmonisation process occurred and continues to occur in order to attain a realistic optimal patentability standard.

The task of attaining a universal but realistic patentability standard is accomplished in the following manner. The chapter begins with an assessment of the universality and cross-jurisdictional characteristics of pharmaceutical knowledge and operation of the pharmaceutical industry. This sheds light on the qualities of pharmaceutical knowledge and forms the foundation for suggestions of optimal patentability standards for this sector at the international level. The chapter then moves onto an overview examination of the rationale for the patentability harmonisation efforts. This forms the basis for the subsequent individual examination of some of the international regimes that were instrumental in setting patentability standards that are consequently applied in the two countries compared in this study. Some of these instruments have a direct bearing on patentability standards, for instance the TRIPS Agreement. Others only brought to the fore particular aspects that are operative in the limbs to patentability standards and play a supplementary, yet significant role in establishing an optimal international standard, for instance the Paris Convention. That is to say the chapter not only looks at instruments that had the express intention of controlling patentability, but also the instruments that have a consequential effect even if it was unintended. An assessment is made of how these instruments can and are being used and also optimised for setting patentability standards that are suitable to the stakeholders in the two countries being studied. This assessment also briefly extends to patentability instruments that are designed for the regions of the two jurisdictions under study. This is because it is at this level that knowledge localization and clustering is observed and therefore studying harmonisation of patent law at regional level would be useful in revealing patentability issues peculiar to the countries under study.

3.2 The international environment of pharmaceuticals activities

Since the basic law of science applicable to pharmaceutical and related technologies is the same and applies everywhere, there is an underlying unified technology which in

of the two regimes: Milgrim R.M. 'Trade secret protection and licensing- a true alternative', in Costner T.E. (ed) *Patent law review- 1972* (1972) New York: Clark Boardman Co, p.376.

principle can be applied everywhere.⁴²⁸ In knowledge economies therefore, knowledge resulting from innovation and inventive activities is not confined to national boundaries. The globalization of knowledge has been defined as the intensified interaction and interlinking of knowledge systems located in distant places.⁴²⁹ As such, there is potentially a random dispersion of knowledge or research output worldwide.

However, the globalization of knowledge has limitations. Knowledge intensive industries tend to be geographically clustered to particular regions as opposed to being uniformly or randomly distributed across the world.⁴³⁰ This spatially selective expansion of knowledge is more pronounced in pharmaceutical industries.⁴³¹ This is not incidental but fundamental in high-technology industries. As a result, over time there emerges centres of knowledge in particular regions of the world.⁴³²

This regional knowledge clustering could be within particular countries and also between closely interrelated regions.⁴³³ The local political boundary can play a role in determining the extent of those knowledge clusters and sometimes the regional centres develop out of close-knit collaborations and alliances amongst industry actors across borders.⁴³⁴ That is to say political intervention of national states does not exclusively play a role in fostering the technological growth of those centres. National innovations systems play a role whereby the national government intervene in the markets in attempt to boost the competitiveness of national firms. For instance governments could seek to support local high-technology and inventive firms with

⁴²⁸ Freeman C. 'The "national system of innovation" in historical perspective' (1995) *Cambridge Journal of Economics*, p.5-24, p.15.

⁴²⁹ Giddens A. *Consequences of Modernity* (1990) Cambridge, Polity Press, p.64.

⁴³⁰ Storper M. 'The limits to globalization: Technology districts and international trade' (1992) *Economic Geography*, p.60-93.

⁴³¹ Zeller C. 'North Atlantic Innovative Relations of Swiss Pharmaceuticals and the Proximities with Regional Biotech Arenas' (2004) *Economic Geography*, p.83-111. Some assert that the growth and diffusion of intellectual human capital was the main determinant of where and when the American biotechnology industry developed: Zucker L.G., Darby M.R. and Brewer M.B. 'Intellectual human capital and the birth of the U.S. biotechnology enterprises' (1998) *The American Economic Review*, p.290-306.

⁴³² Maskell P. Towards a Knowledge-based Theory of the Geographical Cluster (2001) *Industrial and Corporate Change*, p.921-943.

⁴³³ Cooke P. 'Regional innovation systems, Clusters, and the knowledge economy' (2001) *Industrial and Corporate Change*, p.945-974, p.952.

⁴³⁴ McKelvey M., Alm H. and Riccaboni M. 'Does co-location matter for formal knowledge collaboration in the Swedish biotechnology-pharmaceutical sector?' (2003) *Research Policy*, p.483-501.

incentives or other frameworks intended to make firms more competitive.⁴³⁵ As a result, the pharmaceutical knowledge although freely available globally tends to remain embedded in particular regions where there is government support or a conducive environment for research work.

The regional affinity of high-technology fields has a profound consequence for understanding pharmaceutical R&D activities at the global stage. Basic research knowledge, although valuable,⁴³⁶ becomes inadequate to remain competitive over rivals and applied knowledge takes more prominence.⁴³⁷ The applied knowledge is enhanced by proximity of the knowledge-generation stakeholders within a region and the constant interaction between the producers and users of the knowledge. As knowledge generation and utilisation becomes increasingly organised and structured, firms rely on tacit knowledge and know-how for achieving competitive advantage.⁴³⁸ This results from the practice and application of that knowledge within those regions.⁴³⁹ Tacit knowledge is exchanged easier over short distances where there is more interaction between those stakeholders.⁴⁴⁰ Because there is the constant loop feeding into the life cycle of knowledge generation, there is more improved knowledge resulting from those interactions. The location or geography of the activity therefore in reality becomes a significant factor for the success of research intensive activities in the pharmaceutical industries.

⁴³⁵ For instance the South African Department of Science and Technology has shifted to a strategy to support biotechnology innovation hubs in selected provinces under the 'Farmer to Pharma Innovation Plan'; a concept that has been used in the UK for some time. Also, empirical research has shown that for investments made between 2002 and 2009 in 27 European countries, investors in biopharmaceuticals were less likely to choose countries with stringent price controls, preferring instead to move investments to countries perceived less stringent: Koenig P. and MacGarvie M. 'Regulatory policy and the location of bio-pharmaceutical foreign direct investment in Europe' (2011) *Journal of Health Economics*, p.950-965; Also Kyle M.K. 'Pharmaceutical price controls and entry strategies' (2007) *Review of Economics and Statistics*, p.88-99.

⁴³⁶ Bush V. 'Science-the endless frontier (1945) Washington DC: National Science Foundation, p.18-19, views 'basic research as the pacemaker of technological progress.'

⁴³⁷ Basic and applied research co-evolve and interacting in a complex and iterative manner. David P., Mowery D. and Steinmueller E. 'Analysing the economic pay-offs from basic research' (1992) *Economics of Innovation and New Technology*, p.79-90. Applied research enhances competitiveness: Stoke D.E. *Pasteur's Quadrant-Basic science and technological innovation* (1997) Washington: Brookings Institution Press, p.73.

⁴³⁸ Johnson B., Lorenz E. and Lundvall B. 'Why all this fuss about codified and tacit knowledge?' (2002) *Industrial and Corporate Change*, p.245-262, p.249.

⁴³⁹ Malerba F. and Orsenigo L. 'Knowledge, Innovative activities and industrial evolution' (2000) *Industrial and Corporate Change*, p.281-314.

⁴⁴⁰ Cornish S.L. 'Product Innovation and the spatial dynamics of market intelligence: Does proximity to markets matter?' (1997) *Economic Geography*, p.143-165.

As a result of this particular characteristic of geographic affinity of knowledge generation and output, unlike the UK which is considered to be one of the global centres of pharmaceutical research, South Africa and developing countries are observed to lack significant pharmaceutical centres or complementary industries.⁴⁴¹ The region will in turn have less developed research capacities to address their health related and pharmaceutical needs and only resort to external providers for fulfilling those needs. To move to a stage where they can produce their own, they need coordinated strategies to forge alliances and develop regional research capabilities.⁴⁴²

There have been suggestions that national technology policies, designed to give national firms competitive advantage based on superior technology have some limitations in a globalized world but there is evidence that if national governments internationalize its national cooperative R&D programmes while retaining their national objectives there is potential for national industries to thrive.⁴⁴³ It is important that South African develops its own R&D infrastructure.⁴⁴⁴ The market size may not be attractive to entry of new innovative drugs by foreign firms.⁴⁴⁵ The trend by home firms in developed countries toward shifting R&D for new pharmaceuticals abroad slowed down in the early 1980s.⁴⁴⁶ Therefore, there must be an impetus on South

⁴⁴¹ There is acknowledgement by the South African government that pharmaceutical and biotechnology R&D lags behind comparable developing countries and hence the development of the 'Farmer to Pharma' Innovation Plan by the Department of Science and Technology: www.engineeringnews.co.za/article/dst-to-build-south-africas-bioeconomy-2008-07-04.

⁴⁴² Tijssen R.J.W. 'Internationalisation of pharmaceutical R&D: how globalised are Europe's largest multinational companies?' (2009) *Technology Analysis & Strategic Management*, p.859-879, p.875. Publicly funded health related research is considered to be helpful in this regard: Henderson R, Orsenigo L. and Pisano G. 'The pharmaceutical industry and the revolution in molecular biology: Interactions among scientific, institutional and organizational change' in Mowery D.C. and Nelson R.R. (eds) *Sources of industrial leadership: Studies of seven industries* (1999) Cambridge: Cambridge University Press, p.276. An endogenous process of coalitional change has been observed with the parties that have attained a considerable R&D capacity: Shadlen K.C. 'The political contradictions of incremental innovation: Lessons from pharmaceutical examination in Brazil' (2011) *Politics and Society*, p.143-174

⁴⁴³ Fransman M. 'Is national technology policy obsolete in a globalised world? The Japanese response' (1995) *Cambridge Journal of Economics*, p.95-119, p.118.

⁴⁴⁴ Pharmaceutical and biotechnology researchers have suggested that the R&D infrastructure presents an opportunity to address many national health problems, http://www.pub.ac.za/docs/bio2biz2009_pharm.pdf.

⁴⁴⁵ Authors argue that innovation leading to new pharmaceuticals specific for that market is dependent on the size and predicted profitability of that market: Linn J. and Acemoglu D. 'The market size in innovation: Theory and evidence from the pharmaceutical industry' (2004) *The Quarterly Journal of Economics*, p.1049-1089, p.1084.

⁴⁴⁶ Schnee J.E. 'International shifts in innovative activity: The case of pharmaceuticals' (2001) *Columbia Journal of World Business*, p.122-132. Recently though there have been indications that some alliances are emerging whereby R&D is carried out in South Africa, but it is mostly with not-for-profit organizations and academic institutes in the US.

Africa and developing countries to establish and sustain centres of pharmaceutical research directed to their local and regional needs. This is possible given that today's pharmaceutical R&D is no longer exclusively a stand-alone activity by single large companies, but can rather be defined by a complex web of inter-firm agreements and alliances that link the complementary assets of one firm to another.⁴⁴⁷ Pharmaceutical companies form the nodes in large-scale scientific networks that include biotechnology firms as well as universities.⁴⁴⁸

It is suggested in this thesis that the strategies adopted for engagement in international debates on the appropriate patentability standard should reflect a forward-looking position of harnessing inventive and innovation potential and moving away from a *laissez-faire* attitude to pharmaceutical R&D by South Africa.⁴⁴⁹ 'Moving from technology user to knowledge producer and innovator, however, cannot be effected without significant changes in the traditional institutions and the habits and practices of economic agents in developing countries, notably those related to learning, linkages, long-term investment and innovation.'⁴⁵⁰ There has to be active organization of frameworks to meet those targets. Indeed it has been observed that the globalization of markets and harmonization of laws has meant an increased significance of the R&D of the pharmaceutical industry of South Africa and other developing countries at the world stage.⁴⁵¹

⁴⁴⁷ It has been found that broad-based company capabilities, complementarities and similarities are factors that directly influence alliance formation between pharmaceutical and biotechnology companies, particularly when the biotechnology companies are newer and this influence is even more significant than other factors like patent common citations and patent cross-citations which are indicators of the research, science and technology relatedness between the pairs predicted to forge alliances: Rothaermel F.T. and Boeker W. 'Old technology meets new technology: Complementarities, similarities and alliance formation' (2008) *Strategic Management Journal*, p.47-77. Some have suggested that intra-company, the large pharmaceutical organisational pyramid is an obsolete model, preferring instead the dividing of big firms 'into a constellation of highly focused centers of excellence designed to improve transparency, increase the speed of decision making, and restore freedom of action to the scientists actually conducting the research', Garnier J. 'Rebuilding the R&D engine in Big Pharma' (2008) *Harvard Business Review*, p.68-76, p.72.

⁴⁴⁸ Gassmann O. and Reepmeyer G. 'Organizing pharmaceutical innovation: From science-based knowledge creators to drug-oriented knowledge brokers' (2005) *Creativity and Innovation Management*, p.233-245, p.235.

⁴⁴⁹ Kruss G. 'Balancing old and new organisational forms: changing dynamics of government, industry and university interaction in South Africa' (2008) *Technology Analysis & Strategic Management*, p.667-682, p.675.

⁴⁵⁰ Mytelka L. 'Pathways and Policies to (bio) pharmaceutical innovation systems in developing countries' (2006) *Industry and Innovation*, p.415-435, p.418.

⁴⁵¹ Fabio P. and Massimo R. *Innovation and industry leadership* (2007) Washington: John Hopkins University, p.134-135.

It can be concluded that pharmaceutical knowledge has a significant dual character at global level. The knowledge has a seemingly conflicting quality. It is universal and global but has tendency for regional clustering. Therefore legal engagement on patentability at global level must be appreciative of these realities if the UK and South Africa have the desire to develop and sustain technological capacities appropriate for their states and regions through the patentability standards they prescribe or support.⁴⁵² The patentability suggestions they make at international platforms should acknowledge that innovation and invention activities is drawn to areas that are conducive for such activities.

3.3 The international harmonizing legal frameworks

Protecting one's invention is important not only in one country, but often around the world.⁴⁵³ As established in the preceding chapter, South Africa and the UK have their own laws and trading customs that developed in their particular histories. Most other countries also have their local patent laws.⁴⁵⁴ That means protecting an invention worldwide is an involved task that requires the adjustment of patent specifications and other formal and substantive obligations to specific requirements of the individual countries where protection is sought. To overcome this daunting task, for more than a century, some effort was spent in trying to harmonize patentability standards among different countries. South Africa and the UK have both been part of this process. The shift from the industrial era to the era of the knowledge-economies necessitated and expedited the blending of national and international law-making processes in order to standardise how patents are granted in different jurisdictions. The optimization and reform of local patentability requirements therefore takes some influence from international instruments that were initiated historically to attain standardised patent protection amongst trading partners. These international instruments range from

⁴⁵² Commentators argue that obstruction of work on the harmonisation of technical patent law is counterproductive and misguided in view of industrial realities: Straus, fn.264, p.57.

⁴⁵³ It is acknowledged that market segmentation by geographical regions still continues as a result of company patenting strategies and, to a lesser extent, as a result of patent fees. For example, the GSK patent pool shows patents for neglected tropical disease are obtained, counterintuitive, mainly in the developed countries, revealing that there must be a strategic element to such a decision.

⁴⁵⁴ For a survey of historical patent laws of the world see Chartered Institute of Patent Agents, *Patent laws of the world* (1899) London: CIPA.

procedural and formal rules and customs for obtaining a patent to substantive rules governing patentability. They also range from regional institutions to international treaties that seek to prescribe the requirements of the appropriate patentability levels for protecting inventions by patents.

In the midst of the resistance, or at least unease about convergence or harmonization of patenting requirements,⁴⁵⁵ there are legitimate grounds for the continual harmonization of the substantive patenting criteria. However, in order for different states to embrace a harmonized patent system, there are several pre-conditions to be met by the participating states. Ideally, the countries must have evaluated the classical justifications that sustain the patent system existence, including a cost-benefit analysis, and found it to be suitable for their locality.⁴⁵⁶ In the previous chapter it was established that the patent system is a system that promotes and protects inventing activity by conferring rights on individuals as rewards so that they are encouraged and incentivized to disclose their inventions to the public domain. The politicians or government policy makers engaged at international level patentability negotiations have to be convinced to effectively participate in a harmonized international system plan, which in their local constituencies may be perceived to mean loss of national identity or would face resistance from local lawmakers for the adopted instrument to be implemented.⁴⁵⁷ An important factor to the success of any international proposal is that the political stakeholders should accept a model that emphasizes invention and innovation, R&D and technology policies based on cross-jurisdictional economic interrelations rather than any isolationist stance that assumes domestic self-sufficiency, which was feasible in less-intense knowledge economies.

⁴⁵⁵ Commentators criticise the standards as ‘international norms that do not fit African realities, needs and priorities’: Ringo F.S. ‘The Trade-Related Aspects of Intellectual Property Rights Agreement in the GATT and legal implications for Sub-Saharan Africa’ (1994) *Journal of World Trade*, p.122-123.

⁴⁵⁶ Colonies generally did not have this freedom of choice and there are now very few countries that have no patent system. There are compromises to be made in any system; in the classical justification of the patent system, benefits accruing have to be more than costs.

⁴⁵⁷ Both the UK and South Africa have parliamentary mechanisms for scrutiny of treaties before approval; notably there were constitutional debates on the role of the legislature and executive which arose from the signing and coming into force of the Agreement establishing the WTO in South Africa: Harrington J. ‘Scrutiny and approval: the role of Westminster-style Parliaments in treaty-making’ (2006) *International and Comparative Law Quarterly*, p. 121-160, p. 144-146. Cf. Alabi M.O. ‘The legislatures in Africa: A trajectory of weakness’ (2009) *African Journal of Political Science and International Relations*, p.233-241, asserting that unlike their developed counterparts, African legislatures are seen as constrained in the capacity to effectively influence and scrutinize public policy and law making processes.

As a consequence therefore any proposed statutory changes must be mutually and directly or indirectly beneficial to the country's domestic invention and development mandate and international trading mandate in order to motivate the legislatures' resolve that is needed to implement them.⁴⁵⁸ The resultant patent benefits are assumed to filter to society or the public of the country. The necessary statutory changes must also be perceived to benefit industry in the countries concerned in order to encourage the lobbying of statutory changes that political actors might tend to ignore.⁴⁵⁹ The industry benefits are essential because on the one hand there would be no point in having a patent system in place that is not in use⁴⁶⁰ and on the other, industry has proven the ability to lobby an unconvinced legislature for monumental statutory changes. That is to say therefore, there exists a symbiotic relationship between the law-makers, both internationally and locally-mandated, and the industry stakeholders to be controlled by those rules. Without attaining this delicate harmonization equilibrium, the system would fail to address the concerns of industry. As Coleman reminds us 'patenting is not obligatory',⁴⁶¹ an off-balance system would consequently be of limited relevance in practice.

There has been a significant similarity of statutes in countries over the years concerning patentability.⁴⁶² Given the convergence of technology-creation and innovation activities, it is logical that the patentability laws be refined towards true similarity beyond the pseudo-similarity in the statute books. Hence, substantive patent law harmonisation fulfils the needs of technology-generation and knowledge-intensive industries beyond their localities or jurisdictions. It does this by lowering the need to carefully study multiple patentability requirements in multi-country patent application, litigation or enforcement efforts for the same invention or technology.

⁴⁵⁸ There are assertions that pharmaceutical companies canvassed legislative players to bring about TRIPS, Drahos P. and Braithwaite J. *Information feudalism: Who owns the knowledge economy* (2002) London: Earthscan, p.14. Others assert that the TRIPS Agreement was established on a *quad pro quo* basis, with states advancing parochial issues on the agenda: Lehman B.A. 'Intellectual property as a trade, health and economic issue' (2003) *St John's Journal of Legal Commentary*, p.417-427.

⁴⁵⁹ Economic nationalism by politicians mitigates against regional political and economic integration initiatives, which are beneficial to businesses involved in cross-border businesses and 'this explains why in Southern Africa there is so much inertia but little progress' in harmonisation initiatives: Chingono M. and Nakana S. 'The challenges of regional integration in Southern Africa' (2009) *African Journal of Political Science and International Relations*, p.396-408.

⁴⁶⁰ Grubb, fn.256, p.45.

⁴⁶¹ Coleman A. *Intellectual Property Law* (1994) London: Longman Group Ltd, p.40.

⁴⁶² As shown in chapter two and as will be shown later in the chapter, for example that South Africa law is based on the EPC.

This in turn means harmonization creates certainty of patent rights and patentability standards across the jurisdictions participating in the harmonisation. Industry thrives on certainty of protection afforded by the granted patent in different jurisdictions. The more certainty is brought to the patent worldwide, the more relevance and significance of the international patent system is created for the users.

It is submitted that harmonization should be more than the simplification of the administration of the system or imparting certainty and clarity for the user. It should be in tandem with the philosophy and justification of the optimal patent system. That means the desirability of the similarity of laws is premised on attaining and perpetuating the ideals of the elements to be protected in an invention. This is directed to the intrinsic qualities that the patentability standard should always seek out of a patentable invention. The tension in this process is that the local innovation and inventing policies usually seek to protect their own knowledge and inventions yet these are universal. The standpoint adopted in this thesis is that an identical invention must be given identical protection at the international level. Other promotion strategies and supplementary mechanisms for supporting the inventing activity may differ between countries according to their needs but not the patent protection for the ensuing invention.⁴⁶³ That is to say the patentability standard between South Africa and UK must be similar even though the respective domestic policy makers may employ different mechanisms of promoting internal innovation.

The thesis now turns to examine some of the international instruments that have a bearing on the patentability standards in South Africa and the UK. It highlights and examines the features that were introduced by the instruments as they relate to the limbs to patentability in the two countries under study. Some of these instruments introduced aspects that were only incidental to patentability but form the basis of setting an optimal patentability standard for international pharmaceutical inventions. Observations are made of how the patentability elements from the international instruments were integrated into both South Africa and the UK laws.

⁴⁶³ Rzakhstanov Z. 'Regulatory policy, value of knowledge assets and innovation strategy: The case of the Orphan Drug Act' (2008) *Research Policy*, p.673–689.

3.3.1 The Paris Convention

Over a century ago, some form of harmonisation of patent laws started with the Paris Industrial Property Convention of 1883.⁴⁶⁴ The desire for harmonised patent laws was influential and laid the foundation for establishing the Paris Convention.⁴⁶⁵ The Convention was founded on the principle of reciprocity such that inventors from member states could enjoy foreign protection for their inventions. This instrument reduced the practical hardship faced by inventors desiring to have protection in other countries by securing them the same filing date and priority in other countries.⁴⁶⁶

This Convention guaranteed the nationals of all member states the same treatment that was received by a member's own nationals, at least notionally.⁴⁶⁷ This is the concept of national treatment that is prevalent in contemporary international agreements to which South Africa and the UK are party to. Countries joined the Convention with the expectation of patent protection for their citizens abroad.

The principle to be extracted from this instrument is that it presents a foundation upon which to base patentability standards for inventions to be patentable in multiple jurisdictions. Under this harmonising framework is established the concept that applicants are, irrespective of origin, not prejudiced of rights subsisting in their inventions.⁴⁶⁸ The merit of the invention rests upon the qualities of the invention, and not the background of its originator. This Convention is thus a platform upon which appropriate harmonised standards could be set. The patentability standards should not

⁴⁶⁴ Paris Convention for the Protection of Industrial Property, 20 March 1883, 828 U.N.T.S. 107, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at the Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on June 14, 1967 and as amended on September 28, 1979. The UK acceded in 1884 while South Africa only acceded in 1947. There have been constant revisions of the Convention since its inception: Paterson G. *The European patent system: The law and practice of the European Patent Convention*, 2nd ed (2001) London: Sweet and Maxwell, p.13. The UK ratified the latest version in 1969, which took place in 1967 in a Revision Conference in Stockholm: Notification date 10 March 1969. http://www.wipo.int/edocs/notdocs/en/paris/treaty_paris_7.html. South Africa also acceded to the 1967 (Stockholm) text, in 1974: Notification date 24 December 1974 http://www.wipo.int/edocs/notdocs/en/paris/treaty_paris_60.html

⁴⁶⁵ Neumeier F. 'Unification of European Patent legislation on the Common Market' (1967) *Modern Law Review*, p. 725-737, p. 726.

⁴⁶⁶ Vojacek J. 'A survey of the principal national patent systems' (1936) New York: Prentice-Hall, Inc, p.21.

⁴⁶⁷ Art 2(1) of the Paris Convention.

⁴⁶⁸ Paris Convention, Art.2(2).

deprive the inventors the rights in their inventions as a result of originating or being based in a foreign territory yet the invention benefits society at large, even beyond borders.

Practically, this Convention allows inventors in a signatory country to file an application in their home country first and then file corresponding applications within one year in any other signatory country.⁴⁶⁹ The filing date for the second applications is recognised to be the date the patent was first filed in the original country. This means this legal instrument is directed mainly at establishing priority.⁴⁷⁰ This is an important advantage for prior art purposes, on which novelty and non-obviousness assessments and other patentability requirements are based.

The Paris Convention is not accurately a harmonising instrument.⁴⁷¹ It is unsurprising that its features contributing to patentability standards could be seen as of limited value. This is because it only provided for easier access to foreign patent systems through the priority system and national treatment principle. The Convention was directed at allowing applicants from another signatory country to be treated just like resident citizens of the foreign country with respect to the patent application and prosecution process only. There were no express arrangements for standardising patentability requirements in the national treatment received and priority that was claimed. Therefore for the instrument to be more useful, countries would additionally have to have similar substantive patentability standards. The current similarity of the UK and South African patentability standards will be examined in more detail in subsequent chapters.

The establishment of priority for foreigners helps in the creation of a system that is appreciative of foreign prior art. It counteracts the effect of an invention communicator being treated as the true-and-first inventor. This sets the theme for establishing strict novelty, which is now in existence both in South Africa and the UK. As seen in the historical analysis in the previous chapter, the Paris Convention establishment occurred when there was a still a remnant of worldwide legalised

⁴⁶⁹ Paris Convention, Art.4C(1).

⁴⁷⁰ Paris Convention Art.4A(1).

⁴⁷¹ Torremans, fn.189, p.29.

misappropriation practices and so nations were becoming interested in protecting their nationals over larger geographical areas. However, they did not necessarily have an interest in providing reciprocal protection to foreigners *per se* themselves. Recognition of foreign applicants was more of a trade-off or a by-product. Therefore, the full potential integral to the Convention's foundational principles were not attained because of this stance.⁴⁷² It is also likely that due to the developmental stages some of the advanced economies were in at that time as net consumers of technology, there was no motivation to fully embrace and enforce this standard. A paradigm shift gradually occurred out of the realisation that a jurisdiction that is becoming net-exporter of technology needs global patent protection to maintain its competitive advantage globally.

The Convention's limited harmonising effect and substantive patentability utility does not detract from its significant contribution to patentability requirements setting. It has been said by the WTO Appellate Body that the national treatment principle has been 'the cornerstone of the Paris Convention and subsequent IPR international conventions'.⁴⁷³ The impact of the Paris Convention has further been magnified by the TRIPS Agreement. TRIPS Agreement, Art.2 requires WTO members to comply with the minimum requirement of the Paris Convention even if they are not members of the Convention.

The Convention also established a mechanism whereby inventions are patentable if there is acknowledgement of the true inventor.⁴⁷⁴ This principle took a while to be accepted especially with the existence of the convenient and pragmatic first-to file system which emphasises the first to reach the patent office rather than the one to invent. Building on this foundation is the idea that the purpose of patent protection should be directed to the originator or inventor with the exclusion of undeserving individuals. Both South Africa and the UK observe this principle. This right is incorporated into UK law as a result of EPC Art.62. The Patent Act 1977, s.7 requires an inventor (or joint inventor) or deviser to make a patent application in the same way as Patents Act 1978, s.27. Consequently, the Convention is a foundation of a system

⁴⁷² Paterson, fn.464, p.13.

⁴⁷³ United States – Section 211 Omnibus Appropriations Act of 1998, Appellate Body Report, WT/DS176/AB/R, 2 January 2002, para.241.

⁴⁷⁴ Paris Convention, Article *4ter*.

that imposes a moral obligation for the granting of patents to the originators of the invention. Thus, the Convention supports the idea that the inventors have to have natural rights in the invention that receives protection, a standard suggested in the previous chapter.

Furthermore, the recognising of originators of inventions for patent grant prevents a convoluted definition of newness. Vaver suggests that even an intelligent IP-lay person would not understand the definitional and linguistic meanings of patent statutes which may articulate one thing whilst meaning another.⁴⁷⁵ The standard should be such that when newness is assessed, it should not be possible for one individual to re-invent old knowledge, especially of foreign origin or claim it as their own. The starting point for any enquiry into the novelty of an invention is enhanced when there is a clear identity of the originator of the patentable knowledge, because it is from this standpoint that prior art can be properly demarcated. A practical illustration of this is when small inventors approach big companies whereby they are given an option to either to disclose their inventions, with no guarantees that the firms will not usurp their ideas, or simply lose audience and the opportunity to commercialise the invention.⁴⁷⁶ This is significant as it has been suggested above that the smaller biotechnology inventor, characteristic in both the UK and South Africa pharmaceutical industries, plays an important role in pharmaceutical research output.

The Paris Convention was intended for purposes other than establishing a harmonised patentability standard. It however introduced and established the fundamental principles and components that have a remnant effect that are usefully incorporated into a global system that seeks to optimise patentability standards. It has been shown that South Africa and the UK both embrace these principles.

⁴⁷⁵ Vaver, fn.11, p.147.

⁴⁷⁶ Wilkof N. 'Protection of trade and other secrets: A property right, equitable right or contractual obligation? Does it matter?' 14 December 2009, Lovells LLP Lecture Series, London.

3.3.2 Patent Cooperation Treaty

The chapter now turns to the Patent Cooperation Treaty (PCT)⁴⁷⁷ which is a procedural instrument that has some aspects that impact on substantive patentability at the global dimension for both the UK and South Africa. The PCT generally provides a mechanism for patent applications across different jurisdictions. It allows for a single international application to be made in local patent offices designating member states in which protection is sought.⁴⁷⁸ In other words, the PCT's focus is to simplify the procedural aspects of making applications in different countries.⁴⁷⁹ Alluding to the fact that the instrument may play multiple roles, the view of some delegations to this treaty negotiations was that 'one of the aims of the...PCT, which should be the principal aim above all other aims, is to save effort, time, work and money – both for the applicant and for the national offices where patents are sought for the same invention in a number of other countries.'⁴⁸⁰ By implication therefore the treaty could be viewed as one that functions more than just as a procedural convenience mechanism. A wide array of secondary functions has been attributed to the PCT. For instance, commentators state that the 'instrument aims to contribute to the progress of science and technology, to perfect the legal protection of inventions, ...to foster and accelerate the economic development of developing countries through the adoption of measures designed to increase efficiency of their legal systems instituted for the protection of inventions.'⁴⁸¹

The instrument has the effect of standardising and harmonising the process of filling patent applications simultaneously in many countries because of the uniform requirements for applications. After the application is made, a search and examination is conducted by one of the search authorities.⁴⁸² A report is issued on the state of patentability requirements. This implies assessment is made of novelty, non-

⁴⁷⁷ The PCT was signed on 19 June 1970, came into force on 1 June 1978 and was amended in 1979, 1984, and 2001.

⁴⁷⁸ In South Africa, Chapter VA (section 43A-43F) of Patent Act 1978 is inserted by s.38 of Act no. 38 of 1997, date of entry into force 16 March 1999. Date of entry into force in the UK was 24 January 1978 by Patents Act 1977, s.89.

⁴⁷⁹ PCT Art 1(2) provides that one of its objects 'is to simplify and render economic the obtaining of protection for inventions...'

⁴⁸⁰ Document PCT/DC/7, Observations of the delegation from Austria.

⁴⁸¹ Baxter J.W. *World patent law and practice*, 2nd ed (1973) Sweet and Maxwell: London, p.209.

⁴⁸² The International Bureau of WIPO in Geneva receives the application from the receiving office and sends it to a patent office designated as an International Search Authority.

obviousness, industrial applicability and patentable subject matter in accordance with the Treaty provisions.⁴⁸³ However, these are non-binding in the member states and are only indicative of validity as ‘the objective of the international preliminary examination is to formulate a preliminary and non-binding opinion’ of validity.⁴⁸⁴ If a member state has patentability standards that are significantly different from those of the treaty, the search report will be of less use, especially in many borderline cases of patent validity.

Unexamined patents can end up being administrative inconveniences.⁴⁸⁵ A patent system of unexamined or inadequately examined patents falls short of the public information justification that is attributed to the existence and perpetuation of an optimal patent standard as suggested in the previous chapter. Advocates for establishment of the PCT system in fact ‘thought that the interest of the public would, to a great extent, be served if the application were made public within a relatively short period of time after filing.’⁴⁸⁶ Therefore, this treaty is of importance when examination of the patent disclosure made to the public is emphasised. The UK, unlike South Africa, examines patent applications. South Africa, on the other hand, theoretically benefits from this instrument as there is an absence of substantive pre-grant examination when a patent is applied for through the national route. The Patents Act 1978, section 34 and Patent Regulations 1978 Rule 41 only prescribes formal examination.

South Africa can complement the quality of granted patents by introducing a search and examination for the national route or making PCT search reports compulsory for the international application route, which is currently barred for international applications.⁴⁸⁷ This is important in light of the statistics that reveal that almost half of court disputed patents were found to be invalid.⁴⁸⁸ In industrial inventive activities

⁴⁸³ PCT Art.33, PCT Rule 64.

⁴⁸⁴ PCT Art.33(1).

⁴⁸⁵ Seville C. *EU intellectual property law and policy* (2009) Cheltenham: Edward Elgar, p.73.

⁴⁸⁶ WIPO, *The first twenty-five years of the Patent Cooperation Treaty (PCT) 1970-1995* (1995) WIPO Publication, Geneva, p.10.

⁴⁸⁷ South African Patent Act s43F(3)(j), substituted by s6 of Act no. 58 of 2002, barring the public the right to require the patentee to provide anyone with search reports of the patented subject matter issued in any country after the expiry of five years after grant.

⁴⁸⁸ There are estimates that almost half of granted South African patents are invalid based on the number of success in infringement defenses or failed prosecutions. Generally, Harms L.T.C. ‘The role

reliant on patents for extensive prior art searches,⁴⁸⁹ a situation where a high number of patents that fall below the required patentability levels are allowed to be in existence, even for a short time before disputes could be lodged, are unhelpful. It can even prevent others from entering the market. A redeeming assumption for allowing some potentially invalid patents would be that the patentee would be prevented by patent maintenance costs from maintaining a patent which in all likelihood would be held invalid in litigation. However this only applies to smaller-sized inventors; larger firms can afford to maintain doubtful patents.

The PCT is not an instrument for the actual grant; that is left to the national patent offices. The main advantage of the PCT in this respect is that it delays the entering into national phase of the application. This means that the patentee has time to experiment and validate the invention before proceeding with cross-jurisdictional protection. It also gives them time to reflect on whether their application actually meets the patentability standards in light of the search report.⁴⁹⁰ This can in effect increase the quality of patents granted under this route. The public education justification of the system in the two jurisdictions is therefore potentially enhanced as a result of the delay mechanism for applications made under the PCT.

The PCT is also helpful with regard to the quality of the patented inventions at the international level. Some patent applications would not be pursued in other jurisdictions if it is determined that they would not survive validity assessments. That is because when the application is made the applicant 'receives information on prior art and patentability early enough to decide whether or not to file in other countries.'⁴⁹¹ In addition, in some peculiar way, the public store of knowledge is enriched with new but obvious knowledge, whereby the applicant discloses the new information in an application but then considers this to be below the obviousness

of the judiciary in the enforcement of intellectual property rights: intellectual property litigation under the common law system with special emphasis on the experience in South Africa' (2004) *European International Property Review*, p.483-492.

⁴⁸⁹ More efficient patent search and ranking tools have been designed to facilitate high-technology R&D because patent literature is seen as an invaluable source of knowledge progression: Li Z., Tate D, Lane C. and Adams C. 'A framework for automatic TRIZ level of invention estimation of patents using natural language processing, knowledge-transfer and patent citation metrics' (2012) *Computer-Aided Design*, p.987-1010.

⁴⁹⁰ Tritton G. (et al) *Intellectual property in Europe* (2008) London: Sweet and Maxwell, p.70.

⁴⁹¹ Document PCT/DC/7.

bar.⁴⁹² As a result, even competitors and third parties can be nudged in the direction of the applicant's research interest and acquire some insight into the new but non-inventive knowledge.

The concept of priority developed under the Paris Convention is further modified under the PCT. PCT Art.11(3) states that the filing date of an international patent application 'shall be considered to be the actual filing date in each designated State.' This means that, whilst the Paris Convention provides for an automatic right in international priority whenever a national application is made, the PTC provides for an automatic right to convert an international application into a national application within 20 months from the priority date of the international application.⁴⁹³ This is beneficial for applicants to the extent that at this stage after the priority date, they would be in position to establish which jurisdictions their patents would be valid in. At this point, making the decision to protect an invention in the two countries for instance is then dependent on the domestic patentability standards as perceived by the applicant.

The PCT is a procedural and formalities instruments. However, it is concluded that it plays a crucial role in patentability determination because it standardises the definition of prior art and priority amongst the member states. These are important elements in the definition and determination of patentability as will be seen in more detail in subsequent chapters dealing with the novelty and non-obviousness requirements. The instrument also provides the option of examination of applications, thus fulfilling the public disclosure justification for the patent. As a result the instrument plays a significant role in the assessment of South African and UK patentability standards for inventions that emanate from foreign jurisdictions.

⁴⁹² After the expiration of 18 months WIPO publishes applications, unless were withdrawn earlier, together with the international search report, which is contained in the copies sent to PCT Contracting States.

⁴⁹³ Paterson, fn.464, p.19.

3.3.3 The Agreement on Trade Related Aspects of International Property Rights

The General Agreement on Tariffs and Trade (GATT) negotiations commenced when the nations of the world recognized the desirability of international trade agreements that prevented national protectionism that existed.⁴⁹⁴ The GATT is a multilateral instrument governing international trade aimed at reducing trade barriers. The Uruguay Round created the TRIPS Agreement. The Uruguay Round also established the WTO to oversee GATT and TRIPS. The TRIPS Agreement is primarily the result of concern among developed countries that lobbied for protection against international piracy of IPRs.⁴⁹⁵

The TRIPS Agreement formally recognizes the need to promote ‘effective and appropriate means for the enforcement’⁴⁹⁶ of IPRs and provides for procedures for the multilateral prevention and settlement of disputes relating to private IPRs. One of the practical effects on patents has been the harmonization of the world’s patent laws on minimum protection requirements. To this end, the TRIPS Agreement requires that all signatories enact domestic legislation, or any appropriate measure, to implement the minimum levels of patent protection provided by the Agreement.⁴⁹⁷ Thus, developed and non-developed signatories alike must adhere to an international baseline for patent protection and ensure effective, expeditious, and impartial application of patent rights. This means the patent granted in the UK and South Africa should theoretically be similar, in terms of minimum standards in novelty, non-obviousness, industrial application and excluded subject matter.⁴⁹⁸ However variations of patentability between the two jurisdictions could occur as a result of the adoption of standards higher than the minimum or different domestic interpretations of what those minimum standards are.

⁴⁹⁴ Byrne J.G. ‘Changes on the frontier of intellectual property law: An overview of the changes required by GATT (1995) *Duquesne Law Review*, p.121-137, p.125. Although ‘the South African government...purposely adopted a policy of secrecy regarding its position in the GATT’, it was understood it participated on the basis of tariff reductions, implementation of a more liberalised trading system than formerly and an endeavor to enter world markets competitively: Eisenberg G.S. ‘South Africa, countertrade and the General Agreement on Tariffs and Trade’ (1993) *Stellenbosch Law Review*, p.143-175, p.143-145.

⁴⁹⁵ Correa C.M. and Yusuf A.A. (ed) *Intellectual property and international trade: The TRIPS Agreement*, 2nd ed (2008) AH Alphen aan den Rijn: Kluwer Law International, p.30.

⁴⁹⁶ TRIPS Preamble.

⁴⁹⁷ TRIPS Art.1(1).

⁴⁹⁸ TRIPS Art.27(1).

As shown in the previous chapter, it is generally accepted that patents existence are justified as they encourage innovation and dissemination of practical technical knowledge. The TRIPS Agreement Art 7 affirms that patents ‘should contribute to the promotion of technological innovation and to the transfer and dissemination of technology’ in the global trading regimes. The TRIPS Agreement therefore has intrinsically the justifications as suggested in the previous chapter that patentability standards should encourage and incentivise invention and innovation and the transfer of knowledge to the public domain. Therefore both South Africa and the UK as signatories have the mandate to design patent laws that achieve this standard.

The TRIPS Agreement Art.7 affirm the notion that patents involve a balance of rights between patent holders and the public that can be extracted from the classical justifications of the patent system. Continuing the theme of rewarding inventors with monopolies, while preserving an informed public domain for society seems to be the centre of the protection regime presented by this instrument as it provides that the whole purpose of the protection should be ‘to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.’⁴⁹⁹ This is a critical point that any domestic patentability standard must seek to attain. The definition of what is patentable must not be detrimental to the interests of either party to this delicate balance. Therefore, in as much as innovation advancing society is important, so are the interests of knowledge producers in that process.

The TRIPS Agreement is viewed as undoubtedly the most important international instrument on patents.⁵⁰⁰ It has the most impact on patent issues in local patenting regimes. It accomplishes partial harmonisation of patentability by prescribing the minimum patentability standards. However, the TRIPS Agreement does not explicitly define what the minimum standards really are. This in one way can be viewed as its main flaw for clarity and certainty for the international inventor. It only prescribes what may be called *de facto* patentability standards: the minimum standards are stipulated but open to wide interpretation by domestic courts that could be

⁴⁹⁹ TRIPS Art.7.

⁵⁰⁰ Guist J.E. ‘Noncompliance with TRIPS by Developed and Developing Countries: Is TRIPS Working?’ (1997) *Indiana International & Comparative Law Review*, p.69-85, p.70.

substantially different so as to refer to standards at the opposite end of the patentability scale. Chisum observes that ‘as long as inconsistencies persist between courts....it is difficult to claim that *any* sort of “minimum standard” can be said to exist on a global scale.’⁵⁰¹ This makes TRIPS patentability standards more of a theoretical stipulation that can be undermined by the interpretation domestic policy-makers adopt or the assessment methods adopted by courts in developing case law. The existence of different patentability standards across world jurisdictions can be attributed to this aspect. For example, ‘local’ novelty and ‘strict’ novelty requirements can and do meet the TRIPS Agreement obligations of a patentable invention being new. Local and strict novelty respectively refers to recognition of only local prior art and all prior art including foreign prior art for newness assessment. This wide asymmetry in interpretation distorts the handling of other patentability issues that are being discussed, for example the international definition of prior art or the appropriate judicial tools or integers in the enquiry of patentability benchmark attainment by inventions. It will be seen in more detail in chapter five how the newness patentability standard is currently judged in the UK and South Africa.

Given the historical patentability requirements of the UK one had to fulfil based on the nationality or domicile in order to gain protection, TRIPS is an improvement for patentees.⁵⁰² At the start of the internationalisation of IP laws, countries sought to prevent discrimination against their nationals. As it was seen above, this objective was pursued in the Paris Convention by recognising the principle of national treatment. The national treatment principle, continuing under the TRIPS Agreement, protects against discrimination of foreigners *vis-a-vis* nationals. It means that ‘each Member shall accord to the Members treatment no less favourable than it accords to its own nationals.’⁵⁰³ The Paris Convention only sought to enforce this principle of national treatment and no other sets of standards to be complied with in this respect. The TRIPS Agreement on the other hand, although restricting the members in providing no more favourable treatment to its nationals than foreigners, positively prescribes the designing of IP laws that have inherent minimum standards for *all* IPR holders. This

⁵⁰¹ Chisum D.S. ‘Patentability under TRIPS: The need for uniformity’ (2006) *The Indian Journal of Law and Technology*, p.1-7.

⁵⁰² As seen in chapter two, unlike South Africa, the UK historically discriminated against foreigners although in the intervening period this practice was removed.

⁵⁰³ TRIPS Art 3.1.

prevents discriminatory treatment of foreign inventors. For pharmaceutical inventions, the discrimination of foreigners has become a contentious issue in South Africa and policy makers have at times expressed the desire to treat locals differently.⁵⁰⁴

There tends to be some observable differences in the way the TRIPS Agreement standards are viewed in the two jurisdictions under comparison in this thesis. The law makers in the UK and other developed Members States have largely agreed with the private rights arguments, particularly highlighted by pharmaceutical companies, that patents are necessary to encourage the research into and production of better medicines.⁵⁰⁵ The patent must give their proprietor control over the R&D, production and marketing of their new medicines nationally and internationally. There is also a perception that developed signatories support the TRIPS Agreement because it promotes enhanced enforcement of rights in both developed and developing countries by undertaking a proactive marketing and trade surveillance role.⁵⁰⁶ The essence of the argument is that more innovative and better medicines will thus be produced under this model.

This demonstrates that the UK deploys the argument that public interest will be served through allowing the individual or private right to subsist through provision of adequate legal protection to the individual if their pharmaceutical invention meets the patentability standard. Only effective and harmonised legal protection of individual rights can sustain the high-risk investment that results in innovation benefits to

⁵⁰⁴ A shift in South African patent policy has been the desire to offer more protection to domestic inventors or domestic knowledge, a policy which Harms, who is the chair of the Department of Trade and Industry ministerial advisory council and deputy president of the Supreme Court of Appeals, considers 'ill-conceived', Harms L.T.C. 'A few negative trends in the field of intellectual property rights' (2009) *European Intellectual Property Review*, p.540-548, p.545-547.

⁵⁰⁵ An empirical study found that over sixty percent of pharmaceutical inventions would not have been introduced had it not been for patents; See Mansfield E. 'Patents and innovation: An empirical study' (1986) *Management Science*, p.173-181. Also, Drahos P. 'Global Property Rights in Information: The Story of TRIPS at the GATT (1995)' *Prometheus*, p.6-19.

⁵⁰⁶ Callahan/Wasunna, fn.401, p.190-192. Other commentators take the view that the linkage or convergence of trade with IP is not a novel feature with TRIPS but dates back to the first half of the twentieth century and neither was the erosion of public interest introduced by TRIPS but rather is a result of the international patent system securing the private rights of patentees: Menescal A.K. 'Those behind the TRIPS Agreement: The influence of the ICC and the AIPPI on intellectual property decisions' (2005) *Intellectual Property Quarterly*, p.155-182.

society.⁵⁰⁷ The patentability standards and accompanying policy could be said to reflect this standpoint.

The development of new pharmaceutical, biotechnology and others technologies is important to South Africa and developing countries too, in the field of health and combating major epidemic and endemic diseases.⁵⁰⁸ The TRIPS Agreement has been receiving criticism from developing countries for raising patentability standards that impede such ambitions.⁵⁰⁹ Sometimes mistakenly so. Although the end goal is similar, the approach taken by South Africa, and developing countries generally, emphasises that the public interest comes before private interest in patents.⁵¹⁰ Questions however, arise as to the sustainability of this approach wherein there is no feeder mechanism for creation of those inventions that the public asserts control over.⁵¹¹ That is to say a precursor condition is that the patentability standard must allow or encourage inventors to engage in research that will result in future solutions that benefit the public before public interest assertions could be made over that resulting knowledge or technology. Indeed commentators have stated that ‘there is a need for a fundamental change in development strategy and a transformation of SADC economies from being mere producers of raw materials and passive consumers of manufactured goods into dynamic and industrially diversified economies. Central to this project of industrial development and diversification, is more investment in, and

⁵⁰⁷ Smith K.G.D. ‘Profitability, risk and investment in research and development—the UK pharmaceutical industry’, in Teeling-Smith G.(ed) *The pharmaceutical industry and society: A study of the changing environment and economics of the international industry* (1972) London: Office of Health Economics.

⁵⁰⁸ Gastrow M. ‘Great expectations: The state of biotechnology research and development in South Africa’ (2008) *African Journal of Biotechnology*, p.342-348.

⁵⁰⁹ Kongolo T. and Mori M. ‘Is the dilemma of developing countries real under TRIPS?’ (1998) *The Management Review*, p.73-91. Also, Attaran A. and Gillespie-White L. Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa? (2001) *Journal of American Medical Association*, p.1886-1892.

⁵¹⁰ Lanoszka A. ‘The global politics of intellectual property rights and pharmaceutical drug policies in developing countries’ (2003) *International Political Science Review*, p.181-197, p.190-191.

⁵¹¹ Authors assert that the setting of national patent policy is a policy lever that directly contributes to the incentivising and funding for private enterprise to create new pharmaceutical products within a jurisdiction as part of an innovative global collective: Pazderka B. and Stegeman K. Pharmaceutical innovation as a collective action problem: *An application of the economic theory of alliances* (2002) *Journal of World Intellectual Property*, p.158-191. Nwabueze R.N. ‘What can genomics and health biotechnology do for developing countries’ (2005) *Albany Law Journal of Science and Technology*, p.369-432, analyses genomics and health biotechnology that is of actual and potential benefit to developing countries and the strategies that could transform them from mere consumers into producers of IP.

mainstreaming of, R&D.⁵¹² The success of such ambitions to be producers of IP goods rather than merely consumers, seem to be dependent on engaging private players in patent frameworks that are certain to bring some reward to them. Guaranteeing protection if resulting inventions attain the patentability benchmarks is one such way.

Indeed the patent system should be used to encourage research in these fields, as provided for by TRIPS Art.7. International procedures for the dissemination of such technology in the developing countries and to the benefit of the population could primarily be promoted by the patenting standards that are put in place. To nurture the growth of local industries, the patent system could be modelled and perceived by those willing to make research investments to be sustainable in the long-term,⁵¹³ without undue space that allows unfavourable arbitrary policy decisions against that venture. That is to say, it would be counterproductive to the public health cause to have a system that would make scientists, and their venture capitalists, consider investing or engaging in other technology sectors where their patent rights would not be abridged on vague policy grounds.⁵¹⁴

It can be concluded that the TRIPS Agreement encompasses the classical justifications for the patent system to operate effectively in a global society. The prescribed minimum standards seek to make patentable an invention only if it meets the predetermined patentability conditions. This however could be complicated by the fact that there is no agreement generally between South Africa and the UK or developing and developed countries as to the right balance between the interests of the individual against the public in the set patentability standards. As such, the TRIPS Agreement highlights the need for balanced policy setting as this can impact on patentability rules by shifting the balance to either party.

⁵¹² Chingono/Nakana, fn.459, p.406.

⁵¹³ Dimasi J.A., Hansen R.W., Grabowski H.G, Lasagna L. 'Cost of innovation in the pharmaceutical industry' (1991) *Journal of Health Economics*, p.107-142.

⁵¹⁴ Lal D. *Appraising foreign investments in developing countries* (1975) London: Heinemann Educational Books Ltd, p.89-91 and 266.

3.3.4 Substantive Patent Law Treaty (SPLT)

As it has been seen in previous sections of the chapter, there have been numerous attempts to harmonise the procedural aspects of patentability.⁵¹⁵ Substantive patentability harmonization and standardisation has been lagging behind and is to a limited extent. There have been arguments against such moves.⁵¹⁶ Nevertheless, it has been attempted so as to complement the strides made in procedural aspects. This section of the chapter seeks to highlight some of the key milestones in the attempts at multilateral level to harmonize substantive patentability standards. It is suggested here that although the instrument may not have been successful, it presented a platform and opportunity for the examination of substantive patentability elements which are pertinent to pharmaceutical industry activities at the global level.

In the WIPO's Standing Committee on the Law of Patents (SCP), substantive patent law harmonisation through the draft SPLT was perhaps the most ambitious and yet the most unsuccessful patentability instrument proposed at the international stage. It is notable that the UK and South Africa were largely on opposing sides on the negotiation debates on this instrument. Its ambitious aims were met with considerable resistance and magnifying of North-South divisions, resulting in intermittent negotiations and numerous deadlocks. Consequently, patentability harmonisation in this forum could technically either still proceed, albeit with modified goals, or finally declaring that the causes of the negotiations stalling are irresolvable and therefore dropping the whole idea.⁵¹⁷ Whatever the status of the negotiations, it can be pointed out that the needs the instrument sought to address are not automatically eradicated because there was disagreement in the negotiations at this forum. A danger with non-progress is that this instrument may be overtaken by other events which could be adverse to South Africa and developing countries as they may not be party to those

⁵¹⁵ For instance the Paris Convention and PCT.

⁵¹⁶ Reichman J.H.R. and Dreyfuss R.C. 'Harmonization without consensus: Critical reflections on drafting a Substantive Patent Law Treaty' (2007) *Duke Law Journal*, p.85-129.

⁵¹⁷ The former comptroller of the UKIPO has stated that in the harmonisation initiatives under the SPLT, 'if we are not prepared to change, due to misapprehension of our national interests or any other reason, we should indeed also have the courage to say so and refuse another round that would be doomed to fail': Brimelow A. "Not seeing the woods for trees": Is the patent system still fit for purpose?' (2011) *The Journal of World Intellectual Property*, p.230-237, p.236.

break-away negotiations but could be compelled by the need to enter into those resultant regimes by market necessities.⁵¹⁸

Discussions on the draft SPLT started at the fifth session of the SCP.⁵¹⁹ The discussions focused on issues of direct relevance to the standard of grant and validity of patents, in particular, the definition of prior art, novelty, inventive step or non-obviousness, industrial applicability or utility, the drafting and interpretation of claims and the requirement of sufficient disclosure of the invention. At the tenth session of the SCP,⁵²⁰ the EPO submitted a proposal designed to focus on what was referred to as an initial package of priority items including the definition of prior art, grace period, novelty and inventive step. This could be viewed as a reasonable segmented tackling of substantive patentability issues in this committee. According to the proposal, once international agreement was reached on those prior art related issues, discussions in the SCP could then focus on the other broader issues that may be affected by patentability.⁵²¹ While this proposal obtained the support of a number of delegations,⁵²² a number of other delegations opposed it including South Africa, and emphasized the need to examine all the provisions of the draft as a whole.⁵²³ This was an occasion where South Africa and the UK seemed to have opposing approaches to the setting of substantive requirements.

A contentious issue within the discussions for the SPLT was prior art.⁵²⁴ This is important in the sense that many issues of patentability crystallises upon this concept,

⁵¹⁸ According to Kappos, the USPTO is on mission to engage significant patenting players in a regime to harmonise patentability whatever the form of that regime could be: <http://www.directorsroundtable.com/pdf/London%20Patent%20Program%204-4-11.pdf>. Also, the executive director of the American Intellectual Property Law Association asserts that the continued frustration of the goal of a harmonized system by Friends of Development within WIPO could be overcome by like-minded countries agreeing on a harmonized system outside of WIPO if necessary. He stated that 'just as European nations took advantage of Article 19 of the Paris Convention to conclude the EPC in 1973, so too should like-minded countries not fear... to adopt the limited package outside WIPO if necessary': Remarks of Kirk (1991) *American Intellectual Property Law Bulletin*, p.442-43. Also, some American policy-makers promised unilateral action at international forum because of constant resistance by developing countries at WTO: Zoellick R.B. 'America will not wait for the won't-do countries' *Financial Times*, September 23, 2003.

⁵¹⁹ 'Draft Report, prepared by Secretariat' WIPO, Geneva: WIPO/SCP/9/8.

⁵²⁰ The EPO together with the United States and Japan submitted a proposal harmonising patent law: Document SCP10/9.

⁵²¹ Document SCP10/9, p.2-3.

⁵²² 'Statement received from Brazil' WIPO, Geneva: WIPO/SCP/11/4, p.2.

⁵²³ 'Statement received from Brazil' WIPO, Geneva: WIPO/SCP/11/4, p.2, para.5.

⁵²⁴ 'Draft Substantive Patent Law Treaty' WIPO, Geneva: WIPO/SCP/10/4, p.15.

procedural or substantive. If there is no agreement on the definition and handling of prior art there is likely to be no agreement on many other issues on substantive patent law, and indeed procedural law. If the definition of prior art is settled then the substantive or procedural determination of novelty and non-obviousness for instance, becomes less complex.

An example of a mechanism that is intrinsically built into the substantive patentability system and tackled in the SPLT negotiations, is a well-defined and exacting newness requirement. This is not adverse to developing countries. Such requirement promotes the protection of only novel or non-trivial knowledge. Setting a standard that requires patent quality to be of levels where the public is taught something new or previously not known would not have been achievable only when the SPLT was turned into a kind of developmental treaty emphasising broad development objectives. IP academics, IP policy-makers and legislators versed in IP are capable of evaluating this. Developmental and other non-IP officers on the contrary, would have an inclination toward broader developmental goals that are of interest to their wider-composed constituencies.⁵²⁵ Negotiations for a developmental treaty would necessarily have to include a wider stakeholder range.

Besides defining each limb to patentability, the draft treaty also had allowable tests for patentability evaluation.⁵²⁶ Various alternative proposals were negotiated for use in ascertaining whether each limb to patentability was satisfied. These would be helpful to the scientists working in the pharmaceutical field in establishing whether an invention would be judged patentable or not under the new harmonised framework. There would not be the need to know the case law of numerous jurisdictions in order to form an opinion on whether the invention would meet the patentability standards. This aspect of the treaty would have narrowed down tests that could be used in

⁵²⁵ With developing countries it is notable that the negotiations are attended by individuals who have no direct or significant influence in local patent policy and practice, even though there is a fund for attendance at these negotiations. Some commentators state that ‘the truth remains that most delegations from developing countries attending the SCP meeting are members of the diplomatic corps and are not versed in IP’: Visser C. ‘The policy-making dynamics in intergovernmental organisations: a Commentary on the remarks of Geoffrey Yu’ (2007) *Chicago-Kent Law Review*, p.1457-1466, p.1459. Statement of the Group of the Friends of Development, Document SCP/11/4, included a wide array of development goals in the negotiations.

⁵²⁶ These are contained in the ‘Draft Regulation under the Substantive Patent Law Treaty’, Document SCP/10/3 and ‘Practice Guidelines Under the Draft Substantive Patent Law Treaty’, Document SCP/10/6.

assessing patentability. A positive effect of this feature therefore would have been fore knowledge of the test to use in each patentability circumstance. At the same time this would compromise the ability to apply a more situation-specific test to particular circumstances, particularly in addressing new or immature technologies. The tests as applied in both the UK and South Africa would have been narrowed down as a result of this substantive harmonisation instrument.

3.3.5 Summary of the international patentability instruments

The international instruments examined above seek to standardize and harmonize the various essential elements of patentability standards in cross-border patenting. They also seek to prescribe the rules of making the determination as to whether an invention does indeed have those patentability qualities in practice. They contribute components that assist in the formulation of a harmonised patentability standard.

The Paris Convention brought recognition to the international arena that inventors must not be discriminated against by their origin; rather it is the quality of the invention that is to be judged for whether it meets the requisite patentability standards. In global economies this principle has gained more significance than at the time when it was originally proposed. The patentability laws in both South Africa and the UK are grounded on this principle.

The PCT is an improvement to the global patent system as it acts as the interface between the procedural and substantive requirements of the system and complements the practical attainment of the classical justifications of the patent system. It does this by standardising the identification of prior art between independent states, which is a central concept in setting patentability standards or assessment methods. Global agreement on the assessment of novelty or non-obviousness is thus brought closer to conclusion.

The TRIPS Agreement harmonises international patent law by prescribing the minimum patentability standards for inventions to be considered patentable. These have been shown to have been in existence in both the UK and South Africa

legislations prior to the conclusion of the instrument. The standards are however open to different interpretation in the respective national courts.

The SPLT represented a typical instrument that could be used in the interpretation of patentability standards agreed on at an international level. However, differences existed, mainly between the developing and developed nations, particularly on whether the instrument is at present appropriate for setting patentability requirements across the globe. The SPLT also went further and sought to prescribe allowable tests that could be used in interpreting those standards in practice. Both the UK and South Africa would have had to reform their domestic rules of assessing the patentability of inventions. The intended effect of these harmonising instruments is that an identical invention would receive more or less identical practical patent protection worldwide.

3.4 The influence of regional patentability instruments

The chapter now turns to examine instruments that govern patentability at the regional level. The section compares the influence of regional patentability law as exerted on both the UK and South Africa.

Historically there has been a gradual erosion of patent law differences between countries by the harmonization of regional patenting instruments. This trend has been running in parallel with those instruments that can be seen as truly international harmonization in nature. In Europe, the patentability in previously contrasted systems of law is consistently being approximated to a single European patent system, which some membership of the judiciary view as the *de facto* standard inherited into the South African jurisprudence.⁵²⁷

The current European regional patent system, which the UK is party to, is not strictly a regional patent, but it is a bundle of national patents effective in designated nations.⁵²⁸ Commentators assert that reform is needed for ‘a single unified European

⁵²⁷ Harms, fn.488, p.483.

⁵²⁸ Di Cataldo V. ‘From the European patent to a Community patent’ (2002) *Columbia Journal of European Law*, p.19-32, p.20.

patent system, rather the madness of needing to litigate validity and infringement of equivalent patents in every European jurisdiction.⁵²⁹ This reveals that there is a long-standing desire to have a truly European patent more than the one that is currently available. It can therefore be said that European regional influences are already shaping the scope of patent law in the UK.⁵³⁰ Indeed, an EU unitary patent framework has been agreed on that creates a unitary patent and unified patent court.⁵³¹

South Africa on the other hand is not yet bound by any regional instrument of IP law. There is the debate on whether she should indeed be part of the English-speaking African patent regime,⁵³² more than merely as an observer member in this system. As there is still no firm commitment taken to join the regional patent system, the laws in South Africa do not have any formal or binding influence to or from this regional regime.⁵³³

3.4.2 The Strasbourg Convention

This section aims to show how the Strasbourg Convention⁵³⁴ established the norm for generally accepted patentability standards, which are incorporated into both UK and South African law. The Convention is regarded as having laid the ground for internationalization of patent law.⁵³⁵ As regard was paid to the Paris Convention,⁵³⁶ it

⁵²⁹ Taylor R. 'Against an integrated intellectual property code: a response to "Reforming intellectual property law: an obvious and not-so-obvious agenda"' (2009) *Intellectual Property Quarterly*, p.281-287, p.286.

⁵³⁰ Huniar K. 'The enforcement Directive– Its effects on UK law' (2006) *European Intellectual Property Review*, p.92-99, p.92.

⁵³¹ See <http://www.epo.org/law-practice/unitary.html>. Debates remain on the ultimate effectiveness, extent of use and costs of the system: Pagenberg J 'Unitary patent protection in the EU' (2012) *The CIPA Journal*, p.687-693.

⁵³² Some practitioners are opposed to joining of ARIPO, mainly on the basis that it would serve no useful practical purpose and it would degrade the South African patent system practice: Burrell, p.24-25.

⁵³³ There are no regulatory or statutory instrument that proves South Africa is willing to commit to ARIPO, beyond the public utterances that South Africa intends to join by ARIPO Secretariat, Department of Trade and Industry officials and Ministerial Advisory Committee members.

⁵³⁴ *Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions*, opened for signature 27 November 1963, ETS 47, entered into force 1 August 1980 (Strasbourg Convention).

⁵³⁵ For instance, Terrell on Patents, p.7; CIPA Guide to Patents Act, p.40. Pila states that the purpose of the Strasbourg Convention 'is to establish certain foundational principles of European patentability': Pila J. 'Article 53(b) EPC: A Challenge to the Novartis Theory of European Patent History(2009) *Modern Law Review*, p.436-462, p.437.

incorporated principles from earlier established instruments. Importantly, as it turned out, the provisions of the Convention were incorporated into the EPC as will be seen later in the next subsection.⁵³⁷

The Strasbourg Convention was initiated within the framework of the Council of Europe in 1949 with the aim to create a European Patent Office, a proposal which was initially rejected by the Council's committee of experts.⁵³⁸ However, work continued but there was broad division of the harmonization of patent law negotiations into procedural and substantive reforms, which took different paths.

Negotiations on the procedural and administrative aspects of patent law resulted in the Formalities Convention.⁵³⁹ The Formalities Convention provided for establishing maximum requirements for a filing date and other requirements during the application stages of a patent. South Africa and Israel were the only Non-member States of the Council of Europe to join the Formalities Convention.⁵⁴⁰ The UK ratified this Convention in 1955 and later denounced it in 1976.

Work on harmonizing substantive patent law continued and resulted in the Strasbourg Convention in 1963, which the UK signed in the same year. The Convention was ratified in 1977 and entered into force in 1980.⁵⁴¹

The Strasbourg Convention preamble points out that the unification of substantive patent law assists innovation in the European context, more than just within the national boundaries.⁵⁴² The preamble also recognizes that successful unification

⁵³⁶ Preamble states that having regard to Art.15 of Paris Convention.

⁵³⁷ For instance in *Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission)* (Case C-377/98) [2002] FSR 574, para.22, the court noted that in defining an invention the EPC reproduced verbatim the first sentence of the Strasbourg Convention Art.1.

⁵³⁸ The so-called 'Longchambon Proposal' which was rejected by the Consultative Assembly but formed further work for European patent harmonisation: Pila J. 'Article 52(2) of the Convention on the Grant of European Patents: What did the framers intend? A study of the travaux preparatoires' (2005) *International Review of Intellectual Property and Competition Law*, p.755-787, p.756 and Wadlow C. 'Strasbourg, the Forgotten Patent Convention, and the Origins of the European Patents Jurisdiction' (2010) *International Review of Intellectual Property and Competition Law*, p.123-149.

⁵³⁹ European Convention relating to the Formalities required for Patent Applications, signed in Paris 1953.

⁵⁴⁰ South Africa accessed 28 November 1957 and it entered into force 1st January 1957.

⁵⁴¹ Ratification was on 16 November 1977 and entered into force on 1st August 1980.

⁵⁴² Strasbourg Convention Preamble.

significantly contributes to the realization of the global patent. This convention may have been drafted for European states, but membership was later opened to members of the Paris Convention.⁵⁴³ South Africa however did not join the final substantive instrument.

For South Africa, even though it was not party to these negotiations as the UK, the final instrument has had internal influence on the direction of patent law development in its jurisdiction. The current South African Act is based on precedents of the Strasbourg Convention. This soft law influence derives from the association of the country to the earlier negotiations of the final regime. That is, although the participation of South Africa ended with its joining only of the intermediate instrument, it is unsurprising that the subsequent and final substantive convention would be influential in the domestic patentability requirements. As such, South African commentators are of the view that a major milestone on the path to the signing of substantive and procedural patent conventions was the signing of the Strasbourg Convention.⁵⁴⁴

The substantive patentability criteria provisions of the Strasbourg Convention are almost identical to those of the EPC.⁵⁴⁵ Article 1 provides that patent shall be granted for inventions that are susceptible of industrial application, which are new and which involve an inventive step. Article 3 to 5 respectively qualifies what industrial application, newness and non-obviousness are.

Prior to conclusion of the convention, European nations had varied patentability requirements, and the negotiation helped narrow down these divergent views. As a transition condition, Article 12(1)(a), a reservation clause, provided for countries the right to refuse grant of pharmaceutical and food product patents.⁵⁴⁶ This instrument therefore smoothed the transition of the patenting of pharmaceuticals within this regional group, such that it became acceptable for these to be patentable within the various domestic regimes some of which heretofore barred their patenting.

⁵⁴³ Article 10, Strasbourg Convention.

⁵⁴⁴ Domanski A. 'Multinational patent conventions and their role in South African law' (1998) *South African Law Journal*, p.310-321, p.315.

⁵⁴⁵ Wadlow, fn.538, even though the original EPC had 180, while the Strasbourg Convention had 12 articles.

⁵⁴⁶ The UK is part of the majority that did not use this clause, but Italy and Switzerland opted to use it.

3.4.3 European Patent Convention (EPC)

The individual patent systems of Europe have their long histories which, as was shown in the previous chapter, provided the origin of most of the modern patent laws of the world. This section is now concerned with the patentability requirements established under the EPC and with its relationship to the coexisting domestic system in the UK. The statutory drafting of the current South African patent law was copied from this regional instrument.⁵⁴⁷ The aim therefore is to show how the EPC contributed to unifying not only diversified patent laws within the European region, but also had influence in bringing South African laws into more or less similar patentability standards with the UK. This convergence brings closer the attainment of a universal patentability as suggested in this thesis.

By 1949 there were voices that advocated for the setting up of a European Patent Office.⁵⁴⁸ At the time patent customs in Europe were extremely varied ranging from registration systems to systems with some form of search and examination before grant such as that in the UK.⁵⁴⁹ This diversity of laws posed a challenge to the creation of a single European market and for this reason the possibility of a unified patent system of some sort, coexisting with the economic system, was proposed. By 1959 the possibility of a separate patent system alongside national systems emerged and the move towards an EC patent system began. This however was thwarted by the failure of the UK to join the EC and when negotiations on UK membership of the EC finally broke down in 1963 the debate as to whether a European or EC system should be adopted intensified. At the same time a basis for the harmonization of European patent law was established through the Strasbourg Convention. By this stage though, the project had already split into two moves, on the one hand a system for members

⁵⁴⁷ Burrell, p.34. Berman C. 'Patents and trade marks- moves toward internationalism' (1973) *De Rebus*, p.181-183.

⁵⁴⁸ Bossung, O. 'The Return of the European Patent Law to the European Union'(1996) *International Review of Intellectual Property Law Review*, p.287-315.

⁵⁴⁹ Mahne K.P. 'A Unitary Patent and Unified Patent Court of the European Union: An analysis of Europe's long standing attempt to create a supranational patent system' (2012) *Journal of the Patent and Trademark Office Society*, p.162-191.

and non-members of the EC and on the other hand a unitary system primarily aimed at EC membership.

These two diverging paths led to the EPC and the Community Patent Convention (CPC)⁵⁵⁰ and by 1975 both conventions had been signed. However, whilst the EPC eventually came into force in 1977, the CPC never came into force, at least in its original form.

The purpose and object of the EPC is to establish a mechanism within the European states whereby ‘protection may be obtained in those States by a single procedure for the grant of patents, and the establishment of certain standards governing patents so granted.’⁵⁵¹ This is to say the EPC intends to harmonize European patent law both in grant procedure and to a certain extent the patentability standards granted patents.⁵⁵² Therefore the EPC has to be implemented and interpreted with harmonization of patent laws between the states in mind. However this desired situation has not been possible to fully attain in practice. There have been divergent reasoning and decisions between national courts and the Enlarged Board of Appeal for instance.⁵⁵³

EPC Art.2(1) states that patents granted by virtue of this Convention shall be called European patents. Such patents in the UK shall ‘have the effect of and be subject to the same conditions as a national patent.’⁵⁵⁴ To give effect to this provision the EPC was statutory transposed into UK national law by Patents Act 1977 section 77(1). That is a European patent designating the UK is to be treated as a patent under the Patents Act 1977. The only difference is that the European patent as a whole is open for limited period to opposition proceedings before the EPO.⁵⁵⁵ In the end, the granted patents through either route are considered to be equivalent.

Domestic law provided for a mechanism for eliminating inconsistencies between domestic and regional patents though Patent Act 1977, section 130(7). The courts

⁵⁵⁰ Convention for the European Patent for the Common Market as revised, Luxembourg, 15 December 1989.

⁵⁵¹ EPC Preamble.

⁵⁵² Paterson, fn.464, p.24.

⁵⁵³ Paterson, fn.464, p.24-28.

⁵⁵⁴ EPC Art.2(2).

⁵⁵⁵ Third parties can launch opposition in the EPO within nine months after grant: EPC Art.99.

have explained, in *Merrell Dow Pharmaceutical Inc v HN Norton & Co. Limited*,⁵⁵⁶ that UK tribunals must construe patentability such that so far as possible it has the same effect as the EPC, being cognisant of the decisions of the EPO.

It has been said that when interpreting, *inter alia*, patentability, regard should be had, not only to the equivalent provisions of the EPC, but also their *travaux preparatoires*, for instance, the official minutes which led to the adoption of the final text of the Convention.⁵⁵⁷ This, in effect, has meant tribunals and courts must treat the preparatory text and foreign decisions interpreting the EPC as persuasive authority.

The UK is bound to follow the patentability requirements in the EPC and is influenced by the EPO or EPC Contracting States interpretation. The difference with South Africa lies in the fact that although the patentability requirements are copied from the same instrument, there is no obligation to observe interpretation by the EPO or the member state. South Africa has to interpret the laws, although derived from the EPC, according to its local policy prescription. This potentially leads to an identical invention assessed for patentability differently in South Africa and the UK even though an identical original statutory source is used. This shows how harmonisation is a complex undertaking that goes beyond mere similarity of laws in statute books.

The UK is bound to interpret patentability in line with EPC. Although South African courts are not bound to follow European law, they have however gleaned assistance from the interpretation of EPC patentability law. In *McCauley Corporation Ltd v Brickor Precast (Pty) Ltd*,⁵⁵⁸ MacArthur J. resorted to EPO policy guidelines for elucidation of terms that have a bearing on patentability limbs, where he said ‘a similar view is expressed in the European Patents Handbook’ and ‘I proposed to follow that approach in considering whether the present invention is new.’

Although such similar patentability interpretations may be achieved in some cases, as more official policy is formulated that may be dissimilar in the two jurisdictions, the interpretation of the statutes may progressively differ. As such, disparities in national

⁵⁵⁶ [1996] RPC 76, para.12.

⁵⁵⁷ CIPA Guide to the Patents Act, p.1240.

⁵⁵⁸ 1989 BP 314 (CP), p.334.

law continue to grow between the two regions and nations under comparison in this study. That is, in using a very similar law derived from an identical source, there is still the possibility of disparities in patentability interpretation in the protection of identical inventions in South Africa and UK. The need for similar obligations in patentability interpretation is manifest if identical inventions are to be protected to the same extent in what are becoming progressively transnational innovative pharmaceutical activities.

It is important that harmonizing instruments highlight the basic tenets upon which ideal patentability standards should be built. A robust patentability mechanism devoid of subjective influences is needed to deal with the technical realities of the pharmaceutical industries which spans beyond the confines of any particular country. Any international instrument, proposed or reconsidered, must embrace the justifications for an optimal standard in order to be acceptable and implemented by the respective stakeholders. Instruments that seek to deviate from this would have to be carefully considered to establish how it would enhance the established patentability rules.

3.5 Conclusion

The harmonization of patentability standards follows an intricate network of paths. Continual optimization of the system means gains through one forum can be relinquished in another forum if the potential consequences of international agreements are not carefully studied as to how they would impact on patentability of inventions. Thus, coordinated and integrated reforms are crucial to attain a clear, consistent and robust patentability standard especially within a system that is forward looking and far-sighted. Not only should attention be paid to the harmonization of patentability standards and methods of patentability assessment but also to the formalities rules that can influence the substantive patentability standard.

Patents granted in the UK and South Africa do not exclusively originate in these countries. This is an indication of the cross-jurisdictional and globalized nature of the inventive and industrial processes and the necessity of foreign protection for

inventions. There can no longer be a view of indifference as to whether inventions by foreigners are protected or not as was in the UK historically. On the other hand there has to be a paradigm shift to move South Africa from being a simple deposit system of patents by foreigners and international actors into a regime where these patents represent technology generation and exploitation within the domestic environment. It is suggested that countries focus on making international patentability standards work within a framework that is also appropriate for their needs.⁵⁵⁹

Harmonization of patentability can start or consolidate a culture of invention and innovation across borders. In order for the patent system to optimally promote and protect inventions, the basic tenet is that there must be a worldwide agreement on how an identical invention receives identical protection. Although different assessment methods of an identical invention do lead to the same result, there are situations where this is not so and it is unhelpful to have to predict the likely result of validity for a single invention using varied assessment methods of different parts of the world. In the next chapters, there will be examination of whether the respective patentability assessment methods in the UK and South Africa for the patentability limbs achieve this benchmark.

⁵⁵⁹ For instance commentators, pointing out that the current pharmaceutical R&D pipeline for most neglected and tropical diseases remains weak, suggest strategies that would allow international collaborative drug discovery relying on clear IP systems: Nwaka S, Ramirez B, Brun R, Maes L, Douglas F, et al. 'Advancing Drug Innovation for Neglected Diseases-Criteria for Lead Progression.' (2009) *PLoS Neglected Tropical Diseases* 3(8): e440. doi:10.1371/journal.pntd.0000440.

CHAPTER FOUR

UNPATENTABLE AND EXCLUDED SUBJECT MATTER

4.1 Introduction

The thesis so far has mainly focused on the philosophical and theoretical aspects of the general patentability requirements as applied in the two jurisdictions. Attention now turns to the detailed examination of the specific individual limbs to patentability. The first limb to be explored is the requirement that to be patentable an invention is not to be constituted of excluded subject matter and the complementary question of how subject matter is considered a patentable invention in law.

The continual release of new pharmaceuticals into the market is usually attributed to innovation and invention. In industry, innovation is generally considered as the generation and turning of new ideas into marketable products and services.⁵⁶⁰ Others have conceptualised innovation as ‘a process that begins with an invention, proceeds with the development of that invention, and results in the introduction of a new product, process or service to the market place.’⁵⁶¹ It is noted that there tends to be an interchange in the use of the invention and innovation terms which may be acceptable within business circles but could be misleading in the context of patent law.⁵⁶² There are caveats to be attached to such definitions if innovation and invention is to be clearly understood and distinguished in the context of unpatentable and excluded subject matter in patent law.⁵⁶³ Innovation is broader in the sense that ‘it has a

⁵⁶⁰ Kirchhoff B.A. *Entrepreneurship and dynamic capitalism: the economics of business firm formation and growth* (1994) Westport: Praeger Publishers Inc.

⁵⁶¹ Edwards K.L. and Gordon T.J. *Characterization of innovations introduced on the US market in 1982: Final Report* (1984) Small Business Administration: The Futures Group, USA., p.1.

⁵⁶² Piatier A. ‘Innovation patent, invention patent, or both’ in Kingston W. (ed) *Direct protection of innovation* (1987) Lancaster: Kluwer Academic Publishers, p.125, stating that ‘invention and innovation are often confused...Facts fight a losing battle against the tyranny of categories generated by human mental activity’, and asserts, generally, that it is necessary to separate the two meanings of the word innovation, referring to the new product on the one hand and the progression from invention to marketing of the product on the other .

⁵⁶³ Dutfield, for instance, warns that the use of scientific metaphors and analogies, although useful in explaining the key science to a wider audience, may lead to misleading conception of the real science and inappropriate expansion of patentable subject matter: Dutfield G. ‘Patent law, the emerging biotechnologies and the role of language in subject matter expansionism’ in Rimmer M. and McLennan

definition that turns on the interpretation of the key phrase “new or significantly improved” whilst invention is directed to new and non-obvious ideas.’⁵⁶⁴ That is to say what qualifies for an invention in law covers more restricted and narrow subject matter than what could be generally regarded as innovation in business circles, making the conceptual translation from the business context into law of potentially protectable subject matter intricate.

A further restriction on what could be patented in the context of patent law is that even subject matter alleged to be inventions in law can also be excluded from patentability. In both the UK and South Africa, legislation narrows down what could be patentable by explicitly excluding some categories of subject matter from patentability.⁵⁶⁵ This is to say that the pre-determined standard of what is patentable is set by the explicit exclusion of some alleged inventions from patenting. This provides the policy-makers with the lever to adjust the patentability standard by excluding categories deemed not to be fulfilling the purpose of the patent system, for instance scientific theories which if were patentable would block the downstream advance of subsequent technologies.⁵⁶⁶ Excluded subject matter is therefore important for its role in determining the extent ‘public goods’ fall outside the realm of individual control.⁵⁶⁷ This comports with the justification for patents that optimal patentability must balance private and public the interests, as established in chapter two.

A. *Intellectual property and emerging technologies* (2012) Cheltenham: Edward Elgar Publishing Limited.

⁵⁶⁴ Kahn M. ‘Measuring innovation and development: A case for treatment’ *Conference proceedings of the innovation for development: Frontiers of research, policy and practice symposium*, 24-26 February 2010, University of Witwatersrand. Also, Ruttan asserts that if a practically significant and precise Schumpeter distinction between innovation and invention is needed, the term innovation would simply be preceded by an appropriate adjective such as ‘technical innovation’ and ‘[i]nvention then becomes a special subset of technical innovation on which patents can be obtained’: Ruttan V.W. ‘Usher and Schumpeter on invention, innovation, and technological change’ (1959) *Quarterly Journal of Economics*, p.596-606, p.603. Also, Kingston, fn.2, p.354.

⁵⁶⁵ Most of these exclusions in some jurisdictions, Canada and the United States for example, are judicially created, see *Crowne-Mohammed E.A.* ‘A review of the as “such” exclusions to patentable subject matter in the United Kingdom: Lesson for Canadian and American courts’ (2010) *Albany Law Journal of Science and Technology*, p.457-486, p.459.

⁵⁶⁶ Ohlmeyer/Zhou, fn.33.

⁵⁶⁷ Shaffer G. ‘Recognising public goods in WTO dispute settlement: Who participates? Who decides? The case of TRIPS and pharmaceutical patent protection’ (2004) *Journal of International Economic Law*, p.459-482, p.461: in the context of new pharmaceutical knowledge-generation where the knowledge may have private and public attributes, public goods are those considered non-excludable in their benefit.

On another dimension, the categorising of excluded matter makes the assessment of what qualifies for patenting easier. Thus, the explicit statutory listing of unpatentable subject matter helps with identifying if a particular scientific activity or output thereof is indeed an invention or considered patentable under the law. Debates remain on how excluded subject matter should most appropriately be assessed as there are overlaps between some of the excluded categories and also as to the appropriate stage when the assessment of whether subject matter is indeed a patentable invention should be carried out in patentability evaluation.⁵⁶⁸ The thesis concentrates on the methodologies and tests for making this judgement.

The thesis focuses on pharmaceutical inventions. However as alluded to in the first chapter, this sector is multidisciplinary. As such, it is appropriate to examine excluded subject matter in the sectors integral to the operation of the industry and life cycle of the pharmaceutical invention. This is important given that some of the categories of excluded subject matter contribute to the conception, actualisation or improvement of the final pharmaceutical product and that the pharmaceutical processes and methods are intractably linked with various excluded subject matter.⁵⁶⁹

The section will begin with an exploration of the pharmaceutical industry innovations and inventions with reference to the issues that arise in the context of assessment of excluded subject matter. The section will then turn to an examination of what an invention is, with the objective of identifying subject matter that is excluded from patentability by virtue of not being defined as patentable inventions in the laws of both jurisdictions. There will then be a discussion of what is explicitly excluded from patentability and the approach that is taken in accessing the exclusions. Not all exclusions categories will be under scrutiny.⁵⁷⁰ Moreover, detailed focus will be on fields that enhance the generation, processing and analysis of vast amounts of

⁵⁶⁸ Pila J. *The requirement for an invention in patent law* (2010) Oxford University Press: Oxford, p.58-59.

⁵⁶⁹ For instance, in *Fujitsu Ltd's Pat. App* (1997) RPC 608, the Court of Appeal examined the patentability of software that allowed chemists to design new chemical compounds and was found to be excluded subject matter as such.

⁵⁷⁰ Under examination in this study are the 'as such' exclusions and what is typically referred to as exceptions will not be covered. Focus will be on the 'as such' exclusions which are mainly directed to the exclusion of abstract subject matter or subject matter covered by other IP law especially copyright law insofar as the invention in the patent or patent application relates to that those items *per se* or as such.

pharmaceutical research information, for instance software and business methods as these have been controversial and have a significant bearing on the success of the pharmaceutical venture.⁵⁷¹

4.2 The innovation cycle in pharmaceutical industries

The patent system grants protection for inventions. A robust and meaningful definition of what constitutes an invention and how subject matter could properly be conceived as invention is important as it helps in the determination of appropriate thresholds of categories of subject matter for which a patent may be granted.⁵⁷² As it has been noted that ‘whoever controls the meaning of “invention” controls what could be patented,’⁵⁷³ it is important for industrialists to know which of their research activity or output will be captured by the definition of an invention and thus protectable. This section introduces how patentable inventions are defined in law and how industry tends to conceive it. Understanding patentable subject matter helps in the assessment of whether innovations and inventions encountered in pharmaceutical activities fall within those boundaries and hence are patentable.

Scholars assert that early patent grants were directed to innovation and only indirectly to invention and contemporary this has been reversed to offer protection to invention directly and only innovation indirectly.⁵⁷⁴ This evolution in the nature of legal protection offered by the patent was seen in chapter two, whereby historically the patent system also protected those who merely practically introduced new arts into local economies rather than create them. Innovation is more concerned with

⁵⁷¹ For instance, Debnath demonstrated predictive computer modelling that eliminates the need to carry out expensive experiments on a large chemical series and also resulted in promising candidate molecules for HIV treatment and showed the predicted activity in reality and were patented by pharmaceutical firms. Debnath A.K. ‘Generation of predictive pharmacophore models for CCR5 antagonists: Study with piperidine- and piperazine-based compounds as a new class of HIV-1 entry inhibitors (2003) *Journal of Medicinal Chemistry*, p.4501-4515.

⁵⁷² Pila J. ‘The future of the requirement for an invention: inherent patentability as pre- and post-patent determinant’ in Arezzo E. and Ghidini G. *Biotechnology and software patent law* (2011) Cheltenham: Edward Elgar, p.55. Schmookler J. *Invention and economic growth* (1966) Massachusetts: Harvard University Press, p.12-17.

⁵⁷³ *CFPH Application* [2005] EWHC 1589, para.10.

⁵⁷⁴ Kingston, fn.638, p.2-3.

commercial ends than invention which focuses more on technical result.⁵⁷⁵ Since pharmaceutical activity occurs mainly in commercial settings, it can be argued that to industrialists there could be the expectation that to be useful for protecting what they may indiscriminately perceive and define as inventions or innovations, the protection offered by the patent must not then effectively be undermined by how the subject matter is ultimately defined as unprotectable in patent law.⁵⁷⁶ Nonetheless, in law, the definition of invention and innovation remains different. Therefore, when seeking patent protection, the legal rules as they protect the invention must be clearly understood and then appropriately fitted into the commercial context.

Others are of the view that the differentiation between invention and innovation is not of practical value.⁵⁷⁷ Some analysts state that for pharmaceuticals ‘because of the near-perfect identity between what is invented and what is innovated...it would make little difference to the chemical and pharmaceutical firms from the strict point of view of protecting any discovery, whether the patent system protected innovation indirectly or directly.’⁵⁷⁸ Indeed, that may be the case but the thesis asserts that it is helpful to separate these especially because the inventive process which results in the final invention occurs in intertwining and overlapping R&D stages and in diverse fields of technology that may involve some excluded subject matter.⁵⁷⁹ For example, in what has become a routine and significant contributor to new medicines pipeline, innovative or inventive pharmaceutical compounds are created *in silico* long before it is known whether they could exist in reality.⁵⁸⁰ In addition, the overlapping stages in

⁵⁷⁵ ‘In scientific and industrial environments, there is a major difference between innovation and invention’ with the innovation status ‘acquired when society adopts this, apparently new, artifact within a community of consumers that boasts certain legitimacy’ and invention characterised by ‘a special capacity to solve certain specific problems’: Cavallucci D. ‘A research agenda for computing developments associated with innovation pipelines’ (2011) *Computers in Industry*, p.377–383, p. 378.

⁵⁷⁶ The perception of how the courts would ultimately adjudicate matters has been seen as influential in the delineation of rights: Barzel Y. *Economic analysis of property rights*, 2nd ed (1997) Cambridge: Cambridge University Press, p.98.

⁵⁷⁷ Cullis R. *Patents, inventions and the dynamics of innovation: A multidisciplinary study* (2007) Cheltenham: Edward Elgar, p.6.

⁵⁷⁸ Kingston W. (ed) *Direct protection of innovation* (1987) Lancaster: Kluwer Academic Publishers, p.13.

⁵⁷⁹ Caraça J., Lundvall B. and Mendonça S. ‘The changing role of science in the innovation process: From Queen to Cinderella?’ (2008) *Technological Forecasting & Social Change*, p.861–867.

⁵⁸⁰ The term *in silico* is coined from the reference to Silicon Valley’s fame to computers and has gained popularity within pharmaceutical discovery practitioners, with more pharmaceutical companies developing *in silico* tools in the past two decades: Shekhar C. ‘In *Silico* pharmacology: Computer-aided methods could transform drug development (2008) *Chemistry and Biology*, p.413-414. Computer programs *per se* are not patentable but such created compounds may be.

R&D make it difficult to identify which aspects of the process could be classified as technical and thus contribute to the invention aspect and which ones are commercially inclined and thus more likely to be classified as innovation.⁵⁸¹

Besides the ramifications of the inaccurate conceptualisation of innovation and invention, the category of subject matter that qualifies for protection can be of concern. Before the advent of the TRIPS Agreement, which has mandated the protection of both product and process type of inventions, there were debates and division as to whether the pharmaceutical product should be excluded from patentability at all, but now the debate has shifted such that the patent system is usually cited as critical for the protection of pharmaceutical products.⁵⁸² The view commonly held is that in patents for pharmaceutical products ‘the disclosure is a chemical formula, which is identical for both the laboratory sample embodying the invention and for tonnage production.’⁵⁸³ The relative ease with which the final pharmaceutical product can be identified and copied makes the patent system the best choice for protecting these inventions. Advances in analytical technologies and chemical retro-synthesis make it easier to figure out the theoretical starting materials of the final product.⁵⁸⁴ Nevertheless, on its own, such a view that emphasises supremacy of product protection would seem narrow and would not reflect appreciation of the entire pharmaceutical undertaking.

The controversy and emphasis on product protection has tended to overshadow the equally important role of patents in protecting the pharmaceutical processes by which those products are produced.⁵⁸⁵ Inventive and innovative processes are important and

⁵⁸¹ Caraça *et al*, fn.579, p.866, a multi-channel interactive innovation model has been proposed, wherein there is a multiplicity of intertwining innovative processes and feedback channels compared to earlier linear innovation models or the slightly improved chain-linked model of innovation which, respectively, assumed that the R&D stages occurred in a linear fashion or one-directional sequential cycle.

⁵⁸² For instance, Yu P.K. ‘A tale of two Development Agendas’ (2009) *Ohio Northern University Law Review*, p.465-573, especially, p.506-507; Dufield G. and Suthersanen U. *Global intellectual property law* (2008) Cheltenham: Edward Elgar, p.115.

⁵⁸³ Kingston W. *Innovation, creativity and the law*, (1990) Kluwer Academic Publishers, p.121.

⁵⁸⁴ Even low cost analytical methods can have high analytical capabilities: Kaale E, Risha P. and Layloff T. ‘TLC for pharmaceutical analysis in resource limited countries’ (2011) *Journal of Chromatography A*, p.2732–2736.

⁵⁸⁵ Though important, process claims are considered to be of less economic value and difficult to monitor than product claims and hence the practice that is considered more useful is product-by-process claiming which gives a monopoly on the product by whatever means it is produced: Kartal M. ‘Intellectual property protection in the natural product drug discovery, traditional medicine and

play a significant role in the sustainability of a pharmaceutical firm.⁵⁸⁶ Masking the importance and contribution of inventive or innovative processes, for instance, is the fact that ‘the Trade journals report relatively few processes, service and management innovations and tend to capture product innovations.’⁵⁸⁷ Therefore indicators and indices of pharmaceutical innovation and invention levels have arguably understated the role of inventive processes and the continuing need to protect them.

There is little benefit in reverse engineering and retrosynthesis of products alone.⁵⁸⁸ The innovative and inventive industrial-scale processes give a competitive advantage to industrial firms.⁵⁸⁹ The processes, which may be based on excluded subject matter, are important to the practical implementation of inventions and innovation into industry reality. These inventive and innovative processes are helpful to the realisation of more efficient scale-up projects and the resulting pharmaceutical product.⁵⁹⁰ Some commentators have even observed that ‘in all sectors ... a large proportion of innovative activity takes place outside research laboratories, e.g. in design and planning, or in the production plants themselves.’⁵⁹¹ The competitive advantage of the firm, therefore, does not reside only in the final product produced but also in the efficiency of the processes of producing it, aspects of which may be deemed excluded from protection.⁵⁹²

herbal medicinal products’ (2007) *Phytotherapy Research*, p.113-119. *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46, para.88-91, decided that UK should not accept product-by-process claims as a matter of practice.

⁵⁸⁶ ‘[T]he design and optimization of synthetic routes for active molecules is at the very core of the business’: Federsel H.J. ‘Process R&D under the magnifying glass: Organization, business model, challenges and scientific context’ (2010) *Medicinal and Bioinorganic Chemistry*, p.5775–5794, p.5793.

⁵⁸⁷ Acs Z.J. and Audretsch D.B. ‘Innovation in large and small firms: An empirical analysis’ (1998) *American Economic Review*, p.679-690, p.680.

⁵⁸⁸ ‘Of processes, pills and profits’, *The Economist*, 11/09/96, Vol. 341, Issue 7991.

⁵⁸⁹ Scale-up processes continue to present problems as there is a multiplicity of variables to be addressed even for simple processes: Portillo P.M., *et al* ‘Quality by design methodology for development and scale-up of batch mixing processes’(2008) *Journal of Pharmaceutical Innovation*, p.258–270.

⁵⁹⁰ *Guidance for Industry: PAT - A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance*: Pharmaceutical CGMPs (September 2004) US. Department of Health and Human Services: Food and Drug Administration.

⁵⁹¹ Williams D. and Kang S., ‘Manufacturing and production’, in Jacobsen T.M. and Wertheimer A.I. *Modern pharmaceutical industry* (2010) Sudbury: Jones and Bartlett Publishers LLC.

⁵⁹² Emphasising the need for process innovation, it has been observed that ‘pharmaceutical manufacturing operations are inefficient and costly... Low efficiency is predominantly due to ‘self-imposed’ constraints in the system (e.g., static manufacturing processes, focus on testing as opposed to quality by design’: Hussain A.S. ‘An innovative, consensus building tool for the 21st century’ (2006) *Journal of Pharmaceutical Innovation*, p.9-10.

A typical pharmaceutical process or the ensuing product is brought into the market by a series of multidisciplinary and integrated stages and activities,⁵⁹³ some of which do not fall under the patentable categories or the definition of patentable inventions. As such, whilst working on what will be a patentable output, it would be difficult for the scientist or industrialist to discern a clear division in what would be excluded in patent law in the enabling or platform technologies relied upon. Hence, the statutory construct of what is within the legal definition of a patentable invention is important. At the same time, the legal definition must be concomitant with the operational principles and realities of those industries where innovation and invention is emphasised for survival. Indeed, some innovations that have considerable technical contributions could be outside of the system by virtue of being in the non-patentable category. The conceptualisation of what is patentable is therefore not as clear cut as it would initially be thought especially if it is taken from the position of the person in industry. The thesis now turns to the definition of patentable invention and excluded subject matter in law, examining the two jurisdictions in turn.

The United Kingdom

4.3 Definition of patentable inventions and excluded subject matter

The legal definition of an invention is a complex concept that impacts on the exclusion of some subject matter from patentability. To further complicate matters, the definition sometimes has to encompass and define a technology that has not come about.⁵⁹⁴ Even more difficulty is encountered when it is acknowledged that the rate of technology evolution is very high.⁵⁹⁵ Even current technology is susceptible of refinements as there are always advances in previously unpredictable directions,

⁵⁹³ Bennani Y.L. 'Drug discovery in the next decade: innovation needed ASAP' (2011) *Drug Discovery Today*, p.779-792, p.782-784, quoting Janssen stating that 'a good scientist in someone who succeeds in getting the different scientific disciplines to work in harmony with one another' in recognition of the multidisciplinary nature of the pharmaceutical R&D.

⁵⁹⁴ During Parliamentary debate, there was consensus that the definition must be flexible to keep up with technology changes: Hansard, HL Deb 15 February 1977 vol 379 cc1409-12. The Strasbourg Convention, forming the basis of much harmonised patent law, did not expressly define the term invention.

⁵⁹⁵ Tessensohn J.A. and Yamamoto S. 'Japan: utility models- improvement to the system' (2005) *European Intellectual Property Review*, n.119-121.

rendering inadequate a definition which may have previously sufficed. It is likely that a rigid statutory definition of an invention would prevent judges in developing the law to keep up with advances in industry.⁵⁹⁶

The question of what inventions are has been posed and debated in court.⁵⁹⁷ Establishing this would assist in assessing whether an innovative or inventive output by scientists is patentable. It has been acknowledged that it is difficult to have a certain definition of what characterises an invention.⁵⁹⁸ The term has not been satisfactorily defined in any patent act, and it is questionable as to whether a precise definition can ever be given.⁵⁹⁹ Lord Hoffmann, prescribing the sidestepping of establishing whether or not subject matter is an invention in a patentability enquiry, stated in *Biogen Inc v Medeva*⁶⁰⁰ that ‘judges would therefore be well advised to put on one side their intuitive sense of what constitutes an invention until they have considered the questions of novelty, inventiveness and so forth.’

Another issue for consideration is also ascertaining whether or not what is alleged to be an invention is patentable under law. As seen in the previous chapter, patentability in the UK is to some extent influenced by external instruments to which it subscribes to at the international and regional levels. A definition of patentable inventions has been canvassed at the international arena and an all-encompassing definition is indicated under the TRIPS Agreement. TRIPS Art.27(1) requires Member States to grant patents for all fields of technology. This obligation has been used by those countries, notably the US, for allowing the patenting of pure software and life-forms.⁶⁰¹ However, the broad language in TRIPS is narrowed by the fact that the TRIPS Agreement itself, also allows some exclusions to what is included within the

⁵⁹⁶ Lord Irvine, fn.27, p.336.

⁵⁹⁷ For instance, in *Generics v Lundbeck* [2009] UKHL 12, para.12, refers to the statute as one ‘which notoriously does not define “invention.”’ Also, Prescott sitting as a Deputy Judge in *CFPH LLC’s Patent Application* [2005] EWHC 1589, remarked ‘what is an ‘invention’...is a topic bedeviled by verbal formulae - and by the sweeping of problems under the carpet.’

⁵⁹⁸ *CFPH LLC’s Patent Application* [2005] EWHC 1589, para.15.

⁵⁹⁹ *Loc cit.* Patents Act 1949, s.101 positively defined an invention, and also South Africa Patents Act 1952, s(1)(v) but were seen as inadequate.

⁶⁰⁰ [1996] UKHL 18.

⁶⁰¹ ‘US govt promoting patent extremism in the European Parliament’, available at www.swpat.ffii.org/papers/index. Also, in the US, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) established that Congress had intended patentable subject matter to ‘include anything under the sun that is made by man.’

concept of patentable inventions. These, generally, are public policy and morality exceptions to the definition of patentable inventions.⁶⁰² Thus it could be said that the definition of patentable invention is constrained between these parameters.

At regional level, the excluded subject matter from patentability is found in EPC Art.52 and Art.53. The thesis in this chapter focuses on Art.52 and not Art 53 which generally deals with exceptions to patentability. The international influence for wider patentability of subject matter in the European definition of patentable inventions was observed in *Aerotel Ltd. v Telco Holdings Ltd & Ors Rev 1*,⁶⁰³ where the court stated that:

‘First there has been some political pressure on Europe to remove or reduce the categories of non-inventions. Part of that has come, from the fact that TRIPS does not have the same explicit categories of non-invention as the EPC...

Some of the Art.52(2) excluded categories are not fairly within the description “field of technology” and so not within TRIPS (e.g. aesthetic creations) but others seem to be within it – the paradigm example being computer programs. Hence the pressure. Whether “methods for doing business” are a “field of technology” within the meaning of TRIPS is perhaps debatable.’

On the domestic level, the 1977 Patents Act, s.1(1) prescribes that ‘a patent may be granted only for an invention in respect of which the following conditions are satisfied... and references in this Act to a patentable invention shall be construed accordingly.’ This according to some commentators⁶⁰⁴ either means any innovative or inventive research output that complies with the conditions set out in the subsections of the Act is deemed a patentable invention or the subject matter must both be an ‘invention’ and satisfy the conditions. The former approach, as opposed to the latter, seems to be the preferable definition of an invention in UK law because it allows the definition to remain current and applicable to emerging fields of technologies and an

⁶⁰² TRIPS Art.27(2) and (3).

⁶⁰³ [2006] EWCA Civ 1371, para.16.

⁶⁰⁴ Colston C. ‘Genetic engineering – Failure to invent? The House of Lords’ decision in *Biogen Inc v Medeva plc* (1997) *Intellectual Property Quarterly*, p.521-529, p.522.

effective definition would almost be impossible to achieve as demonstrated during the EPC negotiations.⁶⁰⁵

In *Genentech Inc's Patent*,⁶⁰⁶ it was considered essential to identify the invention accurately when making assessment of whether subject matter is not excluded from patentability. This case was concerned with a new synthesis method of a compound identical to one that occurs in nature and thus alleged to be consisted of excluded subject matter according 1977 Patents Act, s.1(2). Lord Mustill considering whether the statute additionally requires the applicant to have made an invention as opposed to the alternate interpretation of whether it merely possesses the patentability requirements of section 1(1) stated that ‘compliance with these four conditions turns the invention into a “patentable invention” and then section 1(2) goes on to exclude certain matters from the scope of “invention” – not “patentable invention”’.⁶⁰⁷ The Court of Appeal in *Biogen Inc v Medeva*⁶⁰⁸ essentially followed this approach of establishing whether an invention has been made and separately whether the invention was new, involves an inventive step and capable of industrial application.

Lord Hoffmann, giving a majority opinion in the House of Lords rejected this evaluation approach in *Biogen Inc v Medeva*⁶⁰⁹ stating that initially seeking whether there is an invention will lead to unnecessary complexity and will ‘almost invariably be academic’ and the important requirement is to simply evaluate whether subject matter in new, inventive and industrially applicable. He was of the view that the four patentability conditions in section 1(1) reduce the class of inventions that could be patented and probably covers every aspect of the meaning of the term invention.⁶¹⁰ Lord Mustill, sitting in the same House, did not accept this approach saying sometimes ‘close conceptual analysis of the nature of patentability will not be a waste

⁶⁰⁵ *Ibid*, p.522-523. For changes in the definition of inventions see generally *Comments on the first Preliminary Draft Convention relating to a European patent law of 14 March 1961 (Articles 11 to 29)*, Council of Europe Doc IV/2071/61 – E (1961) 4 and *Proceedings of the 1st meeting of the Patent Working Party held at Brussels from 17 to 28 April 1961*, Council of Europe Doc IV/2767/61-E (1961) Section 5, 4. *Swift Application* [1962] RPC 37, para.44, per Lord Parker CJ.

⁶⁰⁶ [1989] RPC 147, per Mustill, p.262.

⁶⁰⁷ *Ibid*, and a definition in compliance with the TRIPS Agreement.

⁶⁰⁸ [1995] RPC 25.

⁶⁰⁹ [1996] UKHL 18, para.44.

⁶¹⁰ *Ibid*, para.42-43.

of time.’⁶¹¹ Some commentators have rejected the UK conceptualization of what an invention is, in preference to the EPO approach which considers the definition of an invention on the basis of whether the subject matter has technical character as separate from the secondary criteria of patentability.⁶¹²

The pharmaceutical field is inundated with inventions derived from seemingly excluded categories, for instance products of nature.⁶¹³ Agreement on what constitute a patentable invention or an excluded category paves the way for clarity in the patenting of some pharmaceutical inventions embodying products of nature which, as shown in chapter one, are a source of new pharmaceuticals or motivation for their derivation.

The 1977 Patents Act defines what an invention is by expressly listing what is excluded from the definition of an invention.⁶¹⁴ Prescott notes that ‘in telling us about patentable inventions, the Patents Act 1977 does not try to define what an invention is. Instead it contains a list of things that are not inventions.’⁶¹⁵ A potential limitation to the usefulness of this exclusion listing tool is that technological development is now of an intertwining and converging nature. The pharmaceutical inventions are integrated with elements from the different fields of technology, as it has been shown in the previous subsection. As a result, it will be difficult to simply look at the list and apply it to judging whether the invention is excluded.

Another difficulty is that the listed items have no common thread linking them.⁶¹⁶ It has been said that it is policy exclusion that make up this list. For example, in *Fijitsu Limited’s Application*,⁶¹⁷ Laddie LJ said the items in Art.52 were excluded for reasons of public policy. As such, it cannot be predicted that a similar article to that in the list

⁶¹¹ *Ibid*, para.5, and was of the view that it was not matter that the court should address in that instance.

⁶¹² Pila J. ‘On the European requirement for an invention’ (2010) *International Review of Intellectual Property and Competition Law*, p.906-926, p.908-909.

⁶¹³ Du Pont’s strategy of entering human pharmaceuticals research was launched through the synthesis of the analogues of the natural compound chloramphenicol in order to improve it, Hounshell D.A. and Smith J.K. *Science and corporate strategy: Du Pont R&D, 1902-1980* (1988) Cambridge: Press Syndicate of the University of Cambridge, p.465. Also, Bull A.T. and Stach J.E.M. ‘Marine actinobacteria: New opportunities for natural product search and discovery’ (2004) *Trends in Microbiology*, p.491-509.

⁶¹⁴ Patents Act 1977, s.1(2).

⁶¹⁵ *CFPH*, para.18.

⁶¹⁶ *Aerotel Ltd v Telco Holdings Ltd* [2006] EWCA Civ 1371, para.9.

⁶¹⁷ [1996] RPC 507, p.530.

will be handled in a similar way.⁶¹⁸ This makes it complicated advancing arguments for or against inclusion of related fields into the exclusion listing.

The listing, although useful, cannot in practice always resolve cases where an invention consists partly of items in the list and some that are not. Nowadays, for example, routine R&D of traditional pharmaceutical inventions is highly integrated of many excluded and non-excluded components and therefore has a higher probability of ending in disputes resulting in court action.⁶¹⁹ For optimisation of the system, the patent system needs to provide a means and guidance of evaluating the contribution or degree of integration of excluded and patentable matter that is necessary for the invention to be deemed not excluded from patentability as a whole. The next subsection will examine how the courts have sought to resolve this.

The excluded subject matter list as found in Patents Act 1977, s.1 implements EPC Art.52. Sub-sections (2) lists the various categories of excluded subject and is among the statutory provisions that are specifically mentioned in s.130(7) of the 1977 Act as having been ‘so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the EPC.’ Hence, the interpretation of these sections must converge with that of the EPC. Reference to EPC cases has therefore occasionally been used by the UK courts in the evaluation of appropriate the degree of integration of excluded and patentable subject matter in an invention.

In *Aerotel*, Lord Justice Jacob went further and advanced an exclusion interpretation that relies more on the Convention than the domestic statute. That is to say that for interpretation of excluded subject matter in the UK, reliance could be placed on the original document than on the implementation domestic instrument. He stated that:

⁶¹⁸ *CFPH*, para.31.

⁶¹⁹ *Examination Guidelines for patent applications relating to biotechnological inventions in the UK Intellectual Property Office* (2013) UKIPO, Newport, UK, para.6-7.

‘Although s.1(2) pointlessly uses somewhat different wording from that of the EPC no-one suggests that it has any different meaning. So we, like the parties before us, work directly from the source.’⁶²⁰

The thesis will now examine the groups of excluded items in the UK in turn.

4.4 The Excluded Items

It has been acknowledged that the excluded categories from patentability have no common theme or purpose amongst them.⁶²¹ In *Aerotel* the court cautioned against arbitrary preference of some excluded category over others in case law, once the policy considerations have been promulgated into law. The court said ‘in our opinion, therefore, the court must approach the categories without bias in favour of or against exclusion. All that is clear is that there was a positive intention and policy to exclude the categories concerned from being regarded as patentable inventions.’⁶²²

In this subsection of the thesis the categories of excluded subject matter will not be examined according to the precise format in the statutory groupings. This serves two purposes. The first is that the express statutory groupings do not identically match between the two jurisdictions under study. The second is that not all the categories will be examined and only those that are pertinent to activities in the modern pharmaceutical industry are considered relevant here.⁶²³ The exclusions of prime examination are found in s.1(2) which ‘essentially covers abstract subject matter that is either ephemeral in nature (like discoveries, scientific theories and mathematical methods), or subject matter that is generally covered by the law of copyright insofar

⁶²⁰ *Aerotel*, para.6. Cf. EPO 1990: T0022/85 *Document Abstracting and Retrieving*.

⁶²¹ *Symbian Ltd v Comptroller General of Patents* [2008] EWHC 518 (Pat), para.23.

⁶²² *Aerotel*, para.21. Also, during the Parliamentary debate on the current Patent Act there was the view that grouping together some of the ‘as such’ exclusions with computer programmes was intended ‘to ensure that computer programmes are construed together with other schemes and methods so that...the exclusion will bite only on so-called computer software (sic) and not on programmes which may be embodied in the hardware (sic)’, Hansard, HL Deb 15 February 1977 vol 379 cc1409.

⁶²³ In *Aerotel*, para.21 and 45, the court stated that courts must approach the categories without bias in favour of or against and accepted that ‘although the policy behind different exclusions is not uniform, the structure of the legislation requires that they ought to work the same way.’

as the patent application relates to those items in-and-of themselves⁶²⁴ such as computer programs.

4.4.1 Discoveries and scientific theories

There are various ways in which inventions are brought about. One way of inventing involves thought and logic where theory is developed and applied to solve problems in most cases basing this on old principles and possibly also new ones.⁶²⁵ Nowadays in industry, hardly any new discovery is made without a preceding theory. At the same time, some surprising results from application of the theory occur and may not only lead to new products but also feed back into fine-tuning and modifying earlier theories. As such, at the earlier point in the R&D chain, where securing priority is important, it is plausible that there is a close association between a discovery, a theory or what may subsequently held to be an invention.

The UK Patents Act s.1(2)(a) is expressly prescriptive of the non-patentability of a discovery and scientific theory. One of the challenges that confront research scientists is how an invention that could be patented is differentiated from a discovery or theory. Picciotto⁶²⁶ observes that TRIPS does not ‘make any attempt to clarify the all-important distinction between a discovery and an invention.’ UK case law provides guidance in this regard.

A discovery is the making available of something that is already available in nature. The mere discovery of a substance does not amount to repeatable method of producing that substance, but only to a one-time process of obtaining that substance. It has been said that ‘while both discoveries and inventions contribute new knowledge to the sum total of human understanding, an invention does so through the application of human endeavour to produce a technical solution to an unresolved technical

⁶²⁴ Crowne-Mohammed, fn.565, p.462. Lord Hoffmann referred to this general group as ‘inherently abstract subject matter’: Pila, J. ‘On the European requirement for an invention’ (2010) *International Review of Intellectual Property and Competition Law*, p.906-926, p.907.

⁶²⁵ Cullis, fn.577, p.2.

⁶²⁶ At p.13, Picciotto.S, ‘Defending the public interest in TRIPS and the WTO’, available at www.lancs.ac.uk/staff/lwasp/sp-trips.pdf.

problem.⁶²⁷ In *Reynolds v Hebert Smith*,⁶²⁸ it was established that a discovery merely disclosed what was not seen whereas an invention involved suggestion of an act that resulted in something new. The principle established therefore is that ‘an invention is a practical product or process, not information about the natural world.’⁶²⁹

An artefact or process that is devised from the making of the discovery is patentable. This principle was extended in *Genentech’s Patent*⁶³⁰ where it was established that an invention is patentable even when it was a result obvious from the making of the discovery.⁶³¹ The same approach was applied in *CFPH LLC’s Application*⁶³² in which the court said ‘an instance of a “soft exclusion” is a discovery. It is well-settled law that, although you cannot patent a discovery, you can patent a useful artefact or process that you were able to devise once you had made your discovery. This is so even where it was perfectly obvious how to devise the artefact or process, once you had made the discovery.’

In the EPO Guidelines⁶³³ it is stated that:

‘To find a substance freely occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which it is obtained or by other parameters and is ‘new’ in the absolute sense of having no previously recognised existence, then that substance per se may be patentable.’

Reasoning to the same end is found in Directive 98/44/EC, which is concerned more specifically with biotechnological inventions, which have been held to be a subset of chemicals compounds, albeit more complicated ones.⁶³⁴ The Directive states that

⁶²⁷ Laurie G. ‘Intellectual property protection of biotechnological inventions and related material’: www.law.ed.ac.uk/ahib/publications/online/INNOGENscopingpaperpatents.doc, p.4.

⁶²⁸ (1903)20 RPC 123, p.126.

⁶²⁹ *Kirin-Amgen Inc. v. Hoechst Marion Roussel*, [2005] RPC 9, (H.L.), p196.

⁶³⁰ [1987] RPC 553, p.556.

⁶³¹ Also in *Genentech Inc’s Patent (Human Growth Hormone)* [1989] RPC 147, p.202 (C.A.).

⁶³² [2006] RPC 5, para.34.

⁶³³ EPO Examination Guidelines 2.3.1.

⁶³⁴ *Amgen Inc v Chugai Company Ltd*, 927 F.2d 1200, 1206 (Fed. Cir 1991).

‘material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.’⁶³⁵ This view seems to embrace the natural right justification of patents which recognises the labour input in coming up with inventions.

The Court of Appeal, in *Fujitsu Limited’s Application*,⁶³⁶ prescribed the criteria that differentiate whether discoveries are patentable or not and this lies in the technical contribution that it makes to the state of the art. In his judgment Aldous LJ stated:⁶³⁷

‘However, it is and always has been a principle of patent law that mere discoveries or ideas are not patentable, but those discoveries and ideas which have a technical aspect or technical contribution are. Thus the concept that what is needed to make an excluded thing patentable is a technical contribution is not surprising. This was the basis for the decision of the Board in Vicom. It has been accepted by this court and by the EPO and has been applied since 1987. It is a concept at the heart of patent law.’

The principle of technical contribution in Aldous LJ’s judgment in *Fujitsu* was referred to and followed by Neuberger J in *Kirin-Amgen Inc v Roche Diagnostics GmbH*,⁶³⁸ stating that ‘[i]t is ... a principle of patent law that mere discoveries or ideas are not patentable, but those discoveries and ideas which have technical aspect or make a technical contribution are. Thus the concept that what is needed to make an excluded thing patentable is a technical contribution is not surprising.’ Technical contribution is viewed therefore as the criterion that is decisive for finding for patentability for what is potentially an excluded discovery.

⁶³⁵ Directive 98/44/EC, Art 3(2).

⁶³⁶ [1997] RPC 608.

⁶³⁷ [1997] RPC 608, p.614.

⁶³⁸ [2002] RPC 1, especially para.535.

4.4.2 Computer and computer-related inventions

The thesis now turns to examine the exclusion of computer and computer-related inventions from patentability. This is a group of exclusions that are interrelated and interconnected, central of which is the computer program.⁶³⁹

It is now accepted that in pharmaceutical research activity, it is no longer the lone scientist working alone on a lab bench that finds the pharmaceutically useful compounds but a team or collaboration of scientists relying on computers and automation for worthwhile output.⁶⁴⁰ The courts have observed that ‘[a]ll modern industry depends upon programmed computers...’.⁶⁴¹ Jacob LJ observed that there is an exponential increase in the number of business methods and computer program patents.⁶⁴² Patent administrators also make the same observation.⁶⁴³ This has given rise to the need for the courts to properly demarcate appropriate boundaries of how this exclusion is to be objectively and consistently made. In *Symbian Ltd v Comptroller General of Patents*,⁶⁴⁴ the court observed that ‘the issue raised on this appeal requires us to consider the reach of the exclusion of “programs for computers” from patentable inventions, a topic which is inherently difficult and on which there is apparently inconsistent authority domestically and in the EPO.’

Exclusions in the computer-related category are found in the Patents Act, s.1(2)(c) and (d). An illustration of connectivity of these fields as experienced in industry would include the so-called chemical informatics field which uses computer programmes and interface displays in simulating chemical compounds or chemical processes.⁶⁴⁵ The typical exclusions of an invention in this field could therefore be on

⁶³⁹ Shemtov N. ‘The characteristics of technical character and the ongoing saga in the EPO and the English courts’ (2009) *Journal of Intellectual Property Law and Practice*, p.506-514, p.507, defining computer-implemented as inventions ‘implementation of which involves the use of a computer, computer network, or other programmable apparatus, with features realized wholly or partially by means of a computer program.’

⁶⁴⁰ Frearson J.A. and Collie I.T. ‘HTS and hit finding in academia – from chemical genomics to drug discovery (2009) *Drug Discovery Today*, p.1150–1158.

⁶⁴¹ *Research in Motion v Inpro* [2006] EWHC 70 (Pat), Pumfrey J., p.187.

⁶⁴² *Aerotel Ltd v Telco Holdings Ltd* [2006] EWCA Civ 1371, para.17.

⁶⁴³ See generally *Examination Guidelines for patent applications relating to biotechnological inventions in the UK Intellectual Property Office*, September 2007, UKIPO, Newport, UK.

⁶⁴⁴ [2008] EWCA Civ 1066, para.1.

⁶⁴⁵ Gardner S.P. ‘Ontologies in drug discovery’ (2005) *Drug Discovery Today*, p.236, DOI: 10.1016/j.ddtec.2005.08.004.

the ground of consisting of computer programs, display of information or even mathematical methods which are excluded according to s.1(2)(a). Examples of problems solved by using chemical informatics are in the managing of the complicated data in pharmaceutical discovery and screening and the molecular modelling processes.⁶⁴⁶ Related to this is an algorithm which is a method for solving technical problems and ‘may be suitable for implementation in a computer program but is not itself a computer program.’⁶⁴⁷ Thus, it has been asserted that ‘the purposive use of mathematical algorithms in providing solutions to technical problems in the field of drug discovery or related technical fields can provide opportunities for securing valid patents.’⁶⁴⁸ Computer programs, business methods and display of information dissect every aspect of pharmaceutical discovery activity.⁶⁴⁹

The 1949 Act had no *expressis verbis* rules for computer programs. There were applications for software patents filed even though they did not succeed. Although previously ‘the trend of the UK cases has been to deny the patentability of software-related invention’,⁶⁵⁰ the UKIPO observed that in practice some computer-dependent invention are patentable while others were not.⁶⁵¹ Though the EPC and the Patents Act excludes the patenting of computer software, business methods or algorithms as such, it is possible to patent such inventions if they involve technical consideration or technical effect. It has been said for example that ‘in deciding if a method is a business method, consideration is given to whether the overall contribution is in a technological area.’⁶⁵² Hence this category is generally excluded from patentability if there is no substantial technical contribution made other than by the thing as such, although the difficulty lies in resolving the extent of the contribution.

The thesis will now turn to examine the approach to exclusions for computer programs as a particular illustration of this group with the objective of establishing the

⁶⁴⁶ Available at <http://grids.usc.indiana.edu>.

⁶⁴⁷ Christie A. and Syme S. (1998) ‘Patents for algorithms in Australia’, Sydney Law Review, available online at <http://www.austlii.edu.au/cgi-bin/disp.pl/au/journals/SydLRev/1998/23.html>

⁶⁴⁸ Cookson B.E. ‘Protecting mathematical innovation in the life sciences’ (2005) *IP and IT law*.

⁶⁴⁹ *Guidance for Industry: PAT - A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance: Pharmaceutical CGMPs* (September 2004) US. Department of Health and Human Services: Food and Drug Administration.

⁶⁵⁰ Christie/Syme, fn.647. *Slee & Harris' Application* [1966] RPC 194.

⁶⁵¹ At <http://www.patent.gov.uk/press/press-release/press-release-2006/press-release-20061027.htm>.

⁶⁵² ‘Can I patent business methods’ (2006) Available at http://www.intellectual-property.gov.uk/faq/patents/business_methods.htm.

features of the exclusion approach in the UK jurisdiction without reciting the law that specifically applies to the other subject matter within this group.

4.5 Exclusions approaches in particular to computer programs

Pharmaceutical activities significantly rely on computers, from the research tools used in the R&D stages to the production plants.⁶⁵³ New research tools and fields are continually developing, such as bioinformatics, which has a role to play in data storage, management and analysis in the quest to develop pharmaceuticals for unmet medical needs or more effective and safer ones using computational programs for *in silico* modelling and simulation of disease targets and biological systems.⁶⁵⁴ Execution of inventive pharmaceutical processes is reliant on computer or computer-implemented inventions.⁶⁵⁵

There is general agreement that an invention is excluded from patentability if it has no technical contribution. However, inventions are becoming increasingly highly integrated with the excluded matter such that the excluded subject matter may form complex matrix with aspects embodying the essential technical character of the invention. To add to the complexity of making the distinction, there is general confusion on what should be characterised as technical in patentability assessment.⁶⁵⁶

⁶⁵³ Computational technologies have been used by pharmaceutical firms, for example Wyeth, to shorten the R&D process and the scale-up and synthesis of new compounds: Potoski J. 'Timely synthetic support for medicinal chemists' (2005) *Drug Discovery Today*, p.1115-120, or Abbott, to generate, merge and coordinate molecular data from different pharmaceutical discovery sources early in the R&D process: Holzman T. And Hebert E. 'Transforming the work of early-stage drug discovery through bioprocess informatics' (2005) *Drug Discovery Today*, p.61-67.

⁶⁵⁴ Whittaker P.A. 'What is the relevance of bioinformatics to pharmacology?' (2003) *Trends in Pharmacological Sciences*, p.434-439.

⁶⁵⁵ Computational analysis for virtual molecules and use of information technology is considered an integral step in an affordable pharmaceutical discovery model: Scott W.L. and O'Donnell M.J. 'Distributed drug discovery: Linking academia and combinatorial chemistry to finding drug leads for the developing world diseases' (2009) *Journal of Combinatorial Chemistry*, p.3-13. Medicinal and computational chemists have been shown to use novel computer-aided design programs in their routine pharmaceutical discovery efforts: Ritchie T and McLay I 'Should medicinal chemists do molecular modelling?' (2012) *Drug Discovery Today*, doi:10.1016/j.drudis.2012.01.005. For example, computer-automated design of pharmaceutically-active compounds has been shown to yield innovative and patentable molecules although the software does not always produce exploitable results: Hartenfeller M, Zettl H, Walter M, Rupp M, Reisen F, et al. 'DOGS: Reaction-Driven de novo Design of Bioactive Compounds' (2012) *PLoS Computational Biology*, doi:10.1371/journal.pcbi.1002380.

⁶⁵⁶ Esteve A. 'Patent protection of computer-implemented inventions vis-à-vis open source software' (2006) *The Journal of World Intellectual Property*, p.276-300, p.279.

In addition, in the UK there is preference for the convergence of the assessment of excluded subject matter with that of the EPO but this has not been fully achieved.⁶⁵⁷ As such, in patentability assessment it has not always been clear as to how and when the evaluation of the excluded subject matter is to be made.

In the past the practice in the UK for making patentability decisions was to look first for ‘technical contribution’ by the alleged invention into the known art.⁶⁵⁸ If there was none the subject matter would be deemed not to be an invention. If it had some technical contribution, it was then assessed for obviousness.⁶⁵⁹ The ‘technical contribution’ test was the assessment of whether an invention adds something new to the stock of public knowledge.⁶⁶⁰ The technical contribution test emanates from *Vicom/Computer-related invention*.⁶⁶¹

In *Genentech Inc’s Patent*,⁶⁶² the Court of Appeal approved the reasoning of the Board of Appeal in *Vicom*. The Court of Appeal in *Merrill Lynch*,⁶⁶³ which also adopted the *Vicom* approach, making the ‘technical contribution’ approach part of UK precedent, had Fox LJ saying:

‘The position seems to me to be this. *Genentech* decides that the reasoning of Falconer J. is wrong. On the other hand, it seems to me to be clear, for the reasons indicated by Dillon L.J., that it cannot be permissible to patent an item excluded by section 1(2) under the guise of an item which contains that item – that is to say, in the case of a computer program, the patenting of a conventional computer containing that program. Something further is necessary. The nature of that addition is, I think, to be found in the *Vicom* case where it is stated: ‘Decisive is what technical contribution the invention makes

⁶⁵⁷ In *Symbian*, Court of Appeal, observed that the chequered history of the UK and EPO approaches to exclusions generally has not been fully resolved and showed willingness to depart from its previous line of authorities, but not in this case: generally Lundie-Smith R. ‘How much longer can *Aerotel/Macrossan* test survive? (2011) *Journal of Intellectual Property and Practice*, p.6-7 and Wilson D. and Sharp C. ‘Patents: patentability of computer programs’ (2009) *European Intellectual Property Review*, n.17-19.

⁶⁵⁸ *Fujitsu Ltd’s Application* [1997] RPC 608. The test used in the EPO at that time, developed in *Hitachi T258/03*, was only used as a cross-check to confirm that the UKIPO ‘technical contribution test was the right one: *Patent Office—Practice Note* [2006] RPC 6, para.3.

⁶⁵⁹ *CFPH*, para.44.

⁶⁶⁰ *CFPH*, para.70.

⁶⁶¹ (T208/84) [1987] E.P.O.R 74, para.16.

⁶⁶² [1989] RPC 147.

⁶⁶³ [1989] RPC 561, per Fox LJ, p.569.

to the known art'. There must, I think, be some technical advance on the prior art in the form of a new result (e.g., a substantial increase in processing speed as in *Vicom*).'

Since the UK decision in *Fujitsu*, the EPO shifted from its technical contribution approach to adopt the 'any hardware' approach.⁶⁶⁴ This approach departing from the technical contribution approach, developed from the EPO's jurisprudence so-called trio of cases.⁶⁶⁵ Assessment is made by asking whether the claim involves the use of physical hardware, however mundane, and if it does, Art.52(2) does not apply.⁶⁶⁶ One would first look for 'technical features' in the invention or the alleged invention.⁶⁶⁷ If it has none, it was rejected as not being an invention. The technical feature definition is said to be broader or more literal than the UKIPO practice in the sense of holding more subject matter as being technical.⁶⁶⁸ The assessment would then consider if it was old or obvious, ignoring everything that is not a technical feature. This in effect meant the UKIPO under its test considered excluded subject-matter initially while the EPO did so at the end of patentability analysis. According to Prescott,⁶⁶⁹ the UKIPO considered excluded matter under the novelty description, while the EPO did so under the inventive description.⁶⁷⁰ Nonetheless, since these approaches are based on the same legislation, they were expected to produce the same results when properly applied and the UK courts have sought to achieve this.

Prescott in *CFPH LLC's Patent Application* held that the EPO was correct in no longer using the 'technical contribution' test⁶⁷¹ with the suggestion that the UKIPO

⁶⁶⁴ *Aerotel*, para.26. Marsnik S. and Thomas R.E 'Drawing a line in the patent subject-matter sands: does Europe provide a solution to the software and business method patent problem' (2011) *Boston College International and Comparative Law Review*, p. 227-327, p.310.

⁶⁶⁵ *Pension Benefit Systems* (T931/95), *Hitachi* (2004) T258/03 and *Microsoft/Data Transfer* (2006) T424/03. Shemtov N. 'The characteristics of technical character and the ongoing saga in the EPO and the English courts' (2009) *Journal of Intellectual Property Law and Practice*, p.506-514, provides a detail review of the EPO case law relating to exclusion unpatentable subject matter.

⁶⁶⁶ *Aerotel*, para.26.

⁶⁶⁷ *CFPH*, para.45.

⁶⁶⁸ *CFPH*, para.45 and 87.

⁶⁶⁹ *CFPH*, para.46.

⁶⁷⁰ *Pension Benefit Systems Partnership* established that the technical contribution approach is to be used for assessing the inventive step.

⁶⁷¹ *CFPH*, para.94.

should follow such departure.⁶⁷² The first step of the formulated test under *CFPH* was to identify ‘what is the advance in the art that is said to be new and non-obvious (and susceptible of industrial application).’⁶⁷³ The second step is to consider whether the alleged invention is indeed an invention. In other words, the second step tests whether the invention is not of excluded subject matter under the description of an invention under EPC Art.52. According to the Examination Guidelines of the EPO, it is clear that the test of whether there is an invention within the meaning Art.52 (1) is separate and distinct from the question of whether it is new, inventive and susceptible of industrial application.⁶⁷⁴ Thus, Park⁶⁷⁵ asserted that the invention must satisfy the patentability requirements of newness, non-obviousness and industrial applicability after which it is established if it is a non-excluded invention under Art.52(2).

In *Research in Motion (UK) Ltd v Inpro Licensing SARL*,⁶⁷⁶ Pumfrey J approved this approach that in essence extracts the technical contribution of the invention to evaluate the degree of excluded subject-matter. He stated that ‘it is now settled...that the right approach to the exclusions can be stated as follows. Taking the claims correctly construed, what does the claimed invention contribute to the art outside of the excluded subject-matter.’⁶⁷⁷ In other words, as the Court of Appeal later observed in *Aerotel*, Pumfrey was ‘warning against saying “well the claim involves the use of a computer program so it must be excluded.”’

The Court of Appeal gave a more structured prescription on how to evaluate whether inventions are of patentable subject-matter in *Aerotel Ltd v Telco Holdings Ltd (and others)* and *Macrossan’s Application*⁶⁷⁸ (*Aerotel/Macrossan*). It is considered the ‘technical effect’ approach with a rider.⁶⁷⁹ Under the test, one asks whether the invention defined in the claim made a technical contribution to the known art, and if it

⁶⁷² There were suggestions that CFPH approach will have the effect of changing the practice in the UKPO and UK courts. <http://ipgeek.blogspot.com/2006/10/british-court-of-appeal-reviews.html>, but Kitchin J was not so convinced in *Crawford’s Application* [2005] EWHC 2417 (Pat), para.11.

⁶⁷³ *CFPH*, para.95.

⁶⁷⁴ Guidelines for Examination in the EPO, Part C, Chapter IV, patentability, EPO.

⁶⁷⁵ Generally, in Park J. ‘Has patentable subject matter been expanded? A comparative study on software patent practices in the European Patent Office, the United States Patent and Trademarks Office and the Japanese Patent Office’(2005) *International Journal of Law and Information Technology*, p.336-358.

⁶⁷⁶ [2006] EWHC 70 (Pat).

⁶⁷⁷ [2006] EWHC 70 (Pat), para.186.

⁶⁷⁸ [2006] EWCA Civ 1371.

⁶⁷⁹ *Aerotel*, para.26(2) and 38.

did Art.52(2) applied, with the rider that novel or inventive purely excluded subject matter did not count as technical contribution.

The Court laid out a structured way of patentable subject-matter evaluation, which the UKIPO was to immediately follow.⁶⁸⁰ It is considered a re-formulation of the order of the *Merrill Lynch* steps.⁶⁸¹ The test is made up of common four-steps to be followed for the different listed exclusions to patentability:⁶⁸²

1 Properly construe the claim.

2 Identify the actual contribution

3 Ask whether it falls solely within the excluded subject-matter

4 Check whether the actual or alleged contribution is actually technical in nature.

Of the first step, the court said ‘you first have to decide what the monopoly is before going onto the question of whether it is excluded.’⁶⁸³ Lord Mustill, in *Genentech Inc.’ Patent*⁶⁸⁴ emphasised the importance of making a patentability evaluation that is in line with the monopoly conferred on the patentee. Lord Hoffmann has emphasised that claims are the benchmarks for assessing whether the patentee deserves the monopoly.⁶⁸⁵

The assessment then moves onto making valuations of the contribution made by the invention: ‘The second step – identify the contribution - is said to be more problematical. How do you assess the contribution?...In the end the test must be what contribution has actually been made, not what the inventor says he has made.’⁶⁸⁶

⁶⁸⁰ <http://www.patent.gov.uk/press/press-release/press-release-2006/press-release-20061103.htm>.

⁶⁸¹ *Aerotel*, para.41; *Symbian*, para.30.

⁶⁸² *Aerotel*, para.40. In *HTC Europe Co Ltd v Apple Inc* [2013] EWCA Civ 451, para.44, the Court of Appeal said ‘it remains appropriate (though not strictly necessary) to follow this approach.

⁶⁸³ *Aerotel*, para.42.

⁶⁸⁴ [2003] RPC 203.

⁶⁸⁵ *Conor*, para.19, stating the patentee deserves that the patentability of their invention be judged according to their claim and not according ‘to some vague paraphrase based upon the extent of his disclosure in the description.’ Also, in *Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd.* [2004] UKHL 46, para.18-21.

⁶⁸⁶ *Aerotel*, para.43.

The courts have emphasised the ultimate objective of the whole analysis: ‘what has the applicant really added to human knowledge?’⁶⁸⁷ Confirming that the disclosure of a racemate does not amount to the disclosure of its enantiomers, the court in *Generics (UK) Limited and others v H Lundbeck A/S*,⁶⁸⁸ said that in conceptualizing subject matter as an invention, it is not enough to determine that it contributes to the art, but must do so sufficiently to justify a patent. Part of the justification of the patentability standard lies in encouraging inventors disclosing to the public new knowledge that advances the state of the art. This, as asserted in chapter two, must feature in patentability assessment to ensure a method that achieves the purposes of the patent system.

Thirdly, the analysis then seeks to discern whether the essence of added knowledge is in excluded subject matter. ‘The third step– is the contribution solely of excluded matter? – is merely an expression of the “as such” qualification of Art.52(3).’⁶⁸⁹ Fox LJ said in *Oneida Indian Nation's Application*,⁶⁹⁰ ‘even if there was a technical contribution, if the result was still within an exclusion then that is the end of it.’ Jacob LJ put it this way in *Aerotel* ‘the “technical contribution” theory was adopted by this court but with the important rider that inventive excluded matter could not count as a technical contribution.’⁶⁹¹

The fourth step seeks to confirm that the contribution is indeed technical. It was thought that the fourth step of checking whether the contribution is ‘technical’ may not be necessary because the third step should have covered this.⁶⁹² The High Court, for instance, said in *IGT / Acres Gaming Inc, Re*,⁶⁹³ ‘the fourth or last step is just a cross-check, because “technical” is too vague a test to be used on its own.’ Nonetheless, it is a necessary check under the proper test. The court, in *Symbian*,

⁶⁸⁷ *IGT Application* [2007] EWHC 1341 (Ch), para.22. Kitchen J. ‘How much for how little’ (2009) *Chartered Institute of Patent Agents Journal*, p.522-527 asserting that for pharmaceutical patents the claims must reflect the actual advances made by the inventors and Pila, fn.612, claiming that the contribution to the art is the invention and therefore the need to define an invention in a way that recognizes the invention as the manifestation of different human inventive activities and seeking to reward contributions to the industrial arts.

⁶⁸⁸ [2009] RPC 13.

⁶⁸⁹ *Aerotel*, para.45.

⁶⁹⁰ [2007] EWHC 0954 (Pat) para.10.

⁶⁹¹ *Aerotel*, 85.

⁶⁹² *Astron Clinica Ltd v Comptroller-General* [2008] RPC. 14, para.49, Kitchin J. was of this view.

⁶⁹³ [2008] EWHC 568 (Pat), para.20.

emphasised that this step is not optional as the UKIPO had tended to do with applications for patents.⁶⁹⁴

Although the test in *Aerotel/Macrossan* clarified the appropriate practical exclusion approach, there are still some issues that have been hard to settle. Overall, the approach by the UK domestic courts is said to be consistent.⁶⁹⁵ There are others who are not convinced.⁶⁹⁶ Some have gone further and suggested that the UK courts have failed to apply Art.52 in good faith.⁶⁹⁷ The TBA in *Duns Licensing Associates/Estimating sales activity*⁶⁹⁸ was of the view that the approach in the UK is different from the EPO approach because there was confusion between the legal concept of invention as used by the EPO and the ordinary meaning of invention which is used in *Aerotel/Macrossan*.

Furthermore, there is still some divide perceived between the domestic and EPO approach to exclusions, suggesting that optimal patentability standards may not yet have been attained.⁶⁹⁹ The EPO exclusions approach has been considered by the courts to be the inappropriate one.⁷⁰⁰ The Patents Court in *Halliburton's Applications* did not accept the argument that it should abandon the *Aerotel/Macrossan* approach as it differed from the EPO approach and follow the EPO.⁷⁰¹ Birss J, detecting 'a familiar and illegitimate submission which has been made before by those who argue that the EPO's approach should be followed...' said the 'EPO's approach when applied as a whole and correctly' should be similar to the UK and 'difficulties perceived in the UK with the way the EPO approaches computer implemented inventions are genuine jurisdictional concerns of a respectful nature.'⁷⁰² The decisions

⁶⁹⁴ *Symbian*, para.8.

⁶⁹⁵ Feros A. 'A comprehensive analysis of the approach to patentable subject matter in the UK and EPO' (2010) *Journal of Intellectual Property and Practice*, p.577-594.

⁶⁹⁶ Pila J. *The requirement for an invention in patent law* (2010) Oxford: Oxford University Press, p.334. Ballardini R.M. 'Software patents in Europe: The technical requirement dilemma' (2008) *Journal of Intellectual Property and Practice*, p.563-575.

⁶⁹⁷ *Decision T0154/04, Duns Licensing Associates*, 15 November 2006, Board of Appeal, EPO, para.12.

⁶⁹⁸ (T154/04) (Unreported, October 1, 2007) (EPO (Technical Bd App)).

⁶⁹⁹ For instance, Patentability of computer software case G3/08.

⁷⁰⁰ *Cappellini's Application/Bloomberg LLP's Application* [2007] EWHC 476 (Pat), para.9, Pumfrey J applying *Aerotel*, said whilst he was in agreement with the result, he was of the view that the EPO reasoning was incorrect.

⁷⁰¹ [2011] EWHC 2508(Pat), para.4.

⁷⁰² *Halliburton Energy Services Inc's Patent Applications* [2011] EWHC 2508 (Pat), para.4 and 79.

of the EPO are persuasive but not binding authority,⁷⁰³ although the Court of Appeals could depart from its previous decision if it is of the opinion that the EPO has formed as settled view that differs from one arrived at in a previous UK decision, but is not obliged to do so if it is of the view that the jurisprudence was plainly unsatisfactory.⁷⁰⁴ In *Halliburton's Applications*,⁷⁰⁵ the court observed without deciding, whether the question of the EPO approach is a consistent and settled one, saying the precedent in *Aerotel/Macrossan* was binding on UK courts and that the apparent difference with the EPO approach was that the EPO approach goes together with a special approach to inventive step. It is therefore likely that the UK courts would continue following the *Aerotel/Macrossan* approach as the EPO approach is not considered settled so as to be followed.⁷⁰⁶

It is submitted that the adoption by the UKIPO of the exclusion approach identical to that which will be used by the courts imparts certainty in high technology fields engaged in inventive activities. It is helpful that the tests applied by the patent office and courts consistently result to the same outcome. In addition, this brings closer the idea of uniform standards and practice throughout the region such that research output could be subjected to the same practical exclusion rules. It is logical to have an identical law interpreted in an identical way, especially starting at the examinations stages in the patent offices.

South Africa

4.6 Definition of patentable inventions and excluded subject matter

It has already been shown that patent law in South Africa was historically developed from British influences. With the advent of partially harmonised European patent law, the practice continued, with South Africa receiving influence from the European laws. This was through the adaptation and use of the EPC in promulgating the current 1978

⁷⁰³ *Genentech's Patent* [1989] R.P.C. 147.

⁷⁰⁴ *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444. Also, *Human Genome Sciences Inc v Eli Lilly and Company* [2011] UKSC 5, para.87 decided, *inter alia*, that 'while national courts should normally follow established jurisprudence of the EPO, that does not mean we should regard each reasoning of the Board as effectively binding on us.'

⁷⁰⁵ [2011] EWHC 2508 (Pat), para.79.

⁷⁰⁶ *Ibid*, para.79(iii) and (v). Also, *HGS*, para.87.

Patents Act as seen in chapter two and three. Despite similarities that would be expected, there are differences in the domestic statutes of the two jurisdictions under study.

Patents Act 1978, s.25(1) begins with positively defining a patentable invention as one that is new, and involving an inventive step and capable of being used or applied in trade or industry or agriculture. This means that to be patentable an invention has to meet these three conditions of patentability as is the case in the UK.

The statutory definition of a patentable invention, like the UK statute, is neutral on whether subject matter should first be judged as an invention before satisfying the prescribed patentability conditions or it simply has to meet the prescribed conditions. There has been no case to provide guidance as to which approach should be taken in South Africa. In the UK this was partially resolved in case law and also by reference to the EPC as the founding instrument as was seen in the previous section.

Under the South African 1978 Patents Act s.25(2), as in the UK statute, the definition of an invention makes reference to subject matter that is expressly excluded from what is considered a patentable invention. This exclusion is directed to subject matter 'as such' according to s.25(3). That is to say that the exclusion is made on a similar ground as in the UK where the invention is excluded only to the extent that it relates to the subject matter as such.

The definition of a patentable invention makes reference to what is excluded from the definition of an invention for the purposes of the Act by listing the subject matter in section 25(2). What is noteworthy is that the list has no indication of whether it is exhaustive or not as the UK counterpart which is non-exhaustive. This section will now discuss the listed exclusions in the groupings that were used for discussing the UK exclusions.

4.7 Excluded Items

The Patents Act 1978 makes a list of excluded items from patentability. There is a qualification for these exclusions, which is similar to the one in the UK statute. Section 25(3) provides that the exclusion is made ‘only to the extent to which a patent or an application relates to that thing ‘as such’’. Inventions possessing these items in and of themselves are unpatentable, but could be patentable to the extent of embodying other allowed subject matter.

The most common criterion amongst these exclusions is their abstract or mental nature, which is the position in the UK. Taking this reasoning further, commentators have stated that the exclusions are based on the doctrine of ‘mental steps’ which states that *res communes* mental processes will not exclude from patentability an apparatus whose subject matter results to an identical method or process as one that can be carried out by the human brain.⁷⁰⁷ Therefore, even if the subject matter of some inventions may seem to be in the excluded categories, the inventions may not merely be considered unpatentable on the basis of physically carrying out an identical abstract or mental function.

4.7.1 Discoveries and scientific theories

The Patents Act s.25(2) provides that discoveries and scientific theories are not patentable. It is often difficult to differentiate between the discovery or theory and the method of applying it, but the South African courts have addressed this. For example, in *Hay v African Gold Recovery Co*⁷⁰⁸ it was established that:

‘chemical affinity is, however, a law of nature, which... can no more be patented than the law of gravity. If the matter rested there, there would be nothing more to say about it. But when a natural principle or chemical law is applied in a novel way to some practical and useful purpose, the process by which it is done may well be patented. That is beyond all question.’

⁷⁰⁷ Burrell, p.38.

⁷⁰⁸ (1896) 3 OR 244, p.260.

That would be to say that to receive a patent, one has to generally physically change something in a new and unobvious manner.⁷⁰⁹ In other words, there has to be some transformation of the physical world through the discovery or theory. This is a similar principle to the UK exclusion of discoveries and theories from patentability in which the application of the discovery or theory is patentable.

What is perhaps debatable is how a substance occurring naturally in the body or in nature and subsequently characterised would be treated in South Africa. In the UK, since the coming into effect of the current patent statute there has been some impact on the principle of excluding discoveries through the influence of the Biotechnology Directive and domestic case law development that takes into consideration external judgments of the EPO. In the EPO Manual⁷¹⁰ for instance, it is stated that:

‘To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect.’

Authors express some unease with the patenting of naturally occurring biological compounds regardless of the novelty of the process that isolates the naturally occurring material in view of the fact that the material has always existed.⁷¹¹ It is unclear as to what extent this principle would be embraced in South Africa. South Africa has no external obligations on how it should interpret exclusions as the UK has had to do through the subsequent coming into effect of the Biotechnology Directive. Persuasive influence could be gained from a recent US Supreme Court, holding that merely isolating genes that are found in nature does not make them patentable.⁷¹² However, a broad impact of the decision is uncertain as the court was specific and

⁷⁰⁹ Kuhn J.M. ‘Patentable subject matter matters: New uses for an old doctrine’ (2007) *Berkeley Technology Law Journal*, p.89-114, p.89.

⁷¹⁰ Examination Guidelines, Section 3.2.1.

⁷¹¹ Crowne-Mohammed, fn.565, p.469.

⁷¹² *Association for Molecular Pathology v Myriad Genetics*, 569 U.S. 12-398 (2013).

clear in narrowing down its opinion and setting out what is not implicated by the decision.⁷¹³

South Africa seems to have a domestic policy that shows less recognition of the technical contribution of inventions that relate to isolation and characterisation of natural products.⁷¹⁴ This, it seems, is intended to ensure that natural products found in this region are not easily patented by virtue of being scientifically replicated or isolated.⁷¹⁵ Such a view is reinforced by the fact that South Africa promulgated the Patents Amendment Acts of 2005 requiring a declaration for all domestic patent applications that the inventions are not derived from naturally occurring resources in South Africa. A view that has been expressed has been that the South African government does not seem to be focusing on exploitation, but rather on preservation of South African resources.⁷¹⁶ The effect of this position is yet to be seen as there are concerns that this prevents the patenting of pharmaceutically active compounds resembling or derived from those that are natural in South Africa. This is to say that pharmaceutical companies may have less interest in engaging in research that may fall within the scope of natural products found in South Africa if the perception is that the technical input in isolation or characterisation pharmaceutical compounds will not be recognised under patent protection. Indeed, Dutfield warning on the need to strike a balance amongst the stakeholders in pharmaceutical discovery, states that natural products research is relevant to pharmaceutical discovery, although it only forms a part in a wide array of available options for discovery.⁷¹⁷

⁷¹³ *Ibid*, part III, specifying that the decision was not about method claims, or new applications of known knowledge and was not an enquiry about naturally occurring compounds that have been scientifically altered.

⁷¹⁴ Authors point out that although there is promise in nature-derived pharmaceutical products, there is limited support from the South African government for R&D: Rybicki, fn.36.

⁷¹⁵ Harms viewed the intentions of the Draft Intellectual Property Bill of 2009 as laudable in protecting South African natural resources and traditional knowledge, but lamented this protection being superimposed onto IP regimes as it would prevent South Africa's increase in technological capacity through innovation. Harms, fn.504, p.544; Previously, there was the view that South African resources are inappropriately manipulated, especially by foreigners: Visser C. 'Biodiversity, bioprospecting, biopiracy: A prior informed consent requirement (2006) *South African Mercantile Law*, p.497-507.

⁷¹⁶ Dean O., 'Move to reinvigorate IP law' (2011) *De Rebus*, p.10: Also at http://www.commercial-property.co.za/2706_news_Intellectual-Bill-An-Abomination.html. Straus asserts that such measures by government preventing patent protection for such resources, 'stand in clear contradiction to their own argument' of harnessing innovation for economic growth: Straus, fn.281.

⁷¹⁷ Dutfield G., 'A critical analysis of the debate on traditional knowledge, drug discovery and patent-based biopiracy' (2011) *European Intellectual Property Review*, p.238-244, p.241.

4.7.2 Computer and computer-related inventions

The patentability exclusions for computer program and computer-related inventions are similar in the South African statute as in the UK. Computer programs are excluded from patentable by Patents Act s.25(2)(f). Section 25(2)(g) prescribes the exclusion of presentation of information from patentability. Section 25(2)(e) excludes from patentability schemes, rules or methods of doing business. South African commentators have questioned why this should be so. Burrell for instance, contrasting the current position with the position in the former Patents Act, which had no provision expressly precluding these categories, opines that ‘there seems to be no good theoretical reason why such a scheme, rule or method should not be patentable under the current law.’⁷¹⁸

According to commentators, the fundamentals of the UK and South African approaches to the exclusion of computer programs are considered similar.⁷¹⁹ ‘A claim to a computer characterised by having a particular program stored in its memory or to a process for operating a computer is patentable and would not be regarded as a claim to the program *per se*.’⁷²⁰ This, according to Burrell, is not defeated by the ‘clever claim-drafting’ that would seek to disguise the invention as composed of non-excluded subject matter.⁷²¹ This means in exclusions evaluation, substance over form is also important in South Africa and the exclusion decision is not merely made on the basis that the invention contains a computer program.

In South Africa, it is not clear whether the exclusion of computer-related subject-matter utilises an approach based on the so-called ‘technical contribution’ or ‘technical effect’ methods as was the question that has been addressed by the UK courts. As shown above, the UK approach initially used the technical contribution test and there has been a gradual change converging with the EPO approach, albeit a

⁷¹⁸ Burrell Thesis, p.36.

⁷¹⁹ *Ibid*, p.38.

⁷²⁰ *Ibid*, p.32.

⁷²¹ *Ibid*, p.32.

difficult convergence.⁷²² This is particularly evident in the area of computer programs. In South Africa, the nature of the decisive requisite contribution has not been analysed by the courts.

4.8 Exclusions approaches in particular to computer programs

As alluded to above, in South Africa, the courts have not had the opportunity to offer detailed guidance on how the approach to the exclusion of computer programs ‘as such’ should be carried out. This may also be one aspect which highlights the lack of substantive patent application examination as proving problematic as it leads to less guidance on the patentability requirements. Patents for computer programs or computer-implemented inventions have been issued in South Africa, but not many have been contested. In *Murray v Vodacom (pty) Ltd*,⁷²³ the plaintiff sued for infringement of a patent for a computer-implemented invention and the defendant counterclaimed, *inter alia*, that the invention of the patent was not patentable on the ground of consisting a scheme, rule or method of performing a mental act or business according to section 25(2)(e), but this challenge on excluded subject matter was not pursued during trial.

The need to clarify the position on how the actual exclusions would be carried out in South African courts is perhaps evident. This inadequacy seems to be a contribution from multiple sources. Dean argues that IP practitioners are not doing enough to improve the law by bringing arguable case before the courts.⁷²⁴ Justice Harms states that there has been lack of movement in improving the law to keep up with technology development on the part of the legislature.⁷²⁵ There is generally lack of

⁷²² Shemtov N. ‘The characteristics of technical character and the ongoing saga in the EPO and the English courts (2009) *Journal of Intellectual Property Law & Practice*, p.506-514. De Mauny C. ‘Court of Appeal clarifies patenting of computer programs’ (2009) *European Intellectual Property Review*, p.147-151, asserts that the decision in *Symbian* was a move seeking compromise with the EPO position.

⁷²³ [2008] ZACCP 1.

⁷²⁴ Dean, fn.716.

⁷²⁵ *Ibid.*

significant discussion on how patents would be assessed in court for patentability, although there are indications that this may change.⁷²⁶

Such discussions are useful in bringing up the legal issues that are important and would have to be addressed for South African industries to be competitive in global economies where computers are central to most activities. It seems a more meaningful debate would be to clearly formulate the extent South African policy allows the patenting of computer related inventions rather than viewing computer-related patents as totalling unacceptable without due regard to the fact that all competitive industry relies on computers.⁷²⁷ Legal scholars attribute the misconception by policy makers that computer-related inventions are not patentable, to the overlooking of the fact that section 25(3) precludes only what could be called 'pure' software.⁷²⁸ Whatever line of research is chosen by pharmaceutical firms or research firms generally, there are vast amounts of information that needs to be processed and analysed. The primary efficient tools used in R&D have been shown to be computers in various embodiments or applications. It seems, therefore, a clear policy decision would be helpful as currently there are conflicting assertions by the different agencies of government on the extent of the 'as such' exclusion for computer-related inventions.

United Kingdom and South Africa

4.9 Discussion of the general principle to patentability exclusion of subject matter in the UK and South Africa

The general statutory exclusions of subject matter from patentability in South Africa and the UK are comparatively similar. The UK law is based on the EPC, but there have been some differences in domestic interpretation of exclusions compared to EPO or EPC Contracting States with which the courts have expressed preference for

⁷²⁶ *Ibid*, South African Intellectual Property Institute president, making a speech that the institute of patent attorneys will play a more active role in reforming patent law.

⁷²⁷ "SA minister slams software patents": Public Service and Administration minister quoted as saying there's no reason to believe that society benefits from [patent] monopolies being granted for computer programs', <http://tectonic.co.za/?p=2304>.

⁷²⁸ de Villiers C. and Tshaya T. 'Software and business method patents' (2008) *Journal of Information Law and Technology*: http://go.warwick.ac.uk/jilt/2008_2/devilliersandtshaya.

convergence. Although, as Nicholls LJ observed, ‘it would be absurd if, on an issue of patentability, a patent application should suffer a different fate according to whether it was made in the United Kingdom under the Act or was made in Munich for a European patent under the Convention’,⁷²⁹ it is unsurprising that there is less than perfect harmony in interpretation of the statute between the UK and its counterparts in Europe.

At first glance, the South African law is similar to the UK. It is mainly due to the fact that, historically, UK statutes was used in drafting South African law and the current law is based on the EPC. It is unsurprising that there would be some difference between the UK law and South Africa given that it is not bound by the European laws as the UK. South Africa has a domestic statutory patent instrument in which it seeks to give its own interpretation, which may not exactly be synchronous with the objectives of the founding instrument or *travaux préparatoires* which has been gaining popularity as a tool to interpret UK domestic law.⁷³⁰ The South African Patents Act remains a South African statute in all other respects.⁷³¹ As such, it has to be applied and interpreted in view of the prevailing Constitutional order and compatible with other applicable domestic laws. The approach to patentability exclusions must reflect the policy considerations unique to South Africa.

The main exclusion examined in this chapter centred on the use of the phrase ‘as such’ and whether the alleged invention embodies the excluded categories ‘as such’. Making excluded subject matter comparisons with other major patenting jurisdictions, some authors advocate for an approach to the ‘as such’ exclusions that is similar to the UK, stating that ‘the UK courts appear more willing to construe these exclusions strictly and narrowly, in furtherance of the goals of the patent system itself. I suggest that this is the approach that all courts should take in assessing the patentability of an ‘invention’; since broad categorical exclusions of patentable subject matter by the courts defeat the underlying purposes of the patent system by foreclosing entire avenues of progress *ab initio*.’⁷³² It is unclear whether the South African courts would

⁷²⁹ *Gale’s Application* [1991] RPC 305, p.323.

⁷³⁰ *Pila* fn.550, p.110.

⁷³¹ See *Khan’s Chemical Industry cc v Unilever plc* SAPJ June 2004 206 (RTM) 213.

⁷³² *Crowne-Mohammed*, fn.565, p.463-464. Also in *Astron Clinica Ltd & Ors v The Comptroller General of Patents, Designs and Trade Marks* [2008] EWHC 85 (Pat), para.24, the court rejected the

adopt a similar approach as the UK courts, although it could be expected that, to some degree, it would do so in view the commonality of the origins of the statutes.

Despite policy differences that the respective domestic mandates may dictate, the statutory exclusions are seemingly directed towards similar ends for both jurisdictions. It could be said that for both countries the exclusions are ‘of particular interest because it is a statutory codification of certain a priori ‘truths’ or ‘skill’ that seem inappropriate to protect through a patent monopoly.’⁷³³ However if the right balance is not struck in structuring this patentability limb to exclude subject matter considered undesirable for protection, there is the risk that the patent may not attain its purposes of preventing the monopolisation of public goods.

There are significant differences, however, on how the evaluation is carried out. Patents Act 1977, s.1(5) provides some pre-emptive mechanisms of allowing some review and appropriate addition to the exclusions to patentability for domestic industry to remain competitive in globalised world or at least the recognition that the need may arise as technology changes: ‘The Secretary of State may by order vary the provisions of subsection (2) above for the purpose of maintaining them in conformity with developments in science and technology.’⁷³⁴ On the other hand, in South Africa there seems to be no considered policy mechanism for reviewing and keeping the exclusions compatible with technology development and the statute has no such mechanism. The lack of preparedness to keep up with technology has been lamented by members of the judiciary, stating extra-judiciary, that government has the perception that IP was for rich countries and views the patent system with some disdain.⁷³⁵

A phrase that is present in the UK statute but not in the South African one is the ‘amongst other things’ phrase when listing the excluded categories. This turns out to

suggestion that it takes a wide view to the exclusion of computer programs and in *Re Halliburton Energy Services Inc* [2011] EWHC 2508 (Pat), at para.57 the court was in favour of a narrow view to mental exclusion in this case that involved the computer simulation of drill bits.

⁷³³ Crowne-Mohammed, fn.565, p.464.

⁷³⁴ The provision to advance patentability exclusions with changing technology has never been used in the UK and the feasibility of its use is unclear given the obligations to the EPC. The EPC does not have such a provision, but it was acknowledged that the extent of the patentability exclusions can change with times and technology in *Programs for Computers* (G3/08) [2010] EPOR 36, para.7.3.3.

⁷³⁵ <http://afro-ip.blogspot.com/2011/09/stellenbosch-ip-conference-part-4.html>.

be only a difference in the statutes, but practically mean the same. In South Africa there could, and indeed there is no suggestion that there are other additional categories that exist but are not explicitly expressed in the subject matter excluded from patentability. This was a suggestion in the UK, but the courts dismissed it in *Chiron Corp v Organon Teknika Ltd*,⁷³⁶ stating:

‘[W]e do not consider that the words ‘(among other things)’ open up a new range of objections to the conclusion that something new is an invention. Rather it is a recognition that that sub-section is not exhaustive and has therefore not changed the law any further than the subsection itself expressly provides. It seems to us that any other conclusion would be inconsistent with the different emphasis apparent in the EPC.’

The non-exhaustive nature of exclusions listing is dependent on the existence of the power to introduce further categories by the UK Secretary of State if need be, but has never been used therefore the categories are still similar to those statutorily provided for in South Africa.

The interpretation of the statutes shows some dissimilarity when viewed in the context of the respective patenting policies in the two jurisdictions. The interpretation of some of the exclusions in the UK is influenced by subsequent Directives. For example, the Biotechnology Directive plays a role in the interpretation of the patentability of natural products isolated or used in pharmaceuticals. The draft EU Software Patents Directive, which sought to harmonise laws relating to software, but rejected by the European Parliament, would have altered the way the statutory interpretation of the exclusions relating to software implemented inventions are interpreted. On the other hand, in South Africa which has no such dynamic obligations, the judiciary has lamented the stagnancy of the patent law in keeping with technology development and the issues that may arise therein which the legislature is seemingly resistant to modify.⁷³⁷

In some respects, the influence of the TRIPS Agreement would be expected to bring a convergence into the interpretation of domestic law on unpatentable subject matter.

⁷³⁶ [1996] RPC 535, p.606.

⁷³⁷ Dean, fn.683, quoting Harms in a lecture entitled ‘The ossification of IP law’ stating that IP law ‘is not adapting at a rate appropriate for economic growth’ in the era of technology driven economies.

However, it tends to be of less effect in the sense that the TRIPS Agreement allows a wide discretion for member states on what could be excluded from patentability and the interpretation to be attached to this patentability limb.⁷³⁸ South Africa seems to take a conservative approach to what can be patented.⁷³⁹ Public policy is emphasised as the overriding factor to what should be unpatentable, demonstrated for instance in the occasions where the state grants more authority to the Registrar of Patents to invalidate patents.⁷⁴⁰ This is public policy somewhat different to that where ‘knowledge and technology development can be viewed as public goods generated through the recognition and enforcement of private patent rights, provided that the invention is published in a public registry and the rights are limited in scope and time.’⁷⁴¹ The UK courts prescribe a balanced approach in making the ‘as such’ exclusions.⁷⁴²

The use of the phrase ‘as such’ seem to be central to the operation of the exclusions in both the UK and South African statutes and is used to prevent the patenting of the categories scrutinised in this chapter on the ground that they generally lack technical contribution, technical result or technical effect. The UK courts have applied numerous tests in assessing excluded subject matter for this technical aspect as seen above. The case law of excluded subject matter in South Africa is limited compared to the other limbs of patentability and also to the UK, with reported cases showing absence of guidance on excluded subject matter. Authors have suggested that the patentability system of other jurisdictions, imitating the general approach of the UK, could concentrate on the other limbs of patentability, making those limbs more robust

⁷³⁸ Chandiramani N. ‘The legal factors in TRIPS’ (2002) *Economic and Political Weekly*, p.200-203, at p.202. Compared to the TRIPS Agreement, the Draft SPLT provided only for a few categories to be excluded from patentability.

⁷³⁹ Government disregarded protestations to the Bill to protect traditional knowledge under IP rules which has been lamented by practitioners, academics and judges as encroaching on what could be patented in South Africa and destined to ‘change IP law as we know it’, according to Harms: Dean, fn.683, ‘The ossification of IP law’ (2011) *De Rebus*, p.10.

⁷⁴⁰ The Patents Amendment Act of 2005 provided the Registrar with power to invalidate patents where patentee ought to have known they were derived from South African resources; Justice Harms’ view being that this is arbitrary and gives the registrar the unfettered power to determine what extent is the derivation: Harms, fn.504, p.546. Dutfield has pointed out that typical new pharmaceuticals could be said to have a long history of derivation from natural compounds, Dutfield G., ‘A critical analysis of the debate on traditional knowledge, drug discovery and patent-based biopiracy’ (2011) *European Intellectual Property Review*, p.238-244, at p.241. Therefore, effectively the South African government foreclosed a class of substances that could be patented.

⁷⁴¹ Shaffer, fn.567, p.461.

⁷⁴² *Aerotel*, para.9, per Jacob LJ.

as they could be easily offset by broad exclusion of subject matter.⁷⁴³ In South Africa, because of the lack of patent application examination and little challenge on granted patents, this suggestion would be of limited impact. Nonetheless, for those cases that ultimately reach the courts, there is no reason why the suggestion to interpret exclusions narrowly or in a more balanced fashion and developing more robust tests for novelty and obviousness, would not be beneficial.⁷⁴⁴

The UK seems to be proactive in keeping the law on exclusions up-to-date with technology. An example would be the issuance of practice manuals *inter alia* on the excluded subject matter, that seek to adapt to technology development, practice notices in reaction to court decisions and also having a law in place with a mechanism that allows the expansion of exclusions to be made at the discretion of the Secretary of State, although this option has never been exercised. With regard to this, in South Africa there has not been a reform of the law to keep up with technology.⁷⁴⁵ Even though the South African judges have once observed ‘that it is against public interest that persons with inventive minds should be discouraged from giving the result of their efforts to the public in exchange for the grant of a patent’,⁷⁴⁶ there is an absence of a mechanism that monitors whether the balance is attained or a recalibration is needed in the balance between the public and private interest in patentability exclusions made as technology develops. A practice manual is recommended to compensate for these shortfalls.

4.10 Conclusion

Defining what an invention is difficult. Its conceptualization takes influence from diverse stakeholder, as shown in the chapter, with each imposing its own understanding of the meaning of an invention. A recommendation is made that the meaning must be reduced to and aligned with its legal attributes. This would reduce some of the confusion of how courts would ultimately interpret the invention to be.

⁷⁴³ Crowne-Mohammed, fn.565, p.485.

⁷⁴⁴ Some authors emphasize that the patent office is the best place in applying and refining patentable subject matter applicable within a jurisdiction: Golden J.M. ‘Patentable subject matter and institutional choice’ (2011) *Texas Law Review*, p.1041-1111, at p.1075.

⁷⁴⁵ Harms, fn.504.

⁷⁴⁶ *Miller v. Boxes & Shooks (Pty.), Ltd.*, 1945 A.D 561, p.578.

In defining a patentable invention the statutes of both jurisdictions define what is excluded from the definition of a patentable invention. The negative defining of an invention by exclusion is generally centred and directed to assessment of the subject matter that is considered to be the core of the technical contribution, character or feature of the invention. The difficulty in evaluating the technical contribution, aspects or features of the invention lies in the fact that sometimes the technical aspects or features of the invention are not easy to resolve as they are sometimes made up of patentable subject matter and excluded subject matter. Recent UK case law has provided a structured sequence of steps to follow in identifying if an invention is patentable or not under the rule of not consisting of excluded subject matter. Some doubt remains on whether consistency has been achieved when compared with EPO jurisprudence. South Africa on the other hand has not, for some of the excluded categories, addressed the question of the exclusion analysis where patentable inventions are integrated with unpatentable subject matter.

The UK and South Africa have similar statutory exclusions from patentability. There are debates on the items that constitute the exclusion list, with computer programs as such, being the most debated. It is concluded that the critical aspect of the discourse on unpatentable subject matter lies in how the exclusions are actually interpreted in court and that determines if the policy reasons for making the exclusions in the first place are attained. Although the debate on what should be excluded by express statutory listing is likely to remain, the UK seems settled on the categories and how to approach inventions integrated with patentable and unpatentable subject matter. With regards to the South African approach to exclusions, it is noted that there has not been significant application of the methodology in practice and as a result there is some uncertainty as to the position that the courts would take in practice, even though the exclusions are based on the EPC as the UK laws. A recommendation is made of the need to have an express statement of the policy for the exclusions. This could be the foundation of the development of a guideline informing how the contentious exclusions should be approached.

CHAPTER 5

NOVELTY

5.1 Introduction

The novelty of an invention is the cornerstone of the patent system. In chapter two it was established that the patent is premised on advancing the state of the art. This is achieved both if the inventor is encouraged to engage in inventive activities and if there is encouragement for the divulging of that new knowledge to the public for the progression of science. In essence therefore, the patent is pivoted on the resultant making available of new knowledge.⁷⁴⁷

International legal instruments prescribe that member states must have legal mechanisms that protect new inventions, as seen in chapter three. The domestic statutes of the respective jurisdictions prescribe that newness is a quality that must be present in that knowledge that is granted protection. However, assessing whether or not an invention is sufficiently novel is difficult because newness is a binary decision; either something is new or not and yet there is often close resemblance between the old and the new. The legislatures in both jurisdictions provided for qualitative benchmarks for judging novelty. Nonetheless, besides the qualitative assessment that the courts have to carry out as prescribed in the statutes, there is a need to quantify that newness to establish if it meets the statutory benchmark.⁷⁴⁸ It then becomes an issue of evaluating the extent of the newness of that disclosed knowledge as compared to the state of the art in order to make the binary decision.

The long history in the case law of the UK and South Africa has on some occasions shown difficulties in achieving the right balance of what constitutes newness or how it should be assessed.⁷⁴⁹ Contemporary, the UK case *Synthon v SmithKline Beecham*

⁷⁴⁷ Bently/Sherman, fn.265, p.471-472.

⁷⁴⁸ Burrell, p.214.

⁷⁴⁹ Van Der Merwe A. 'The significance of "matter which has been made available to the public" in the assessment of the novelty and inventiveness of a claimed invention' (1995) *South African Mercantile Law Journal*, p.37-45.

*Plc*⁷⁵⁰ epitomises some of the difficulties in the test of what is adequate for novelty in the innovation race in the pharmaceutical field. It is of concern that the Court of Appeal got novelty assessment wrong such that the Supreme Court had to reaffirm the foundation of how newness is to be judged,⁷⁵¹ yet it is a patentability limb that has been part of the system for a long time. It has also been asserted by commentators that in South Africa there could be improvement in the understanding of the concept.⁷⁵² The wider and underlying question that then arises is whether it would really be expected of inventors, whose viewpoint is adopted in this thesis, to know how newness is to be judged from a legal perspective when the senior courts themselves sometimes seem to be unclear on the concept. In both jurisdictions it is critical, therefore, to translate the novelty requirement as legislators intended into a feasible mechanism of practical application of that statutory intent on the required novelty threshold.

The implication of the outcome of the *Synthon* case, which will be explored in more detail below, is more than that newness as a requirement to patentability is to be reassessed and properly understood. The material facts of the case also show how a seemingly straightforward legal principle can give odd results.⁷⁵³ In South Africa, especially, where there is more effort to promote local pharmaceutical ingenuity and production⁷⁵⁴ and transition to research based output,⁷⁵⁵ such seemingly illogical results raise the question, in industry, of the continued relevance and reliability of the novelty criteria as a driver of the development of new pharmaceuticals, especially in light of assertions that they ‘have never been indispensable.’⁷⁵⁶ At face value, it would be difficult to fault industry if there is the perception that the system allows earlier patentees to patent what the scientists do not yet fully know or understand. Such a state of affairs is contrary to the tenets of patents in encouraging novel research output. The policy-makers and the public at large have to remain convinced

⁷⁵⁰ *Synthon BV v SmithKline Beecham Plc* (No.2) [2005] UKHL 59.

⁷⁵¹ With regard to the Court of Appeal reasoning, Lord Hoffman, para.54, stated that ‘[t]his passage again suggests to me serious confusion’ in the application of novelty rules.

⁷⁵² Burrell, para 4.71.2, suggesting ‘the best workable method to test for novelty.’

⁷⁵³ Sharples A. and Curley D. ‘Experimental novelty: *Synthon v Smithkline Beecham*’ (2006) *European Intellectual Property Review*, p.304-311.

⁷⁵⁴ Reddy M. ‘The economic and socio-economic benefits of R&D-based multinational pharmaceuticals on the South African economy’, 2007, Deloitte Consulting (Pty) Ltd.

⁷⁵⁵ Gastrow, fn.508.

⁷⁵⁶ Kingston, fn.2, p.350.

that indeed when one undertakes novelty assessment, the system sifts out undeserving patents and does not impinge on dynamic public knowledge generation.

This chapter will begin with a background of the industrial invention and innovation process as it relates to the main components of the production of novel pharmaceuticals from conception to finished products and the concerns that arise in the protection of those resulting products.⁷⁵⁷ The legal nature of anticipation and how it is to be ultimately assessed in court will be examined. To achieve this, first the decisions in *Synthon* from the High Court, and the Court of Appeal through to the Supreme Court, as they streamline and consolidate the various facets of the law of anticipation, will be explored in detail as a guide to anticipation standards and how inventions attain the novelty limb to patentability in the UK. The practical significance of the case is noted to be the consolidation of the different authorities and novelty aspects from the series of case law on novelty and thus reducing the need to wade through the bulk of decided cases.⁷⁵⁸ There will then be case law examination of the novelty test in South Africa, encapsulating the tension as to the applicable novelty test between the patenting stakeholders. Consequently, from the analysis of these respective pertinent cases, the role of the skilled worker in the understanding and perception of novelty, and the R&D activity in influencing an invention passing the novelty test will be comparatively examined between the two jurisdictions. The significant principle here is a convergent view on novelty between these representative developing and developed economies, particularly of the final legal novelty assessment outcome of an identical invention. In the end suggestions are made on how the industrial and legal spheres would come to have a converging view of what is indeed novel when patenting is the objective.

⁷⁵⁷ Other stages or factors that have no bearing on patentability will not be explored, for instance marketing authorisations and other regulatory approvals needed before the novel invention is practiced.

⁷⁵⁸ Freeland R. 'Disclosure and enablement: The House of Lords clarifies the law on novelty' (2006) *Journal of Intellectual Property Law and Practice*, p.163-165, p.165.

5.2 The Inventing Process

It has been noted that the innovation race amongst pharmaceutical entities is fierce.⁷⁵⁹ The way by which they bring about new products or processes plays a central role in their success. It has been said that ‘the greatest invention of the nineteenth century was the method of invention itself.’⁷⁶⁰ This was when the pharmaceutical industry ‘realised that it could be profitable to put the business of research for new products and development of new chemical processes on a more regular, systematic and professional basis’⁷⁶¹ rather than the sporadic and unpredictable approach adopted during its infancy.

The model has remained unchanged in the last 50 years.⁷⁶² Competition within the industry places a premium on research, such that the successful firms will have an extensive portfolio of new drugs in their research pipeline.⁷⁶³ Typically, research-intensive activities have been the focus of large firms with multiple internalized activities from research to distribution. The smaller entities on the other hand could be classified as specialized biotechnology firms whose activities are directed at selling their discoveries to the larger firms who will commercialize and bear the cost of perfecting the invention for the market.⁷⁶⁴ The synergy therefore between the two is that although they each can develop new molecular entities (NME) on their own, they usually rely on each other for complementary functions for the different stages in the inventive process.⁷⁶⁵

⁷⁵⁹ Generic companies have been noted to play an increasing role in the innovation race, inducing additional competition to originator companies by progressively earlier litigation challenges to ‘basic compound patents on high-sales drugs-indiscriminately...in the hope of winning a few’: Hemphill C.S. and Sampat B.N. ‘When do generics challenge drug patents? (2011) *Journal of Empirical Legal Studies*, p.613-649, p.614-615.

⁷⁶⁰ Freeman C. and Soete L. *The economics of industrial innovation*, 3rd ed (1997) Cambridge, MA: The MIT Press, p.299.

⁷⁶¹ *Ibid.*

⁷⁶² Kaitin K. ‘Deconstructing the drug development process: The new face of innovation’ (2010) *Nature*, p.356-361.

⁷⁶³ Balance R., Pogany J. and Forstner H. *The world’s pharmaceutical industries: An international perspective on innovation, competition and policy* (1992) Hants: Edward Elgar Publishing Limited, p.85. Aronson J.K. ‘Old drugs- new uses’ (2007) *British Journal of Clinical Pharmacology*, p.563-565: for pharmaceutical interventions it is also common to use old drugs for new uses even if they are not patented.

⁷⁶⁴ Gambardella A. *Science and innovation: The US pharmaceutical industry during the 1980s* (1995) Cambridge: Cambridge University Press, p.61.

⁷⁶⁵ Zucker L.G and Darby M.R. ‘Present at the biotechnological revolution: transformation of technological identity for a large incumbent pharmaceutical firm’ (1997) *Research Policy*, p. 429-446.

The need to continually bring about new pharmaceuticals for diseases has brought eminence to the R&D process. R&D is one of the crucial phases in the production of new pharmaceuticals.⁷⁶⁶ R&D involves investigating a wide array of sources of new compounds, as seen in chapter one, in a systematic and efficient fashion. It involves studying the chemical structures of target molecules, screening and testing of candidate molecules and examining the mechanism of action or pathway of the disease. The R&D process is a sequential series of stages, but efficiency is attained when there is a high level of interaction between all the different stages.⁷⁶⁷

The resulting compounds from the quest to find new pharmaceuticals do not always significantly differ from what is already known. This is perhaps where the pejorative view of patents for pharmaceuticals emanates.⁷⁶⁸ The general principle for what could be claimed as new is that ‘no man can have a patent for merely ascertaining the properties of a known substance’,⁷⁶⁹ unless some modification is needed to make it useful for the new use. The reality in pharmaceutical R&D is that a seemingly small difference in chemical structure would for instance result in stereo-selectivity of a compound imparting considerable pharmaco-activity.⁷⁷⁰ Such incremental inventions

⁷⁶⁶ Ballance R., Pogany J. Forstner H. *The world's pharmaceutical industries: An international perspective on innovation, competition and policy* (1992) Harts: Edward Elgar Publishing Limited., p.85. Paul S. *et al* ‘How to improve R&D productivity: The pharmaceutical industry’s grand challenge’ (2010) *Nature Reviews Drug Discovery*, p.203-214.

⁷⁶⁷ Littler D. ‘Marketing and innovation’ in Dogson M. and Rothwell R.(ed) *The Handbook of Industrial Innovation* (1995) Harts: Edward Elgar, p.297.

⁷⁶⁸ Dwivedi G., Hallihosur S. and Rangan L. ‘Evergreening: A deceptive device in patent rights’ (2010) *Technology in Society*, p.324-330.

⁷⁶⁹ *Re I. G. Farbenindustrie A.G.'s Patents* (1930) 47 RPC 239, p.322. A UK exception to the rule for second medical use is discussed in section 7.6.1 of the thesis. At the EPO, the approach to novelty-of-purpose for non-medical use of known products is that a claim to a new use of a known product is possible if the claim identifies the new use as a previously unknown technical effect, such as in *G2/88 Mobil III/Friction Reducing Additive* [1990] O.J.E.P.O. 93, considered in *Merrell Dow*, where a product originally developed as a lubricant to prevent rust was found to reduce friction and was patentable as a new functional technical feature that reduces friction. That is a new purpose had been discovered: Bently/Sharman, fn.265, p.484. The practice at the UKIPO (Patent Manual, para.2.14, October 2013) regarding use claims based on previously unrecognized technical effect is different and based on the position in *Tate & Lyle Technology Ltd v Roquette Freres* [2010] FSR 1, upheld on appeal, where in the known process for synthesizing a sugar substitute maltitol by hydrogenation of maltose, the by-product maltotriitol was found to affect the crystal formation and therefore the patent claim of ‘the use of maltotriitol to modify or control the formation of maltitol crystals’ was found by the court to be anticipated by prior art, as maltotriitol’s previous unsuspected effect has always been to ‘modify or control the form’ of resulting maltitol crystals.

⁷⁷⁰ Agranat I. and Wainshtein S.R. ‘The strategy of enantiomer patents of drugs’ (2010) *Drug Discovery Today*, p.163-170.

have been asserted as a significant incentive to the pharmaceutical industry that should not be discouraged by policy-makers.⁷⁷¹

In the R&D process it is also common that a series of chemical compounds that closely resemble each other is investigated.⁷⁷² Commonly used are Markush claims in respect of a general formula that covers a group of numerous compounds found to be sharing common characteristics or activity.⁷⁷³ It is possible to select some members from the series to claim for protection. Selection inventions are those that select a group of individually novel members from a previously known group.⁷⁷⁴ Selection patents are therefore said to be useful in making and claiming inventions in fields which are generally known.⁷⁷⁵ In litigation however, substantive issues of the selection patents would initially be addressed in the evaluation of the novelty criteria even though it may still be necessary to determine the validity of the selection under the obviousness limb.⁷⁷⁶ In *Dr Reddy's*,⁷⁷⁷ Floyd J concluded that a prior disclosure does not take away the novelty of a specific claim to a compound unless the compound was disclosed in an individual form.⁷⁷⁸ Affirming this principle, Court of Appeal⁷⁷⁹ rejected the argument that the mere disclosure of a generic formula or class of compounds discloses every possible compound falling within that class.

There exists a characteristic divide in pharmaceutical development between South Africa and the UK. NMEs have originated largely in the developed countries. Nevertheless, it is important to note that the nationality of the NME is an ambiguous concept.⁷⁸⁰ This is due to the international nature of the pharmaceutical model and the

⁷⁷¹ Cohen F.J. 'Micro trends in pharmaceutical innovation' (2005) *Nature Reviews Drug Discovery*, p.78-84.

⁷⁷² Barnard J.M. and Wright P.M. 'Towards in-house searching of Markush structures from patents' (2009) *World Patent Information*, p.79-103.

⁷⁷³ PCT Applicant's Guide – International Phase, 14 January 2010, para.5.119.

⁷⁷⁴ Van Overwalle G. 'Policy levers tailoring patent law to biotechnology: comparing US and European approaches' (1999) *UC Irvine Law Review*, p.433-514, p.455-556.

⁷⁷⁵ Jeffs J. 'Selection patents' (1988) *European Intellectual Property Review*, p. 291-301.

⁷⁷⁶ Minssen T. 'Meanwhile on the other side of the Pond: Why biopharmaceutical inventions that were 'obvious-to-try' might be non-obvious' (2010) *Chicago-Kent Journal of Intellectual Property*, p.60-131, p.81.

⁷⁷⁷ [2008] EWCH 2345 (Pat).

⁷⁷⁸ Wyld O. 'High Court considers Markush claims and doctrine of UK selection patents' (2009) *Journal of Intellectual Property Law & Practice*, p147-149, p.148.

⁷⁷⁹ *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* [2010] RPC 9.

⁷⁸⁰ Ballance, *et al*, fn.766, p.86. Boyd notes that cooperating or collaborating parties of different backgrounds have a crucial role to play at various stages and in the eventual success of the discovery

fact that new drugs can be seen as incremental improvements on existing products which may have been developed in other countries. Moreover, there is a trend whereby the research facilities are headquartered in a developed nation even though most of the work, usually preparatory work, is based in another nation. In cases where the disease is largely prevalent in developing countries, an opportunity for the development of solutions to serve the needs of the locality opens up. Thus, an important caveat to the prevailing trend of developed nations dictating research direction would be ensuring a deliberate line of research according to national needs of the country from which the raw data is taken even though the R&D is eventually completed in the headquarters. For instance South Africa is developing an AIDS vaccine against the HIV strain that is prevalent in sub-Saharan Africa, which has entered clinical trial stages even though the final stages are completed elsewhere.⁷⁸¹

The divide also extends to the typical size of the innovating firm found in the different countries. The UK has both the large and small firm sizes, thus complementing each other's research on new disease that affects its population. South Africa has a limited number of large pharmaceutical firms compared to the smaller firms, although this is changing.⁷⁸² However, what could be harnessed from its relative novice in systematic R&D, is that with dedicated investment the '[n]ew entrant, or newly established firms, with no sunken costs or organisational biases toward the old technology, can be far more effective than incumbents in exploiting the new fields.'⁷⁸³

The issue of size also extends to other aspects of the innovative process. Previously when NME discovery resulted mainly from the extensive screening of chemical entities, the critical resource for success was sufficiently large laboratories and screening became a fairly routine and automated task. Now with the complexity of needed NME, which often requires varied investigations, the emerging industrial

process: Boyd M.R. 'The position of intellectual property rights in drug discovery and development from natural products' (1996) *Journal of Ethnopharmacology*, p.17-27.

⁷⁸¹ <http://www.saavi.org.za/1press2009.htm>: The collaboration is of South African scientists with US partners in the different stages of R&D.

⁷⁸² 'Medicines procurement in the public sector: Challenges and opportunities for improvement of medicines procurement in South Africa's public sector- March 2010' (2010) South African Department of Health: Pretoria, p.80-83.

⁷⁸³ Gambardella, fn.764, p.61.

model is ‘relatively small in size... often conducive to the production of ideas of great originality.’⁷⁸⁴ This has meant that there has to be more focus on studying the disease mechanism of action, rather than requiring large scale screenings with low output.⁷⁸⁵ This has impacted on traditional R&D settings by lessening the need to have large, capital-intensive and rigid organisations as almost the only source of new pharmaceuticals.⁷⁸⁶

Hence, it can be plausibly suggested that South Africa can increase its inventive pharmaceutical output.⁷⁸⁷ For instance, it has been observed that visionary scientists made proposals to increase R&D in Britain by order of magnitude seemingly utopian at the time.⁷⁸⁸ South Africa needs a strategic long-term plan on how to improve its innovative pharmaceutical industry that will focus on the most prevalent diseases within its population. One way is to recognise that ‘patents that are wrongly granted can be very expensive to challenge, and perhaps beyond the means or inclination of small and medium enterprises. An accumulation of patents of that sort... may be a serious barrier to entry.’⁷⁸⁹

Experimentation is a critical aspect of discovering new pharmaceutical inventions.⁷⁹⁰ The primary input into pharmaceutical discovery is not only fundamental science or science per se, but it is the complex blend of scientific knowledge and experimental

⁷⁸⁴ Ibid, p.45. For instance, in a study of 16 pharmaceutical firms over a 19 year period, it was observed that beyond a particular point, innovative productivity declined with increasing firm size because ‘despite their use of more resources, large organizations are inherently inefficient so that their very size stands as an impediment to innovative results’: Graves S.B. and Langowitz N.S. ‘Innovative productivity and returns to scale in the pharmaceutical industry’ (1993) *Strategic Management Journal*, p. 593-605, p.604.

⁷⁸⁵ Scott W.L. and O’Donnell M.J. ‘Distributed drug discovery: Linking academia and combinatorial chemistry to finding drug leads for the developing world diseases’ (2009) *Journal of Combinatorial Chemistry*, p.3-13.

⁷⁸⁶ For instance, even micropharma -academia originated start-up companies and research units characterised by being small, innovative, more efficient and product focused - have been identified as capable of fulfilling the R&D shortages in the new pharmaceutical product pipelines: Barden/Weaver, fn.24.

⁷⁸⁷ For instance, South Africa is seen a candidate country that can increase its biopharmaceutical R&D: International Federation of Pharmaceutical Manufacturers Associations, ‘Encouraging pharmaceutical R&D in developing countries (2003) Geneva Switzerland, p.51.

⁷⁸⁸ Freeman/Soete, fn.725, p.300.

⁷⁸⁹ *CFPH's Application* [2005] EWHC 1589 (Pat).

⁷⁹⁰ Thomke S., von Hippel E. and Roland Franke R. ‘Modes of experimentation: an innovation process- and competitive- variable’ (1998) *Research Policy*, p.315-332.

research.⁷⁹¹ Trial-and-error that formerly existed was cost effective, as there was little exploration of the drug mechanism of action, but may not be optimally suitable for more complex disease problems that now need to be tackled.⁷⁹² Increased efficiency in experimental methodologies correlates with the ability and skill to comprehend complex problems in a more economically useful way. With more experimentation there is the increase in ability to use experimental observation more efficiently.⁷⁹³ This allows firms to use theoretical technologies and principles, for instance genomics and bio-informatics, to predict the mechanisms of actions before synthesis in the laboratory or even on scaling-up novel processes.

This lends support to the value of the person who carries out the pharmaceutical work. The value of the skilled person is manifold. Such a person skilled in the art plays a crucial role as the reference point in bringing inventions into the public domain. He is proxy for the standard of what is judged as new. It has been said that successful pharmaceutical firms typically organise their discovery process around skilled scientists.⁷⁹⁴ The companies have to choose the core therapeutic area of focus and then give the scientists the autonomy to research according to their skill. The scientists have 'greater technical competence to pinpoint the best opportunities for technological and even commercial success.'⁷⁹⁵ They are therefore indispensable for both the commercial and the legal decision of the novelty of the research activity or output thereof.

Also important in the inventing process is conducting novelty searches in order to evaluate whether the new compounds will not infringe existing patents or under what circumstances they in turn would be infringed.⁷⁹⁶ This is not within the focus of the

⁷⁹¹ The ultimate success in new product introduction has been correlated to the technological experience of the firm in the given therapeutic area deriving from R&D activities and previous market participation: Nerkar A. and Roberts P.W. 'Technological and product-market experience and the success of new product introductions in the pharmaceutical industry' (2004) *Strategic Management Journal*, p.779-799.

⁷⁹² Gambardella, fn.764, p.42.

⁷⁹³ *Ibid.*

⁷⁹⁴ *Ibid.*, p.45.

⁷⁹⁵ *Ibid.*

⁷⁹⁶ Rockman H.B. *Intellectual Property Law for engineers and scientists* (2004) Hoboken: John Wiley & Sons, p 130-140. Even generic companies are concerned about infringement because the reality is that the chemical processes involved in working a known compound can be new: Laird T. 'Innovation in Generic API Synthesis and Manufacture' (2012) *Organic Process Research & Development*, p.365.

thesis but will be outlined here for how it illuminates the overlaps between a new pharmaceutical's patentability and the enforcement of rights arising thereof. The infringement of patents for pharmaceutical inventions is governed by the detailed statutory rules on infringement,⁷⁹⁷ revocation,⁷⁹⁸ protection from groundless threats⁷⁹⁹ and the defenses that the alleged infringer may raise.⁸⁰⁰ Infringement is classified according to whether it is textual or non-textual depending on whether the infringing acts fall squarely within the claims of the patent.⁸⁰¹ The rules for determining this have proven to be complex in application and much has been written about infringement in this context.⁸⁰² For instance, Brennan traces the UK evolution of the function of patent claims up to the explicit statutory statement as a result of EPC Art.69's role in determining the scope of protection and suggests a critical view of claim construction jurisprudence and methodologies,⁸⁰³ Fisher traces the history of the EPC Art.69 and the underlying sources of divergence between EPC Contracting States in interpreting claims⁸⁰⁴ and Hellfeld traces the divergence in EPC Contracting States in how claims are constructed.⁸⁰⁵ South African authors have traced the source of the tensions and differences between successive South African Supreme Court of

Denicolo V. 'Two-stage patent races and patent policy' (2002) *RAND Journal of Economics*, p.488-501.

⁷⁹⁷ UKPA, s.60 and SAPA, s.65. and acts of non-infringement in UKPA,s.60(5) and SAPA, s.69.

⁷⁹⁸ UKPA, s.72 and s.73 and SAPA, s.61.

⁷⁹⁹ UKPA, s.70 and SAPA s.70.

⁸⁰⁰ UKPA, s.74 and SAPA, s.65(4).

⁸⁰¹ 'It is seldom that the infringer does the thing, the whole thing, and nothing but the thing claimed by the specification': Schreiner JA in *Frank and Hirsch (Pty) Ltd v Rodi and Weinenberger Aktiengesellschaft* 1960 BP162(A), p.177, quoting from *Birmingham Sound Reproducers v Collaro* 1956 RPC 232, p.242.

⁸⁰² Pumfrey N., *et al.*, 'The doctrine of equivalents in various patent regimes-Does anybody have it right?' (2009) *Yale Journal of Law and Technology*, p.261-308: In a review of the doctrine of equivalents in leading jurisdictions, even though the UK judges were not in agreement as to the practical application of the doctrine, it was shown that the law provides that in order for a variant or equivalent to infringe it must fall within the language of the claim, properly interpreted, otherwise it does not infringe even if it amounts to nothing more than unfair copying of the essences of the inventive concept.

⁸⁰³ Brennan D.J. 'The evolution of the English patent claims as property definers' (2005) *Intellectual Property Quarterly*, p.361-399.

⁸⁰⁴ Fisher M. 'New protocol, same old story? Patent claim construction in 2007: Looking back with a view to the future' (2008) *Intellectual Property Quarterly*, p.133-162, concludes that because of the fundamental differences in the philosophy between the EPC members, the matter can only be resolved once a new unification framework is in place.

⁸⁰⁵ Hellfeld A. 'Patent infringement in Europe: the British and the German approaches to claim construction or purposive construction versus equivalency' (2008) *European Intellectual Property Review*, p.364-370, p.368: Critiquing the tools that have been applied by the courts in construing patent claims, saying 'it is simply distracting from the real issues, namely construing the claimed invention (which includes understanding the prior art) and comparing it with the accused product or method.'

Appeal's approach to claim construction and also in relation to UK approaches persuasive in South Africa.⁸⁰⁶

The overarching rule on anticipation which the R&D scientist needs to be aware of is that prior art may disclose the substance of the invention they thought was new. Indeed, in a South African case study of research output that is ultimately patented it was found that the new knowledge and the state of the art was 'bi-directional, capable of overlap',⁸⁰⁷ such that it is difficult to distinguish between the two. At the same time, it is also important to note that patent infringement does not require one to be aware that one is infringing. In *Merrell Dow*, p.90, it was said that 'whether or not a person is working [an]...invention is an objective fact independent of what he knows or thinks about what he is doing.' Peculiar to the UK is the mechanism introduced by Patents Act 1977, s.74A(1) that allows anyone to request a non-binding opinion of whether a particular act or contemplated act infringes on existing patents,⁸⁰⁸ although this will not absolve the infringement unless a specific declaration as to non-infringement has been made.⁸⁰⁹ Therefore the creation of new substances involves a balance between providing new knowledge and guarding against infringing on knowledge that may already be claimed by third parties.

The thesis now turns focus onto the nature of anticipation in the two jurisdictions.

⁸⁰⁶ Burrell, p.256; Visser C. 'The interpretation of patent claims: A chronology of the vestitudes of the pith and marrow doctrine and doctrine of purposive construction in the Appellate Division', in Kahn E. *In Quest for justice* (1995) Durban: Juta Publishers. *Nampak Products and another v Man-Dirk (Pty) Ltd* 1999(3) SA 708, *Aktiebolaget Hässle and another v Triomed (Pty) Ltd* [2002] 4 All SA 138 (SCA), *Vari-Deals 101 v Sunsmart Products (Pty) Ltd* 2008(3) SA 447 (SCA) are the South African Supreme Court authoritative cases, but considered to be unclear on the appropriate principles of purposive construction approach to adopt in the move from the 'pith and marrow' doctrine to the *Catnic* test as embraced in South Africa: Zondo R. *The replacement of the doctrine of pith and marrow by the Catnic test in English patent law: A historical evaluation* (2012) UNISA: Unpublished thesis. p.239-246.

⁸⁰⁷ Lubango L. And Pouris A. 'Is patenting of technical inventions in university sectors impeding the flow of scientific knowledge to the public? A case study of South Africa' (2010) *Technology in Society*, p.241-248, p.242.

⁸⁰⁸ The potential application of this framework has been explored: Phillips J. 'Pouring oil on troubled waters or inflaming the passions? Comptrollers' opinions and the quest for happiness' (2005) *European Intellectual Property Review*, p.226-231.

⁸⁰⁹ Patents Act 1977, s.71 and Patents Act 1978, s.69.

United Kingdom

5.3 Nature of anticipation

The basis of patent systems is that they should grant monopolies in reciprocate for inventions that are new. As the UK's criteria for patentability is based on the EPC, the Supreme Court said on many occasions the practice of UK courts should closely follow those of EPO.⁸¹⁰ Under UK domestic law, Patents Act 1977, s.1(1)(a) provides that a patentable invention should be new. It is elaborated in s.2(1) that the new invention should not be anticipated by prior art. This means the invention must not be found at the priority date in any 'matter (whether a product, a process, information about either, or anything else) which has at any time been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use, or in any other way.'⁸¹¹ Besides the making available of subject matter of the invention, another category of anticipation is when information is found in a patent application and subsequent publication.⁸¹² A consequence of the lack of novelty is patent revocation or refusal of the application.⁸¹³

5.4 The test for novelty

According to some commentators⁸¹⁴ 'the essential standard is 'absolute' and 'global' novelty' against which the invention is measured. This is the one end of the novelty spectrum and considered a high patentability standard to set, compared with other jurisdictions where inventions can be novel according to a less scrutinising criterion.⁸¹⁵ There is now a worldwide general trend towards elimination of local

⁸¹⁰ Tilmann W. 'Harmonization of invalidity and scope-of-protection practice of national courts of EPC member states' (2006) *European Intellectual Property Review*, p.169-173. Also in *Merrell Dow*, p.82.

⁸¹¹ Patents Act 1977, s.2(2). One way of classifying novelty is by dividing it into two groups, novelty by use and novelty by disclosure: Booton D.L. 'Novelty of invention under the Patents Act 1977 and the European Patent Convention' (1996) *Web Journal of Current Legal Issues*, and was so divided in *Merrell Dow*.

⁸¹² Article 54(3) EPC and Section 2(3) of the 1977 Act. *Asahi Kasei Kogyo KK's Application* [1991] RPC 485 held that enabling disclosure applied equally for s.2(2) and s.2(3).

⁸¹³ Respectively s.72 and s.14.

⁸¹⁴ Story A. 'Biopiracy and the dangers of patent over-protection' (1999) *New law journal*, p.158.

⁸¹⁵ Von Braun J. and Pagatch M.P. 'The changing face of the pharmaceutical industry and intellectual property rights' (2004) *The journal of world intellectual property*, p.599-623, p.611.

novelty and this effectively shows increasing respect for foreign inventions and foreign prior art,⁸¹⁶ a principle in line with the natural rights justification as advanced in the second chapter.

Under the novelty limb, the thesis takes the view that certainty and consistency in the treatment of subject-matter under scrutiny is a central ingredient to attaining what is an optimal and balanced novelty standard. The certainty of meeting the newness test is crucial, both for patentee and third party, in the pharmaceutical sectors. It is difficult to research and develop new drugs, gain regulatory approval and recoup costs from sales, if free-riders and those who ‘invent around’ patents have a low inconsistently judged newness standard to attain before they, in turn, are granted a patent⁸¹⁷ or are held to be non-infringing when performing acts resembling those claimed under the new invention.

The balanced standard therefore comes about due to a rigorous disclosure requirement⁸¹⁸ for what the inventor claims to be novel. This builds on the justification suggested in chapter two, which is that the patent is consideration in exchange for new disclosure. Commentators have observed that the novelty requirement is linked to the sufficiency of disclosure requirement although the two concepts are not identical.⁸¹⁹ Allowing a vague disclosure is detrimental to the system. Some have observed that ‘low patentability standards resulting from inadequate disclosure of new bits of information in patent applications would result in failure by those skilled in the art to replicate the inventions.’⁸²⁰

⁸¹⁶ Bagley M. ‘Patently Unconstitutional: The geographical limitation on prior art in a small world’ (2003) *Minnesota Law Review*, 679-726, while others are not so convinced: Crouch D. ‘Is novelty obsolete? Chronicling the irrelevance of the invention date in the US patent law’ (2009) *Michigan Telecommunications and Technology Law Review*, p.53-107.

⁸¹⁷ Grabowski, H. ‘Patents, innovation and access to new pharmaceuticals’ (2004) *Journal of International Economic Law*, p.849-860.

⁸¹⁸ Branstetter L.G. ‘Do stronger patents induce more local innovation?’ (2004) *Journal of International Economic Law*, p.359-370, p.361.

⁸¹⁹ England P. ‘Novelty and sufficiency in a single, pan-European standard’ (2010) *European Intellectual Property Review*, p.467-475, p.470. In *Asahi* p.553, Lord Oliver of Aylmerton observed the overlap, saying ‘this need for an enabling disclosure not only applied to documents cited under Art.54(2) and (3) but is also in conformity with the principle expressed in Art.83 EPC for patent applications must, accordingly, disclose the invention in manner sufficiently clear and *complete* for it to be carried out by the person skilled in the art’ (original emphasis).

⁸²⁰ Kanwar S. and Evenson R. ‘Does intellectual property protection spur technological change?’ (2003) *Oxford Economic Papers*, p.235-264, p.237.

The balanced patentability standard also results from stringent enablement requirements. Disclosures or claims demarcating the effective patent ‘should not be issued that go beyond what is enabled.’⁸²¹ The test should prevent applicants claiming what they predict to be enabled using technology models that can simulate or approximate real life situations, without having achieved this in reality. On the other hand it should prevent third parties using disclosures that are not enabling to anticipate inventions.

Premising the novelty test on enabled disclosures therefore, it could be said that novelty assessment, in its simplicity, involves a factual comparison between the invention and the information disclosed by prior art.⁸²² As a starting point, the prior art document must sufficiently disclose the later invention although sufficiency will not necessarily be in issue in all novelty cases. According to writers⁸²³ the anticipation test for the sufficiency of prior art disclosure by a claimed or later process or method invention is generally that it must give ‘clear and unmistakable directions to do what the patentee claims to have invented’.⁸²⁴ For a new product, the test is that a skilled reader must be enabled ‘at once to perceive and understand and be able practically to apply the discovery without the necessity of making further experiments.’⁸²⁵

5.4.1 Synthron in the High Court

The case *SmithKline Beecham Plc's Patent (No.2)*⁸²⁶ was a revocation application of a SmithKline Beecham Plc (SKB) patent of new crystalline methanesulfonate salt of known paroxetine and its general process of manufacture. This is a compound used in the treatment of depression and related disorders. At the priority date of the patent in suit, Synthron had a prior unpublished concurrent application which related to paroxetine methanesulfonate (PMS) and other close chemical equivalents. The

⁸²¹ Barton J.H. ‘Issues posed by a world patent system’ (2004) *Journal of International Economic Law*, p.341-357, p.347.

⁸²² *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457, p.485.

⁸²³ Cornish W., Llewelyn D. and Aplin T. *Intellectual property: Patents, copyrights, trademarks & allied rights*, 8th edn. (2013) London: Sweet and Maxwell, para.5-18.

⁸²⁴ *Parker J., Flour Oxidising v Carr* (1908) 25 RPC 428, p.457.

⁸²⁵ Lord Westbury, *Hill v Evans* (1862) 4 De G. F. & J. 288, p.300.

⁸²⁶ *SmithKline Beecham Plc's Patent (No.2)* [2003] RPC 33;[2002] EWHC 2573 (Pat).

application described specific experiments for the manufacture of PMS oil, which turned into a waxy solid, characterised as that of the patent in issue except for an infrared (IR) reading.⁸²⁷ Notwithstanding the incorrect IR, Synthon argued that the prior application was enabled as it enabled a man skilled in the art to make PMS. SKB asserted that for an earlier disclosure to be enabling it was a necessary but not sufficient condition for anticipation⁸²⁸ and their crystalline structure was not similar to that of Synthon, having regard to the differing IR spectrums or that their crystalline structure was not an ‘inevitable result’ of practising prior disclosure.

The first instance court’s novelty fact-finding mission was to evaluate whether SKB’s invention was new having regard to Synthon’s prior disclosure. Jacob J (as he was then) pointed out that *Inhale Therapeutic Systems v Quadrant*⁸²⁹ emphasised that anticipation occurred through the ‘inevitable result’ route and also through enabling disclosure.⁸³⁰ To show the ‘inevitable result’ one has to prove that carrying out what is described by the prior art falls within the invention’s claims. If prior art describes something falling within the invention’s scope, the inventions’ claims are anticipated.

The ‘inevitable result’ is premised on showing that the inevitable result of carrying out what is described in the prior art would be a process or product falling within the scope of the invention. In *General Tire & Rubber Co. v Firestone Tyre and Rubber Co. Ltd.*,⁸³¹ Sachs LJ said ‘if carrying out the directions contained in the prior inventor’s publication will inevitably result in something being made or done which, if the patentee’s patent were valid, would constitute an infringement of the patentee’s claim, this demonstrate that the patentee’s claim has in fact been anticipated.’ The ‘inevitable result’ as explained in *Merrell Dow* centred on a claim to an acid metabolite formed in the liver after administration of terfenadine by the subjects, where Lord Hoffmann held that if the specification of the earlier terfenadine was

⁸²⁷ IR is a technique that uses light absorption for the characterisation of simple and complex molecules.

⁸²⁸ [2003] RPC 33, para.94.

⁸²⁹ [2002] RPC 21, para.43-44.

⁸³⁰ Per Jacob, [2003] RPC 33, para.83, quoting Laddie J, para.43. Inevitable result: the principle that for prior art teaching to inherently anticipate the claimed invention, the invention claimed must be the inevitable result of following the prior art teaching. *Merrell Dow* held that a claim to an acid metabolite formed in the liver after administration of terfenadine was anticipated as it was an inevitable result of carrying out directions in the earlier terfenadine patent. Also, *Mobil Oil/Friction Reducing Additive*, Decision G2/88 OJ EPO 1990, 93.

⁸³¹ [1972] RPC 475, p.485.

followed, then the production of the acid metabolite was inevitable, and thus the acid metabolite was part of the state of the art.

Jacob J, at first instance, said it was less of a case of the inevitable result as there were no repeatable experiments that formed any crystals.⁸³² He warned against the ‘mere mechanical application of an inevitable result rule’ and suggested that anticipation be carefully handled where the prior art and the disclosure document make disclosures at different levels of generalities and descriptions.⁸³³ This, on one level confirms that deciding novelty is an involved task. It also serves as a warning to underscore to some observers who believe that this case ‘was certainly not an inevitable result that could have been predicted at the outset of this litigation’⁸³⁴ to tread carefully before discarding the inevitable result argument. In addition, the court has said that the disclosure by inevitable result is possible even where the prior art teaching can be carried out in more than one way.⁸³⁵

For anticipation through enabling disclosure the judge said the pivotal question is whether the earlier disclosure was enabling. This is a principle established in *Asahi*, holding that any piece of prior art must be enabling to invalidate for lack of novelty, although Jacob in *Synthon BV v. Smithkline Beecham Plc*⁸³⁶ was of the view that at that stage in the development of patent law the enabling disclosure doctrine was not fully established but was rather made clear in *Merrell Dow*. The prior enabling disclosure doctrine was elucidated in *Merrell Dow*, where Lord Hoffmann held that Patents Act 1977, s.2(2) does not confine the state of the art about products to knowledge of their chemical composition. It is the invention which must be new and which must therefore not be part of the state of the art. It is therefore part of the state of the art if the information which has been disclosed enables the public to know the product under a description sufficient to work the invention.

⁸³² [2003] RPC 33, para.97.

⁸³³ [2003] RPC 33, para.90.

⁸³⁴ Sharples/Curley, fn.753.

⁸³⁵ *Leo Pharma A/S, Leo Laboratories Limited v Sandoz Limited* [2009] EWHC 996 (Pat) para.58, although the court has to be satisfied that on the balance of probabilities, each way will produce the same result.

⁸³⁶ [2002] EWHC 1172 (Pat), para.32.

Jacob J in the Patents Court had to assess whether the inventors has adequately stipulated how to make the invention and had in essence reached the same result⁸³⁷ as the challengers. In this case the court held that there was adequate disclosure of the existence of the crystals.⁸³⁸ Synthon's disclosure was at the same general level as latter application by SKB and Jacob J held it to be sufficient for the enabling manufacture of PMS, thus the patent was found to be invalid.⁸³⁹

5.4.2 *Synthon* in the Court of Appeal

On appeal by SKB, the Court of Appeal held that Synthon application claims did not specifically mention PMS although it was within the general formula. Although recognizing that disclosure could be extracted from the application, whether it was implicit or explicit,⁸⁴⁰ it however viewed that the application did not make any explicit claim to the crystalline product.⁸⁴¹ This would lead one skilled in the art to think that the focus of the application lies somewhere else other than in the crystalline product. Looking forward from the priority date, it certainly would look like Synthon was not interested in the crystalline structure. To substantiate this view is the fact that PMS was mentioned only as an example in an experiment. If indeed the skilled reader were to conclude that the product is disclosed, he would be inclined to think it was a different form of crystalline structure to that of SKB. This was the essence of the Court of Appeal's enquiry into whether there was prior disclosure. The court concentrated on the description of crystalline PMS in the application. This is consistent with Doble's opinion that 'it is clear that the invention must first be identified and that only then can novelty be determined.'⁸⁴²

The vague disclosure of PMS in Synthon's application, which the trial court held to form part of the state of the art, did not invalidate SBK's patent for lack of newness,

⁸³⁷ [2003] RPC 33, para.93.

⁸³⁸ *Ibid*, para.99.

⁸³⁹ *Ibid*, para.96.

⁸⁴⁰ *Lundbeck A/S v Norpharma SpA* [2011] RPC 23, confirmed that prior art disclosures, on one end, included implicit disclosures and on the other end subject matter may be embedded in a prior art document such that it does not form a disclosure.

⁸⁴¹ *SmithKline Beecham Plc's Patent (No.2)* [2003] EWCA Civ 861, para.51.

⁸⁴² Doble R. 'Novelty under the EPC and the Patents Act 1977: A unified view of Merrell Dow and Mobil' (1996) *European Intellectual Property Review*, p.511-516, p.516.

as it did not make PMS available to the public.⁸⁴³ In other words, enablement was dependent on the information being made available to the public. The Court said for information to be made available to the public it had to enable the skilled reader to implement the disclosure.⁸⁴⁴ Since the skilled worker should be enabled to perform the invention, the Court found that there was no clear and unmistakable directions to make PMS by the Synthon application as required in *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd.*⁸⁴⁵ This was because ‘if they sought to carry out the specific directions of production, they would fail.’⁸⁴⁶ For enablement the Court concentrated on whether directions of making PMS contained strictly in the application would lead the skilled reader to make or think possible to make the crystalline PMS.

5.4.3 *Synthon* in the Supreme Court

The Supreme Court assessing newness, reiterated the basis of the concept of enabling disclosure, as a composite tool used by the courts but with statutory basis. Enabling disclosure is when the prior art document discloses the invention claimed in a later patent and the person skilled in the art is enabled to perform the invention without any undue effort using the prior art and common general knowledge.⁸⁴⁷ Lord Walker stated that enabling disclosure arises in two distinct statutory contexts; explicitly and implicitly.⁸⁴⁸

The effect of the difference between the explicit and implicit contexts for the determination of the state of art is that, in low technology inventions simple disclosure will normally suffice while in the complex and high technology sectors as in the

⁸⁴³ ‘It is now well established that a novelty destroying disclosure must be “enabling” if what it discloses is to be regarded as being “made available to the public”’, para.10, The Patent Office ‘Examination guidelines for patent applications relating to biotechnological inventions in the UK Patent Office’, May 2005.

⁸⁴⁴ *SmithKline Beecham Plc's Patent (No.2)* [2003] EWCA Civ 861, para.8.

⁸⁴⁵ *Ibid*, para.47 and 50.

⁸⁴⁶ *Ibid*, para.51.

⁸⁴⁷ Applied, for instance by Kitchin J, in *Ratiopharm (UK) Limited v Alza Corporation, Janssen-Cilag Limited v Alza Corporation, Janssen-Cilag Limited v Sandoz Limited* [2009] EWHC 213 (Pat), para.72.

⁸⁴⁸ *Synthon*, para.63. There exists complementarities and influence between these disclosures: Ancori B., Bureth A. and Cohendet P. ‘The economics of knowledge’ (2000) *Industrial and Corporate Change*, p.255-287.

pharmaceutical and by extension biotechnological industries ‘assertation of the existence of the invention may have to be accompanied by detailed disclosure enabling a skilled person to perform invention.’⁸⁴⁹

Lord Hoffmann restated the test for novelty under the enabling disclosure route more explicitly. He postulated that anticipation had two distinct requirements, each with its own rules and functions,⁸⁵⁰ which the Court of Appeal failed to satisfy. The Court of Appeal in trying to find the enabling disclosure mixed these, thus finding the patent valid. To succeed Synthon had to prove that their application had disclosed something, which had been patented and separately show that an ordinary skilled man would be able to perform the disclosed invention if he attempted to do so by using the disclosed matter and common general knowledge. He called these requirements respectively, disclosure and enablement.⁸⁵¹

Disclosure is concerned with appropriate description of the invention. In *Hills v Evans*⁸⁵² it was stated that the disclosure ‘must be such that a person of ordinary knowledge of the subject must at once perceive and understand’ the invention. This illustrates that the disclosure is addressed to the skilled worker who is required to understand it. The skilled person in pharmaceutical innovations therefore plays a central role.

In *General Tire* it was established that approaching the invention from different directions or using different methodologies or expressions, can result in anticipation even if it is not immediately discernable from the disclosure that it is the same invention being described. However, an exception to this is where the route that ends up in the invention, compared to other disclosed possible routes is not likely to be taken.⁸⁵³

⁸⁴⁹ *Ibid*, para.64.

⁸⁵⁰ *Ibid*, para.28.

⁸⁵¹ *Ibid*, para.28.

⁸⁵² (1862) 31 L.J. (NS) 457.

⁸⁵³ *Synthon*, para.22.

The prior art, including a patent application as subsequently granted, must therefore disclose an invention, which if performed must necessarily infringe.⁸⁵⁴ This is the overriding factor as ‘if there is more than one possible consequence one cannot say that performing the invention will infringe.’⁸⁵⁵ The flag has to be planted, and is planted when the disclosure is perceived at once and is capable of being performed and is such that if performed it must result in a patent being infringed. In *General Tire* it was put this way: ‘a signpost, however clear, upon the road to the patented invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee.’⁸⁵⁶ As such the disclosure limb is seen as a strict one.⁸⁵⁷ It is submitted that the implication of this is that the novelty standard maintains an equilibrium between allowing challengers retrospectively interpreting disclosures in light of the subsequent technological developments and the predictive claiming by applicant.

Enablement on the other end is concerned with performance of the disclosure. It describes the requirement that the ordinary skilled person would be able to perform the disclosed invention, including the use of appropriate examples.⁸⁵⁸ That is, the question of enablement addresses whether the requirement of ‘if performed’ in the disclosure test is satisfied in fact.⁸⁵⁹ The enablement requirement applies both when the disclosure is in the matter forming the state of the art by virtue of s.2(2) or s.2(3), with the latter settled in *Asahi*,⁸⁶⁰ where the court was of the view that it would be illogical to treat the disclosures differently for purposes of the requirements for enablement merely because of the differences in the means of making available to the public by virtue of s.2(2) or s.2(3). *Asahi*, where in issue was a patent for a physiologically active polypeptide, human necrosis factor produced by genetic engineering and useful in the treatment of human tumours, was decided on the assumed facts that there had been a prior disclosure of the same invention but that

⁸⁵⁴ Some call it the ‘reverse-infringement’ test: Bently/Sharman, fn.265, p.472.

⁸⁵⁵ *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457, p.486.

⁸⁵⁶ *loc cit.*

⁸⁵⁷ *Ratiopharm (UK) Limited v Alza Corporation, Janssen-Cilag Limited Alza Corporation, Janssen-Cilag Limited v Sandoz Limited* [2009] EWHC 213 (Pat), para.73.

⁸⁵⁸ R.27(1)(e) of Examination Guidelines of the EPO.

⁸⁵⁹ Freeland, fn.758, p.164.

⁸⁶⁰ *Asahi*, p.547-548, p.552.

neither the disclosed information nor common general knowledge would have enabled the skilled man to make it.

The Lords also clarified the confusion surrounding the fact that enablement of a prior art disclosure for novelty purposes is the same test as patent enablement for the purposes of sufficiency.⁸⁶¹ This is helpful to inventors in the sense that it is desirable that there must be a consistency of standard for the enablement limb of novelty and enablement for sufficiency.⁸⁶² That is to say novelty assessment is concomitant with sufficiency of disclosure. Indeed the reasoning in *Hill v Evans* supports this view wherein Lord Westbury said ‘[u]pon principle therefore, I conclude that the prior knowledge of an invention to avoid the patent must be knowledge equal to that required to be given by a specification, namely, such knowledge as will enable the public to perceive the very discovery, and to carry the invention into practical use.’

In practical industrial terms, the enabling disclosure can be seen as a continuous event yet in legal terms it is separate concepts describing the instantaneous phenomena. That is to say for the scientist to decide whether the invention is new, as viewed through the specification, judgment is simultaneously on disclosure and enablement. The legal decision-making process resolves the event into separate compartments with different rules to be followed.

5.5 The role of the skilled worker

It can be said that, at face value, the role of the skilled worker was somehow reduced by *Synthon*. Lord Hoffmann acknowledged that the skilled worker would think that the claimed products are different when reading disputed claims,⁸⁶³ which would be a case of non-infringement. This raises the question of what use the skilled workers’

⁸⁶¹ *Synthon*, para28. Batteson. A. ‘Patents: enabling disclosures’ (2006) *European Intellectual Property Review*, n.28, points out that there may be differences in application of each test to the facts, for instance with sufficiency the skilled person may be trying to perform an invention and implicitly has that goal in mind while with novelty’s prior art the disclosure of the invention may not necessarily be identified as such.

⁸⁶² ‘...a compound defined by its chemical structure can only be regarded as being disclosed in a particular document if it has been “made available to the public” and this enabling disclosure for novelty is in conformity with the principles expressed for enablement for sufficiency: *Asahi*, p.552.

⁸⁶³ [2005] UKHL 59, para.9.

thoughts are on reading the disclosure documents if what they conclude is irrelevant in finding for patent validity under the disclosure limb.

This scenario seems to support the Court of Appeal's conclusion of no valid enabling disclosure as there was 'no clear and unmistakable direction' to make the claimed invention.⁸⁶⁴ If the skilled worker is not able to make the claimed product or thinks they are not making an infringing product, it is easy to envision the confusion and lack of clarity on the public from the information that was introduced into the public domain as new under the enabling disclosure doctrine. The system is founded upon the exchange of protection for disclosure of usable information by the public. Opponents of the system would dwell on this point as illustrative of the incapacity of the system to attain that balance.⁸⁶⁵

It is through deeper insight into the novelty rules that these normative concerns are properly addressed. Under the disclosure limb the skilled worker is trying to understand the disclosure of the invention.⁸⁶⁶ Common general knowledge only forms the background to his enquiry and perception of the invention.⁸⁶⁷ Under enablement the skilled worker's thoughts have no direct role to play as assessment is of the ability to perform the disclosed invention and the question is no longer what he would think the disclosure meant.⁸⁶⁸ Once the meaning has been ascertained, the disclosed invention performed is either infringing or not, at which point the skill person's thought is not relevant.

Such apparent reduced role of the person skilled in the art is resolved when one looks at the two-step nature of the test the Supreme Court introduced. This approach resolves borderline cases where for example the skilled person thinks they are doing one thing when in actual fact they are doing another.

⁸⁶⁴ *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457, p.486.

⁸⁶⁵ Olin J.M. 'The disclosure function of the patent system (or lack thereof)' (2005) *Harvard Law Review*, p.2007-2028.

⁸⁶⁶ *Synthon*, para.32.

⁸⁶⁷ *Ibid.*

⁸⁶⁸ *Ibid.*

The Supreme Court said the disclosure limb does not necessarily have to enable.⁸⁶⁹ Disclosure may consist of putting the new information in the public domain; enablement only derived from the ordinary workers ability to analyse and synthesize it. This then, is seen to actually make the role of the skilled worker more critical as they hold the key to the composite enabling disclosure where there is no clear disclosure or it is hard to discern the enablement from the disclosure at once.

Thus in cases where there is disclosure, which is not *prima facie* enabling, the Supreme Court gave the skilled worker a critical role to play. What the courts have to evaluate is the ability of the skilled worker to work out the disclosed invention from the disclosure document and use their common general knowledge to be enabled to successfully work it.⁸⁷⁰ This may mean the capability to decide on appropriate experimentation. The skilled person uses little or no assistance from the disclosure itself to effect the enablement limb.

The sometimes odd and different results or conclusions the skilled worker and the courts would reach are a result of the different perspective they each take towards the problem. If the skilled worker looks at the end result and thinks he made a different product to that described in prior art, it is because his practical obliviousness to the two-step approach as the courts. In his position he is hardly concerned with practically analysing whether a piece of information discloses or enables. In his mind he is concerned with whether or not his labours result in the end product. The court's view is an objective dual view of the situation. With each piece of information the court assesses it on the basis of whether it discloses or enables. The courts will fit every aspect of information in the two categories to come up with the conclusion of enabling disclosure or not.

The rule under the two-stage enquiry is that once disclosure is established, enablement is then assessed. For enablement the question is no longer what the skilled worker would understand from the disclosure. The relevant question is then whether he would be able to perform the invention the court has held to be disclosed. For complex fields such as the pharmaceutical industries, Lord Walker was of the opinion

⁸⁶⁹ *Synthon*, para.29 and 42.

⁸⁷⁰ *Synthon*, para.38.

that a disclosure may have to be accompanied by vast material to assist the skilled worker with enablement.⁸⁷¹ This is opposite to more mechanical inventions where simple disclosure of the invention will probably suffice. Testing the adequacy of the enabled disclosure will be against the assumed skill of the relevant worker or team in that field of technology.

5.6 Impact on R&D and experimentation

The outcome of the two-stage approach *Synthon* could be seen to have impact on how R&D is conducted. Courts in other jurisdictions have been criticised for unreasonably broadening the scope of anticipation, through inherent anticipation, a doctrine stating that the result of practising prior art is anticipated regardless of whether the result was explicitly disclosed.⁸⁷² The criticism for example is for the broadening of inherent anticipation to include chemical structures or subsets that are not ‘measurably produced by strict practice of the prior art’⁸⁷³ as it would have dire consequences for the patentability of many simple compound pharmaceutical structures. The likely risky effect of the Supreme Court method of assessing novelty is that undescribed reactions, intermediate products and processes or by-products of pharmaceutical reactions not directly taught by prior disclosure may be anticipated by the mere fact of being stipulated in the disclosure document.⁸⁷⁴ This would allow anticipation of reactions solely based upon theoretical predictions or extrapolations of the prior art. For example, it could be argued that the mere claim of pharmaceutically active salts is a genus claim, which does not necessary encompass all members of the genus, especially specific crystalline forms.⁸⁷⁵ The inclination to research more on these compounds would, as a result, be limited.

⁸⁷¹ *Ibid*, para.64, per Lord Walker. In accordance with EPO Examination Guidelines: ‘A document takes away the novelty of any claimed subject matter derivable directly and unambiguously from that document including any features implicit to a person skilled in the art in what is expressly mentioned in the document.’

⁸⁷² Jones B.W. ‘Smithkline v. Apotex: Broadening the scope of inherent anticipation and its impact on the patentability of chemical structures’ (2006) *The John Marshal Review of Intellectual Property Law*, p.456-476.

⁸⁷³ *Loc cit*.

⁸⁷⁴ Lim A.S.Y. and Christie, A.F. ‘Reach-through claims in biotechnology: an analysis of the examination practices of the United States, European and Japanese Patent Offices’ (2005) *Intellectual Property Quarterly*, p.236-266, p.238-239, define reach through-claims as ‘an attempt to extend the boundaries of a patent monopoly...to subsequent and future things that have some relationship to the current invention’

⁸⁷⁵ Jones, fn.872, p.468.

The value of experimentation in industry is appreciable and usually accompanies the R&D process. The skilled worker in *Synthon* is allowed to gain insight and learn by mistakes. This explains the factual situation in *Synthon* where the skilled worker had to do some experimentation or manipulation to get some results.⁸⁷⁶ Such experimentation may include overriding some errors within the patent claim itself, on the basis of practical common knowledge. This is safeguarded though, by the fact that skilled worker has to work the invention without undue experimentation⁸⁷⁷ of the R&D type. In *Asahi* the experimentation was differentiated by Lord Jauncey saying ‘Lord Westbury must have meant experiments with the view of discovering something not disclosed. He cannot have meant to refer to the ordinary methods of trial and error which involve no inventive step and generally are necessary in applying any discovery to produce a practical result.’⁸⁷⁸

An undesirable consequence of the test is that in industry, a scientist working in R&D, cannot have absolute confidence or fully depend on prior art disclosures in determining whether an experimentally observed scientific phenomenon could be considered new or not. They would first have to really think about the prior art and whether it is anticipating or not the seemingly new observation. It would in these cases be wise to actually put to test practically the prior art. When getting different results, one would not be sure whether they made any mistakes in their experiments or they have made an invention of their own that may itself deserves a patent. This is because in the pharmaceutical field, there is always an expectation that a formula or process developed in the laboratory is identical to the one offered patent protection.⁸⁷⁹ In *Synthon*, the enabling disclosure was one that needed ‘a good deal of skilled manipulation’ to get it to work.⁸⁸⁰ That is to say R&D processes that result in unexpected results from the prior disclosure have to be validated and tested.

⁸⁷⁶ Lord Hoffmann emphasised the importance of knowing whether it is disclosure or enablement being referred to, in order to judge whether some degree of experimentation is allowed: *Synthon*, para.30.

⁸⁷⁷ *Synthon*, para.31.

⁸⁷⁸ *Asahi*, p.544.

⁸⁷⁹ Kingston, fn.2, p.355.

⁸⁸⁰ *Synthon*, para.15.

At the same time we have to be critical of the environment where anticipating prior art documents are allowed to be riddled with mistakes and inconsistencies.⁸⁸¹ The IP readings were incorrect and the product was wax instead of crystalline, which are the characteristics that scientists use to conclusively identify substances. Lord Irvine opined that ‘the very first need of the business community is legal predictability.’⁸⁸² When the validity of what is posed as prior art is doubtful, it seems to defeat the very purpose of the patenting system. The patenting system premise is to put new information in the public domain. Hitherto, there has never been a reason to qualify this expectation with the fact that it has to be the right and correct information. It has always been a plausible assumption that novelty destroying prior art is accurate and correct at the relevant time. Moreover, with the advance in technology and R&D techniques, it would be expected that there would be a pool of refined methodologies that point out errors. It would be unfortunate that the court could be seen to allow incorrect disclosure information or unworkable processes to be condoned and merely blamed on poor choice of basic methodologies, as was the case in *Synthon*.

It is accepted that the incorrect IR was held a superfluous part of the evidence.⁸⁸³ This makes sense to legal practitioners. However to the scientist in industry, the IR is usually irrefutable proof of the identity of the claimed compound or substance. *Synthon* could have used this technique alone to specify the product, but chose to use the other techniques that add nothing else significant to the identity of the product. Using the other finger-printing techniques is merely confirmatory to what has already been established. Research laboratories equipped with numerous sophisticated equipments is typical of large firms which can absorb the extra costs whilst the smaller biotechnology firms would not plausibly justify extra equipment which performs the same function without improving the efficiency of the pharmaceutical discovery.

This industry discomfort can however be justified by the fact that there has to be a totality of all the evidence and high requirement of analytical techniques. As such, what is not compatible with the rest of the disclosure under examination has to be

⁸⁸¹ Nightingale P. ‘Economies of Scale in experimentation: Knowledge and technology in pharmaceutical R&D’ (2000) *Industrial and Corporate Change*, p.315-359.

⁸⁸² Lord Irvine, fn.27, p.334.

⁸⁸³ Sharples/Curley, fn.753, p.311.

properly scrutinised. Requiring a meticulous exploration of prior art by latter patentees to the level of spotting out mistakes acts a mechanism that consistently keeps the evolving state of art faultless. The laborious exercise of going through the prior art can be expected to be a foundation for good R&D and invariably result in genuinely good novel inventions. This is kept in check and counter-balanced by the appropriate level of skill of the relevant skilled worker in R&D. A lower required level of skill would be excused for the inability to spot out many obvious errors. On the other hand if it is assumed that the skilled worker has a competent degree of skill and experience, it would also be expected he would spot out errors. The problem with the Synthon method was the use of an unsuitable solvent, which the skilled worker would be expected to be able to resolve.⁸⁸⁴ He would also have been able to overcome any methodology problems within a reasonable time.

5.7 The principles of the newness test highlighted

It is well established that the concept of enabling disclosure is not a rule about the ‘inevitable result.’⁸⁸⁵ It is argued here that as a matter of principle, the two concepts are not and cannot be contrary to each other or mutually exclusive. The main logical reason for this is that they are tests that have the same goal, which is to assess whether information is new according to the legislation. It therefore comes as no surprise that the inevitable result of performing Synthon’s disclosure is also an enabling disclosure. The only discomfort is that on the facts of the case the inevitable result only comes after some skilled manipulation of the disclosure in practice.

To reconcile the perspectives of industry and legal practitioners a proposition could be made that the anticipation test could be conceptualised at two levels to be satisfied.⁸⁸⁶ These could be termed the objective and practical considerations. This notion is taken from the words of Jacob J., citing Judge Rogge at the eighth Symposium of European Patent Judges, where he stated that it may not always be possible to decide cases on logical grounds alone, suggesting that novelty assessment of an invention must ‘not be restricted to a purely formal comparison with known prior art, but must include the

⁸⁸⁴ *Synthon*, para.17.

⁸⁸⁵ [2002] EWHC 2573 (Pat), para.86.

⁸⁸⁶ Seymore, fn.26, suggests that patent law reforms should be directed to bridging the gap between the law and the norms of science.

actual information content that which goes beyond the words used.’⁸⁸⁷ The objective considerations are concerned with the theoretical principles that have to be applied and satisfied to prove novelty. It has to do with assessing whether the claimed result is achievable. This could be seen to do more with the theory behind whether the invention is possible or has been identified.⁸⁸⁸ Through the inevitable result route, Jacob J said this tests whether the result is achievable.⁸⁸⁹ Under the enabling disclosure route it tests whether the said invention is disclosed or theoretically been put in the public domain.

The practical consideration operates on case-by-case basis and may be more subjective in nature and includes the ‘actual information content going beyond the words used.’⁸⁹⁰ This is practical or factual or case-by-case assessment of anticipation. This consideration includes information that is intrinsically disclosed or needing no explanation. This seeks to test whether the said invention is in fact achievable.⁸⁹¹ This is the practical side of the invention and tests whether the inevitable result is indeed inevitable in practice. Under the enabling disclosure route this is whether the invention is indeed enabled. Lord Walker said ‘the practical importance of keeping the two requirements distinct will vary with the factual situation’,⁸⁹² showing the influence of the practical consideration in novelty assessment under the enabling disclosure route. Some writers⁸⁹³ opine that ‘enablement is a factual enquiry.’ Laddie J. in *Evans Medical Ltd’s Patent*⁸⁹⁴ said Lord Jauncey in *Asahi* ‘was only saying that describing a result as being achievable was not enough to prove it to be achievable in fact. It is the latter which amounts to enablement.’

It becomes clear that under the novelty limb, the patentability of inventions could be viewed as dependent on these two considerations; the objective and practical elements. Industry players would be well-advised to consider the practical side of

⁸⁸⁷ [2002] EWHC 2573 (Pat), para.92.

⁸⁸⁸ Doble, fn.842, p.515.

⁸⁸⁹ [2002] EWHC 2573 (Pat), para.95.

⁸⁹⁰ Ibid, para.92.

⁸⁹¹ Ibid, para.95.

⁸⁹² *Synthon BV v SmithKline Beecham Plc* (No.2) [2005] UKHL 59, para.64.

⁸⁹³ Sharples/Curley, fn.753.

⁸⁹⁴ [1998] RPC 517, p.535.

inventions before patent application or litigation is pursued. It is then prudent for industry to note that the practical elements can certainly be decisive in some cases.

South Africa

5.8 Nature of anticipation

Anticipation occurs in three ways; that of making subject matter available to the public, matter being contained in an application as subsequently published and from inventions used secretly and on a commercial scale within the Republic.⁸⁹⁵ Patents Act section 25(5) states:

‘An invention shall be deemed to be new if it does not form part of the state of the art immediately before the priority date of any claim to that invention.

(6) The state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way.’

The making of subject matter available to the public can be by description (written or oral), by use or in any other way. This is a similar situation in the UK.

Secret use still anticipates in South Africa, unlike in the UK where it ended with the 1949 Act. The Banks Committee concluded that prior secret use by the patentee as a ground for invalidating patents could not remain in the statutes if compliance with the Strasbourg Convention was to be achieved and recommended the removal of s.32(1)(l) and s.32(2) of the 1949 Act and instead replace with prior secret user right as found in Patents Act 1977, s.64.⁸⁹⁶ In South Africa, the prior secret use does not

⁸⁹⁵ Patents Act 1978, s.25(8) provides for invalidation of a patent of subject matter that forms part of prior secret use.

⁸⁹⁶ Board of Trade, *The British Patent System: Report of the Committee to Examine the Patent System and Patent Law* (1970, Cmnd 4407) (chairman Banks), p.260-261.

only absolve an alleged infringer, but the secret subject matter is deemed to form the state of the art for novelty purposes only.⁸⁹⁷

In terms of s.61(c) of the Patents Act 1978 a patent may be revoked on the ground that the patent is not patentable under section 25.

5.9 The Test for Novelty

The most authoritative case on novelty is *Gentiruco AG v Firestone SA (Pty) Ltd*⁸⁹⁸ which sets out the novelty assessment method for finding of anticipation of an invention. This has been formulated and summarised over the years as a three-step structured enquiry⁸⁹⁹ wherein the court said that the law of anticipation:

‘relates to the claims and not the description of the invention in the body of the specification. Hence the particular claim must be construed to ascertain its essential constituent element or integers. ... The prior printed publication or patent alleged to be anticipatory is then construed... The two documents are then compared to ascertain whether the prior patent was granted for, or the prior printed publication “describes”, the same process, etc., as that claimed.’

The different steps of the structured novelty assessment method have been applied over the years and will be examined in turn below.

A. Ascertain the essential elements or integers of the patent claim.

This is a claim construction exercise that seeks to establish the meaning of the patent to establish whether the patent has been made available to the public.⁹⁰⁰

⁸⁹⁷ Patents Act, s.25(10) direct that prior secret use forms part of the state of the art for novelty purposes only.

⁸⁹⁸ 1971 BP 58 (A).

⁸⁹⁹ *Ibid*, p.138F-139A. Test also summarised in *Netlon Ltd and Another v Pacnet Ltd* 1977 BP 87, p.108F-109B.

⁹⁰⁰ *Adam Emil Sierzputowski v Anglo American Corporation of SA Ltd* 1972 BP 346 (CP), p.350, the court stated that the first task in anticipation assessment is to ascertain the nature of the invention.

Each claim stands on its own. Jansen JA in *Letraset Ltd v Helios Ltd*⁹⁰¹ postulated that:

‘each claim of the complete specification must be considered separately. It is not a question of considering all the claims and the body of the specification as a totality and thereby determining whether “the invention was not new”. Each claim must...be taken separately, and if the claims are ambiguous, no reference may be made to the body of the specification to enlarge or limit its scope (but the body may constitute a dictionary).’

B. The meaning of the prior art document is ascertained.

This is to say the prior making available to the public of matter or patent alleged to be anticipatory is then construed. In this step the court seeks to establish the interpretation and import of the anticipatory document.

There are restrictions on the type of prior art documents that can anticipate an invention. Disclosures that do not enable do not anticipate the invention. In *Letraset Ltd v Helios Ltd*,⁹⁰² the court stated it this way:

‘I should have thought independently of authority that no prior description ought to invalidate a patent unless you could make the thing from the description. I mean unless a person of ordinary skill in the trade could make it from the description.’

The alleged anticipatory document is construed at the date of making available to the public. As such, the construction of the alleged anticipating document, as was the case in *Gentiruco*,⁹⁰³ is made ‘to the exclusion of information subsequently discovered.’ This prevents hindsight. The court in *Gentiruco* warned against the influence of

⁹⁰¹ *Letraset Ltd v Helios Ltd* 1972 BP 243 (A).

⁹⁰² (1972) BP 243, p.273G-274A, cited with approval in *B-M Group v Beecham Group* 1980(4) SA 536 (A).

⁹⁰³ *Gentiruco*, p.139E, approving *Ore Concentration Company. (1905) Ltd v Sulphide Corporation Ltd*. 31 RPC 206, p.224.

hindsight which would unduly increase the anticipatory ability of a prior art document. The court said:⁹⁰⁴

‘If he adopted the process also because of some subsequently acquired knowledge or hindsight induced by the patent in suit, which taught him that it was worthwhile and effective, the example would not test for anticipation.’

C The anticipatory document and invention or claims in suit must then be compared.

In *Netlon Ltd and Another v Pacnet (Pty) Ltd*⁹⁰⁵ Trollip JA said ‘...the exercise is primarily one of construing and comparing the two documents.’ This comparison is done to see to if the anticipatory document was made available to the public through describing the same process or product as the patent in suit. Streicher JA in *Schlumberger Logelco Inc v Coflexip SA*⁹⁰⁶ pronounced that the comparison of the invention to the prior art description seeks to find out:

‘whether it sets forth or recites at least the latter’s essential integers in such a way that the same or substantially the same process or apparatus is identifiable or perceptible and hence made known or the same or substantially the same product can be made from that description in the prior publication; if the description in the prior document differs, even in a small respect, provided it is a real difference, such as the non-recital of a single essential integer, the anticipation fails.’

The authority on the meaning of ‘describe’ in South Africa is the dictum of Trollip JA in *Gentiruco*. The learned Judge of Appeal said:

‘In regard to a prior publication, the ordinary meaning of ‘describe’ means ‘to set forth in words or recite the characteristics of’. Hence for it to ‘describe’ the invented process, etc., it must set forth or recite at least its essential integers in such a way that the same or substantially the same process is identifiable or perceptible and hence made known, or the same or substantially the same

⁹⁰⁴ *Ibid*, p.143D.

⁹⁰⁵ 1977 (3) SA 840 (A), p.861H-862B.

⁹⁰⁶ *Schlumberger Logelco Inc v Coflexip SA* 2002 BIP 35, p.44.

thing can be made, from that description. ‘Substantially the same’ means practically the same, or, to use Lord Westbury’s phrase adopted by Wessels, J.A. in *Veasey’s* case,⁹⁰⁷ the same ‘for the purposes of practical utility’, i.e., substance and not form must be regarded.’⁹⁰⁸

The objective of construing and comparing the prior art document to the invention is to establish whether it has been made available to the public, usually by disclosure or by use. What is of concern is that the Supreme Court of Appeal in *Filta-Matix (Pty) Ltd v Carl Freudenberg*,⁹⁰⁹ under the 1952 Act, said ‘providing a copy to one person hardly amounts to “publication”, although it shows a willingness to publish.’ There are provisions for sharing the invention’s subject matter with those who are involved in the R&D or development of a patent document without risking anticipation, but disclosure to anyone outside of this circle constitutes making available to the public.⁹¹⁰ The current statute is now clear: the state of the art consists of all matter which has been made available to the public by description or use or any other way. This is without discrimination or preference of the method of making available to the public. Disclosure to one person could be said to be publication or making the invention available to the public.

Of interest is how in South Africa the material facts of *Merrell Dow* could be decided, where the fact that volunteers in clinical trials were given terfinadine and therefore, unaware, made the acid metabolite in their liver was held to be anticipated by disclosure, rather than by use. In South Africa the unique situation is that the state of art for novelty is extended by the recognition of prior secret and commercial use under s.25(8) as matter that has been made available to the public by virtue of s.25(6). Harms JA in *McKelvey and others v Deton Engineering (Pty) Ltd and another*⁹¹¹ confirmed that this section ‘extends the state of the art to include use of an invention not available to the public, namely secret use on a commercial scale within the Republic.’ Therefore the administration of terfinadine under clinical trials

⁹⁰⁷ *Veasey v Denver Rock Drill and Machinery Co Ltd* 1930 AD 243, p.269.

⁹⁰⁸ *Gentiruco*, p.139A-C.

⁹⁰⁹ BIP 284 (SCA), p.292D.

⁹¹⁰ Patents Act 1978, s.26(a).

⁹¹¹ [1997] 3 All SA 569 (A), p.573.

conditions would make the terfinadine metabolite to be considered anticipated under South African law.

It has been questioned whether the enabling disclosure doctrine applies in South African law by academic commentators.⁹¹² There has been reticence on whether foreign law on anticipation should be followed in South Africa, especially that of the EPO.⁹¹³ It has been warned that ‘the concept of enabling disclosure should not be imported into South African law.’⁹¹⁴ These views do not seem to be supported by case law on novelty.

MacArthur J in *Elan Transdermal Ltd v Ciba Geigy (pty) Ltd*⁹¹⁵ premised his decision on the assumption that enabling disclosure is part of South African law concluding that ‘on the assumption that the principle of “enabling disclosure” is part of our law- and I bear in mind that Lord Westbury’s statement about anticipatory documents in *Hills v Evans* was adopted by *Veasey*’s case... it is apparent that unless the method of putting the earlier document into operation is so self-evident, it will not be treated as anticipation.’ He stated that UK novelty rules ‘for practical purposes... can be equated to’ the South African provision.⁹¹⁶ This reasoning seems to be careful about legal transplants, wherein the imported rules may not serve the useful purposes served in the original jurisdiction or they are applied contrary to the principles for which they were designed. The argument advanced by the court in *Elan Transdermal* therefore seem to be well-reasoned and supported by rational novelty principles relative to the material facts of the case.

It is unclear though whether the two-staged enabling disclosure method as restated in *Synthon* could be argued as applying in South Africa. In South Africa, after *Elan Transdermal*, the elements of the enabling disclosure method seem to have been unsystematically applied and integrated and yet in *Synthon* the disclosure and enablement requirements were held to be distinct elements of the composite anticipation limb of patentability. Moreover, doubt as to whether the *Synthon* method

⁹¹² Burrell, p.229.

⁹¹³ Burrell, p.229.

⁹¹⁴ Burrell, p.229.

⁹¹⁵ 1994 BP (CP) 1, p.23.

⁹¹⁶ *Ibid.*

applies is compounded as the concept was only raised by the Commissioner of Patents in *Elan Transdermal* but has neither been addressed or approved by the more senior Supreme Court of Appeals which has adjudicated novelty issues since *Synthon*.

This thesis concludes that in the South African case law there does not seem to exist separate disclosure and enablement limbs to anticipation. In the novelty assessment method, the disclosure and enablement rules tend to be used interchangeably. Merely reciting the passages from the UK cases used to develop the doctrine of enabling disclosure does not automatically confer its principles onto the South African assessment methodology. In the UK once disclosure has been established, enablement is then independently assessed and the question is no longer what the person skilled in the art would understand from the disclosure, but whether he would be enabled to perform it. On the other hand, in South Africa after the integers of the patent and interpretation of the prior art disclosure is made, the courts offer little guidance on how the comparison or evaluation is to proceed. The South African courts therefore could be seen as only offering limited guidance on how the disclosure and enablement should be approached.

5.10 Role of the skilled worker

In the assessment of anticipation, the person skilled in the art also plays a crucial role in South Africa as in the UK. Under the previous law, however, the courts were of the view that the person skilled in the art played a minimal role. This view was expressed in *Letraset v Helios*,⁹¹⁷ with Jansen JA saying:

‘But must the court look at the document through its own eyes, or through the eyes of “an ordinary workman skilled in the art”? It appears to be implicit in *Genturico* that the former is the case:-

“Again it is emphasised: The opinions of expert witnesses that a document does or does not anticipate the patent in suit must be disregarded for that is for the courts to decide. “Again” is a reference to the prior discussion of the admissibility of evidence to construe a specification, where it appears that the

⁹¹⁷ (1972) BP 243, 272E-G, citing *Genturico*, citations omitted.

court itself construes the document, and in doing so, has but limited recourse to the skilled worker.’”

The interpretation of the ruling in *Letraset* has evolved, with some arguing that the skilled person has more of a role to play in anticipation assessment. Jansen JA in *Filta-Matrix (Pty) Ltd v Carl Freudenberg*⁹¹⁸ was quoted, citing Lord Reid in *C van der Lety v Bamfords Ltd* 1963 RPC 61, p. 71, as saying:

‘There is no doubt that, where the matter alleged to amount to anticipation consist of written description, the interpretation of that description is, like any document, a question for the court assisted where necessary by evidence regarding the meaning of technical language. It was argued that the same applied to a photograph. I do not think so. Lawyers are expected to be experts in the use of the English language, but we are not experts in the reading or interpretation of photographs. The question is what the eye of the man skilled with appropriate engineering skills and experience would see in the photographs, and that appears to me to be a matter for evidence.’

The interpretation of the meaning of evidence in pharmaceutical industry is sometimes complex. It seems the meaning or significance scientific evidence is more appropriately evaluated through the eyes of the person skilled in the art, although the court makes the final decision. To this effect the courts have stated that there has to be a balance in the contribution that is made by the person skilled in the art in the assessment of the novelty.⁹¹⁹

The focus of the court assessment method seems to be on what the person skilled in the art cannot do in the novelty evaluation rather than how they are relevant in the assessment. The court’s emphasis on this non-involvement is seemingly to prevent, the court being led by the person skilled in the art into a conclusion.⁹²⁰ But this occurs at the expense of the court providing more guidance on how the move is made from having established the integers of the patent claims and the prior art, into the conclusion of whether or not there is anticipation. That is to say, in the quest to exert

⁹¹⁸ 1997 BIP 264(SCA), 294A-B.

⁹¹⁹ *Schlumberger Logelco Inc v Coflexip SA* (2002) BIP 35, p.44.

⁹²⁰ *Ibid.*

authority on the final decision as one to be made by the judiciary rather than the scientist, the role of the scientist in judging anticipation is muddled with uncertainty.

5.11 Impact on R&D and experimentation

The traditional drug discovery practice proved to be unsatisfactory, whereby research started with analysis of the candidate molecules into finding what disease they may treat. The more favourable approach is now the rational drug approach whereby ‘much depends on knowing the nature of the disease and understanding how it affects the body’s chemistry.’⁹²¹ South Africa therefore needs to invest in disease studies that are prevalent in its population to come up with suitable pharmaceuticals. This is because it has been observed that the lack of medicines for diseases prevalent in developing countries is due to the lack of therapeutic innovation.⁹²² The novelty standard should not therefore be a bar in an industry where there is a lot of R&D and experimentation that is directed to finding tangible solutions. The anticipation tests should recognise that experimentation and trial-and-error is an integral part of the process.

The legislature and the courts have been sympathetic to the realities of industry wherein it is standard practice that a new invention will come about via experimentation. Patents Act 1978 s.26(b) provides that a patent is not invalid by reason only of the fact that the invention in respect of which the patent was granted or part thereof was disclosed, used or known prior to the priority date of the invention as a result of the invention being worked in the Republic by reason of reasonable technical trial or experiment by the applicant or patentee. This allows the patentee who sustains R&D for some time with the benefit of not being pre-empted by experimentation disclosures or uses that may be made in the life cycle of the inventive process.

Besides the allowance for the experimentation in coming up with inventions, the law allows some limited experimentation in understanding a patent. This, however, does

⁹²¹ Ballance, et al, fn.766, p.101.

⁹²² Abbott/Graham, fn.34, p.132.

not extend to conducting experiments said to be of the R&D type. In *Transdermal Ltd v Ciba Geigy (pty) Ltd*⁹²³ the court was of the view that when a person skilled in the art has to do further experiments with regard to the alleged anticipating disclosure, the invention will not be anticipated and '[m]ere suggestions made *ex cathedra* without anything backing them up' will not destroy novelty.

The courts seem appreciative of the time and effort that may be put into the R&D and experimentation of perfecting inventions that are subsequently released into the public domain. They are careful in the admission of alleged anticipatory prior art that with the passage of time may appear anticipating. In *Lastraset v Transfertech and others*⁹²⁴ the court stated that '[w]here, as in the present case, there have been considerable development in the field in the period of approximately 20 years that has passed since the date of the publications, the danger of applying hindsight in the construction of the relevant document is considerable, but must be vigorously avoided.' However, no direction was given on how this could be achieved.

UNITED KINGDOM AND SOUTH AFRICA

5.12 Novelty Assessment Suggestions in the UK and South Africa

At the international level, the TRIPS Agreement provided novelty as a minimum standard and left what has been called the 'wobble room'⁹²⁵ for countries to define for themselves. There have been recommendations that developing countries could accommodate the minimum standards into their national development goals by adopting relatively stringent novelty standards for instance.⁹²⁶ Reform and harmonisation instruments like the SPLT was an opportunity to find consensus on

⁹²³ 1994 BP (CP) 1, p.20.

⁹²⁴ 1981 BP 17 (CP), p.29.

⁹²⁵ Reichman J.H. 'From free riders to fair followers: Global competition under the TRIPS Agreement' (1997) *New York University Journal of Intellectual Property Law and Policy*, p.11-63, (described TRIPS as 'leav[ing] developing countries ample 'wobble room' in which to implement national policies favouring the public interest in free competition').

⁹²⁶ Reichman J.H. 'Intellectual property in the twenty-first century: Will developing countries lead or follow' (2009) *Houston Law Review*, p.1115-1185, p.1132-1133.

what would be held as new and the applicable tests at the international level.⁹²⁷ South Africa could have influenced how the assessment is to be made.⁹²⁸

At domestic level, South Africa has not had a review of the patentability requirements. It seems to be a missed opportunity that a review of the UK patentability requirements did not include the novelty limb.⁹²⁹ The review could have also been extended to novelty. Such possible reviews and reforms could include for example, a statutory statement of the novelty assessment methods including an indicative list of the factors that one should consider when assessing newness. This would guarantee clarity to third parties in the certainty and clarity-sensitive pharmaceutical and associated industries. Zakos⁹³⁰ has suggested that ‘there is a need to tailor patent law to accommodate particular industries’ as patent law is increasingly tasked with resolving technology specific issues. Continual reviews and reforms of whether the novelty criterion is still compatible with developments in science and technology is recommendable.

Novelty has unique implications in South Africa. The blanket and unsubstantiated citation of foreign law in South Africa, commonly that of the UK, would not be helpful in illuminating the doctrine of anticipation. South Africa is not bound by foreign law but international dictates of science would persuade one of the need for the judiciary to acknowledge the transnational reach of innovation. There is no reason to deviate from international legal norms regulating science for the sake of exerting independence at the compromise of accepted or universal scientific principles and customs. The judiciary has accepted the similarity of South African novelty statutes to that of the UK, therefore it seems desirable that novelty assessment is influenced by

⁹²⁷ Takenaka T. ‘The best patent practice or mere compromise? A review of the current draft of the Substantive Patent Law Treaty and a proposal for a “first-to-invent” exception for domestic applicants’ (2003) *Texas Intellectual Property Law Journal*, p.259-350, p.297-298.

⁹²⁸ Masungu S.F. ‘International intellectual property standard-setting: A review of the role of Africa in shaping the rules for the regulation of the knowledge economy’ (2004) *African Yearbook of International Law*, p.169-189, p.182-183.

⁹²⁹ Review of inventiveness in the UK by The Patent Office, ‘*The inventive step requirement in the United Kingdom patent law and practice*’, 2005, Newport. (available online at www.patent.gov.uk).

⁹³⁰ Zakos G. ‘Patentability of biotechnology, cloning and nanotechnology’ (2004) *Intellectual Property and IT Law*.

jurisdictions where novelty of the latest technologies have already been adjudicated.⁹³¹

5.13 Conclusion

At first brush the *Synthon* case is a straightforward case, which should not have reached the Supreme Court.⁹³² It is fortunate though that it eventually reached this level, as the court got a chance to clarify and simplify how novelty is tested. The court stated that the novelty question should be approached in a meticulous, two-stage staggered manner, each of which has its own relevant points to consider. In South Africa, novelty assessment is also structured into stages, which makes for easier analysis of the concept. There however does not seem to be clear guidance or at least more detailed rules on how each stage should be approached. A recommendation is made that the South African courts make more detailed pronouncements on the appropriate elements of the structured approach in carrying out the assessment.

The weakness of the novelty assessment tests in both jurisdictions is that they can result in odd results overall or have some subjective elements within them. As Soetendorp⁹³³ observes of corporations that ‘some may prefer to invest in innovation that has been protected by trade secret, rather than a weak patent that carries the risk of litigation’ it is imperative that the risk be minimised by a novelty mechanism that eliminates the possibility of unpredictable results. A suggestion is made that guidance be given by the courts on how to avoid the subjective elements, for instance hindsight, rather than mere statements that it should be avoided. The chapter explored how this could be achieved, a suggestion directed at making the novelty criteria more appreciative of the practice of the science under consideration.

⁹³¹ Thambisetty fn.158, p.3-4, argues that patent law doctrines and interpretation of patentability standards tends to ‘lock-in’ into particular ones over other viable alternatives with the passage of time.

⁹³² Sharples/Curley, fn.753, p.311.

⁹³³ Soetendorp, fn.13, p.83.

CHAPTER SIX

NON-OBVIOUSNESS

6.1 Introduction

It has been said that ‘everything that can be invented has been invented.’⁹³⁴ This can be attributed to and reflects the overwhelming volume of new inventions and the cutting-edge advances made in the state of the art at any one period in time that seem to be of unsurpassable genius. The reality though is that patents will usually be sought for inventions that only have a slight improvement to that which is already state of the art.⁹³⁵ At the onset of research the potential patentee may intentionally look to making a small change in the state of the art. For example, this could be when there is broad patent that exist or in niche research activities where a small improvement could lead to big rewards. Alternatively patentees may find out during the patenting process that there is much prior art that is comparable to what they thought was groundbreaking research.⁹³⁶

It has been said that it is mostly in the pharmaceutical industry where trivial patents are granted and these block access to medicines without enriching the public store of knowledge, which is a cost to society.⁹³⁷ On the other hand, a situation to be avoided is where meticulous research is not able to benefit society as it cannot attain a high non-obviousness bar or where genuine inventions are easily invalidated.⁹³⁸ The non-obviousness requirement therefore serves to prevent these extremes from occurring. In other words the non-obviousness doctrine is designed to attain the optimal equilibrium between the benefits and the costs of the patent system.

⁹³⁴ This quote is attributed, albeit controversially, to US Patent Commissioner Charles H. Duell in a letter to US President McKinley in 1899.

⁹³⁵ Correa C.M. ‘Public health and patent legislation in developing countries’ (2001) *Tulane Journal of Technology and Intellectual Property*, p.1-53, p.23. Dutfield/Suthersanen, fn.380, p.379.

⁹³⁶ It is common in infringement or validity challenges that there be amendments made to the patent specification, for instance under Patent Act 1978, s.61(3) in order to avoid an existing patent.

⁹³⁷ It has been said that the inventiveness criterion is more accurately called the ‘non-triviality’ requirement: Merges R. and Duffy J. *Patent Law and Policy*, 4th ed (2007) London: LexisNexis Butterworths, p.612.

⁹³⁸ It was said that non-obviousness is difficult to establish when a problem had been sought for many years without success: *Samuel Parkes & Co. Ltd. v Cocker Bros. Ltd.* (1929) 46 RPC 241, p.248.

This section will begin with an examination of the statutory definitions of the non-obviousness criteria in both jurisdictions. The current approach toward patentability under the non-obviousness limb will then be analyzed and an evaluation of whether the standard is set at the appropriate level will be made. As an ideal standard, the non-obviousness assessment methods are not to be riddled with loopholes allowing hindsight bias that is introduced later on after the priority date or attacks to patent validity that are fundamentally based on hindsight and therefore unfair to inventors.⁹³⁹ A non-obviousness assessment improvement will be suggested that seeks to balance the competing interests of the opposite extremes of the non-obviousness standard as applicable to pharmaceutical inventions that may be new but uncertain as to whether they are non-obvious.

6.2 The statutory nature of non-obviousness

Non-obviousness is a patentability requirement that was introduced later in the development of the patent system than the other limbs to patentability. This requirement, because of its function, has been upgraded to being perceived as the ultimate standard to patentability.⁹⁴⁰ It was out of the realization that only requiring that a patent be new and useful or be of some utility was not enough to provide incentives for inventing. There had to be an additional requirement that would guard against the obtaining of patents that are simply variants of the state of the art.⁹⁴¹ In new fields of technology where variants are still uncertain, the application of well-known techniques could involve an inventive step.⁹⁴² However, in *Aeomica Inc*,⁹⁴³ it was held that the identification of a human homologue of a previously uncharacterized gene from another species using bioinformatics, and therefore

⁹³⁹ *British Westinghouse Electric and Manufacturing Co Ltd v Braulik* (1910) 27 RPC 209, at p.230.

⁹⁴⁰ Witherspoon J. (ed) *Nonobviousness- The ultimate condition of patentability* (1980) Arlington: Bureau of National Affairs. Merges/Duffy, fn.937, p.612.

⁹⁴¹ *In the US case Great Atlantic and Pacific Tea Co. v. Supermarket Equip. Co.*, 340 U.S. 147 (1950) at 15, it was framed thus: 'it is not enough that the invention must be new and useful, it has to be of such a quality and distinction that masters of the scientific fields in which it falls will recognize it as an advance'.

⁹⁴² Thamisetty, p.187.

⁹⁴³ BL O/286/05.

eliminating the need for wet-lab experiments, was not inventive regardless of the method used to identify the homologue.

6.2.1 United Kingdom

Above the requirement of the invention being novel, the Patents Act 1977, s.3⁹⁴⁴ requires an invention to involve an inventive step. To objectively determine what qualifies as inventive deserving of patenting, the legislature introduced the inventive step, which is essentially a comparison of the prior art and the claimed invention to decide if there is a difference, more than a workshop variation, which warrants a patent monopoly. The statute goes on to explain that the inventive step in an invention could be identified as ‘not obvious to a person skilled in the art, having regard to any matter which forms part of the state of art.’⁹⁴⁵

The test of non-obviousness seeks to make an objective and qualitative determination of the difference between the closest state of art and the alleged invention.⁹⁴⁶ This criteria to patentability is the most difficult to define and apply objectively and uniformly in practice.⁹⁴⁷ The criterion of non-obviousness demands creativity on the part of the inventor.⁹⁴⁸ It complements the newness requirement by making sure that the inventor does not block the public in making obvious modification of the state of art. ‘In effect, it excludes from patentability anything which is technically or practically derivable or discernible from the available information by someone skilled in the relevant art.’⁹⁴⁹ Thus the skilled worker must be free to use material that was ‘lying in the road’ toward the invention.⁹⁵⁰

⁹⁴⁴ Formerly it was s32(f), of Patent Acts 1949. An equivalent provision in the EPC is Art.56.

⁹⁴⁵ 1977 Patents Act, s.2.

⁹⁴⁶ *Molnlycke*, p.112

⁹⁴⁷ By the UKIPO’s own admission, inventiveness is the most difficult to assess. At p.2, para.1.2, and p.7 para2.11, The Patent Office, ‘The inventive step requirement in the United Kingdom patent law and practice’, 2005, Newport. Also, Grubb argues that compared to the novelty criteria, the inventiveness criteria is subjective and most litigated issue in patent law: Grubb fn.256, p.357.

⁹⁴⁸ Willison D.J. and MacLeod S.M. ‘Patenting of genetic material: Are the benefits to society being realised?’ (2007) Available <http://www.cmaj.ca/cgi/content/full/167/3/259>.

⁹⁴⁹ Griffiths A. (1999) ‘Windsurfing and the inventive step’ (1999) *Intellectual Property Quarterly*, p.160-190, p.163.

⁹⁵⁰ *Genentech Inc’s Patent* [1989] RPC 147.

Concerning selection patents, which are common in the pharmaceutical sector,⁹⁵¹ ‘the inventive step in a selection patent lies in the discovery that one or more members of a previously known class of products possess some special advantage for a particular purpose, which could not be predicted before the discovery was made’⁹⁵² For pharmaceutical inventions specifically, it has been said that where there are structural obviousness inclinations, surprising results or advantages may render the compounds non-obvious.⁹⁵³ The consideration for the monopoly retained for the selection, is the public disclosure of the special advantages that the members of the class possess.⁹⁵⁴ Thus non-obviousness in selection patents inversely correlates with the degree of expectancy of results or unique qualities in the claimed invention.

The inventive step has been declared ‘the largest single cause of uncertainty about the validity of patents and hence a frequent inflator of the scales and length of patent disputes’⁹⁵⁵ This could be perpetuated by the courts if they fail to remedy this deficiency with a comprehensive and precise definition of the criteria or elements that are to be considered when assessing an invention’s non-obviousness.⁹⁵⁶ It is therefore important that the approach used by the courts is understood, and will be examined in the sections below.

6.2.2 South Africa

Similar to the UK, the Patents Act 1978, s.25(1) requires that an invention be granted for inventions that involve an inventive step, in addition to being new. Similar to the current UK situation, the Patents Act 1978, s.25(10) prescribes that ‘an invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the

⁹⁵¹ ‘A “selection patent” is a patent under which a single element or a small segment within a large known group is “selected” and independently claimed based on a particular feature not mentioned in the large group’ (Correa C.M. ‘Public health and patent legislation in developing countries’ (2001) *Tulane Journal of Technology and Intellectual Property*, p.1-53) and therefore selection patents are useful in making an invention in fields which are generally known (Jeffs J. ‘Selection patents’ (1988) *European Intellectual Property Review*, p.291-301).

⁹⁵² *In re I. G. Farbenindustrie A.G.’s Patents* (1930) 47 RPC 239 per Maugham J, p.322-323.

⁹⁵³ Grubb P.W. *Patents in chemistry and biotechnology*. (1986) London: Clarendon Press, p.231.

⁹⁵⁴ *Beecham Group Ltd. v Bristol Laboratories International S.A.* [1978] RPC 521, p.579.

⁹⁵⁵ Cornish W., Llewelyn D. and Aplin T. *Intellectual property: Patents, copyright, trademarks and allied rights*, 7th edn. (2010) London: Sweet and Maxwell, para5-28.

⁹⁵⁶ Griffiths, fn.949, p.160.

art, having regard to any matter which forms... part of the state of the art.’ The state of the art comprises of matter from ‘immediately before the priority date of the invention.’⁹⁵⁷ The ‘immediately’ is superfluous and seems to have been included as an unnecessary drafting emphasis delineating the state of the art cut-off day as the day before the application is filled.

Concerning selection patents, the rule in South Africa is similar to and draws from the UK case law. A class of chemicals that exhibit unique characteristics that are not possessed by the group as a whole may be non-obvious in some cases. In *The B-M Group Pty Ltd v Beecham Group Ltd*⁹⁵⁸ the court held that ‘the essence of inventiveness of such a patent in our law would be the discovery that “the selected members” all have some substantial, special, peculiar advantage over the other, unselected members that was not obvious having regard to what was common knowledge at the effective date.’

Due to their common statutory foundations, it is unsurprising that there is a lot of reference to UK decisions in the assessment of non-obviousness in South African courts. Similar to the UK, obviousness is in issue in the majority of IP cases that come to court.⁹⁵⁹ It is upon the courts, therefore, to develop the law and apply the right standard or tests that would not in effect abrogate what the legislature promulgated. The thesis now turns to tests that have been applied by the courts in the two jurisdictions in interpreting statutory obviousness.

6.3 The Structured Approach in Non-obviousness Analysis

6.3.1 United Kingdom

Case law on the concept of the inventive step is framed by the case *Windsurfing International Inc v Tabur Marine (Great Britain)*.⁹⁶⁰ The court laid-out an approach that has come to be of use the world over, including in South Africa, for assessing

⁹⁵⁷ Patents Act 1978, s.25(10).

⁹⁵⁸ *The B-M Group Pty Ltd v Beecham Group Ltd* 1980 BP 343, p.381-382.

⁹⁵⁹ Burrell, p.157.

⁹⁶⁰ [1985] RPC 59.

non-obviousness. It has been said that the *Windsurfing* test does not aim to clarify the meaning of non-obviousness requirements.⁹⁶¹ Rather it seeks to identify the components of the requirement and provide a sequence of steps of what should be under consideration when assessment is made. The structured approach identified four steps to be taken in assessing non-obviousness.

Some writers insisted that these steps be firmly and separately taken at every evaluation.⁹⁶² Other views shy away from placing the judge-made approach on a statutory footing as has been suggested at times.⁹⁶³ At one time after the decision it was even suggested that the steps are wrong and without authority.⁹⁶⁴ The Court, mindful of the need to use court-made tools to fill voids in statutes,⁹⁶⁵ cautioned that there could be over-analyzation of a court-made approach, leading to results that the legislators did not intend.⁹⁶⁶ Ultimately the courts have acknowledged that this approach cannot fit each and every case.⁹⁶⁷

The *Windsurfing* approach first got a rearrangement in *Molnlycke AB v Procter & Gamble Ltd (No.5)*⁹⁶⁸ and further rearranged by Jacob LJ in *Pozzoli v BDMO*⁹⁶⁹ in a quest to clarify the structural approach to be made when assessing obviousness:

- ‘(1) (a) Identify the notional “person skilled in the art”
- (b) Identify the relevant common general knowledge of that person;
- (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

⁹⁶¹ Griffiths, fn.949, p.161.

⁹⁶² Garland P. ‘Patents- revocation, infringement, invalidity through obviousness’ (1997) *European Intellectual Property Review*, p.290-291, p.291.

⁹⁶³ Grant G. and Gibbins D. “‘Inventive concept’-is it a good idea’ (2005) *European Intellectual Property Review*, p.170-175, p.175, the authors conclude that there are dangers when judicial summaries of applicable principles rise to the level of statutory texts, such that tests such as the *Windsurfing* test, actually become a distraction from the compulsory statutory enquiry or questions.

⁹⁶⁴ Gratwick S. “‘Having regard to what was known and used’-revisited’ (1999) *Law Quarterly Review*, p.403-414, p.408.

⁹⁶⁵ Judges, especially in patent law devise and use some mechanism to bridge the gap between general principle and the specific facts of the case, Grant/Gibbins, fn.963, p.170.

⁹⁶⁶ Lord Walker, in *Kirin-Amgen*, para.138-139.

⁹⁶⁷ In *Ranbaxy UK Ltd v Warner-Lambert Co.* [2005] EWHC 2142 (Patents), para.69, Pumfrey J. identified two problems with the test and suggested there could be more he was not aware of.

⁹⁶⁸ [1992] RPC 21, CA.

⁹⁶⁹ *Pozzoli v BDMO* [2007] EWCA Civ 588, para.2.

(3) Identify what, if any, differences exist between the matter cited as forming part of the ‘state of the art’ and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?’

The modified *Windsurfing/Pozzoli* approach has been applied by subsequent courts. Fysh QC sitting as a High Court judge in *Aerotel Ltd v Wavecrest Group Enterprises Ltd & Ors*⁹⁷⁰ followed the modified *Windsurfing/Pozzoli* approach. This modified approach has the advantage of initially settling facts that are rarely in dispute, as step one. That is not to diminish the importance of being careful when judging the identity of the person skilled in the art and the prior art. In fact, it makes sense to first settle the identity of the skilled man ‘for it is only through the eyes of the skilled man that one properly understand what such a man would understand the patentee to have meant and thereby set about identifying the concept.’⁹⁷¹ The more complex decision is usually the identification and assessment of whether indeed there is the inventive concept in an invention under step two. The modified approach therefore motivates the initial settling of the more objective, and usually uncontested, facts in the first question, after which the more subjective facts in question two to four could be decided.

The general approach to obviousness seems to be that the assessment must be considered on the facts of each case. In *Generics v Lundbeck*⁹⁷² the court said ‘the court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.’ Commentators have noted that in *Conor*, the House of Lords ‘did not want

⁹⁷⁰ [2008] EWHC 1180 (Pat), para.124 and 12. It has also been followed in *Eli Lilly & Company v Human Genome Sciences Inc* [2008] EWHC 1903 (Pat), para.266 and acknowledged in *Symbian*, para.16.

⁹⁷¹ *Pozzoli Spa v BDMO SA & Anor* [2007] EWCA Civ 588, para.15.

⁹⁷² [2007] RPC 32, para.72.

to endorse or formulate a particular approach, but instead wanted to stress the importance of the facts and circumstances in each case.’

The statutory requirements in the assessment of obviousness have two paramount considerations that will be considered in more detail in subsequent sections in this thesis. First, the notional skilled worker, whose reference point is to be used in the evaluation, has to be clearly understood. Secondly, the inventive concept, the gist of the non-obviousness requirement, is the aspect that is claimed as an invention, which is to be non-obvious to the skilled technician. These considerations have a determinant effect on the patentability of inventions.

In evaluating obviousness, tribunals have sometimes used the problem-solution approach which is distinct from the UK case law approach.⁹⁷³ The EPO’s problem-solutions approach is stated thus in the EPO Substantive Examination Manual:⁹⁷⁴

- ‘(i) determining the “closest prior art”,
- (ii) establishing the “objective technical problem” to be solved, and
- (iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.’

UK Courts and the UKIPO have not readily followed this approach even though most of the disputed patents are European patents with UK designations. The CIPA Guide to the Patents Act⁹⁷⁵ attributes this apparent anomaly to the fact that the implementing regulations and rules, specifically EPC r.24(1)(c), provide that the description of the patent specification shall disclose the invention in such terms that the technical problem and its solution can be understood and state the advantageous effect, which is not prescribed in section 14 of Patents Act or Patent Rules 1995 or 2007.

⁹⁷³ *Ranbaxy UK Ltd v Warner-Lambert Co.* [2005] EWHC 1242, para.54, Pumfrey J. in finding the patent for atorvastatin, a cholesterol synthesis inhibitor obvious, had to examine both the problem-solution and *Windsurfing* as competing approaches in obviousness analysis. England P. and Parker S. ‘Obviousness in the new European order’ (2012) *Journal of Intellectual Property Law & Practice*, p.805-815, assert that that the advent of the Unified Patent Court provides an opportunity for truly a multi-factorial approach to obviousness.

⁹⁷⁴ EPO Substantive Examination Manual, VI, 8.5.

⁹⁷⁵ CIPA Guide to the Patents Act, 6th ed, p.78.

The problem-solution approach was criticized in *Actavis UK Ltd v Merck & Co Inc*,⁹⁷⁶ with Jacob LJ saying, *inter alia*, the problem it solves is an artificial retrospective reformulation of a problem not necessary faced by the person skilled in the art and that in any event it is contained in the fourth step of the *Windsurfing/Pozzoli*.

There are other approaches that have been used by tribunals to assess non-obviousness. The would-could approach, for instance, seeks to establish whether there is any teaching in the prior art that would have prompted the skilled person faced with the objective technical problem to arrive at the invention rather than merely that he could have arrived at the invention.⁹⁷⁷ There is the obvious-to-try approach which assesses non-obviousness on the basis that the skilled person would assess the likelihood of success as sufficient to warrant actual trial and the invention will be held obvious if it is ‘well worth trying out’⁹⁷⁸ although ‘mere possible inclusion of something within a research program on the basis you will find out more and something might turn up is not enough.’⁹⁷⁹ The obvious-to-try is useful only in cases where there is a fair expectation of success and how much of an expectation is needed depends on particular facts of the case.⁹⁸⁰

The courts have further acknowledged the use of secondary indicia which in certain circumstances could be regarded as a sign of inventive step. Commercial success of the invention, for instance, has been used as an argument that the invention was non-obvious. In *Haberman v Jackel*⁹⁸¹ the enquiry relied on secondary evidence directed at establishing non-obviousness by addressing what has become known as the *Haberman* questions which in summary are:

- (a) What was the problem which the patented development addressed?
- (b) How long had that problem existed?
- (c) How significant was the problem seen to be?

⁹⁷⁶ [2006] RPC 26, para.34 and 40.

⁹⁷⁷ EPO Examination Guidelines, para.5.3.

⁹⁷⁸ *Johns-Manville Corp's Patent* [1967] RPC 479, p.493.

⁹⁷⁹ *St Gobain v Fusion Provida* [2005] EWCA Civ 177. Also, the invention would not be obvious if the skilled worker required skills beyond common general knowledge and the amount of trial-and-error required of the skilled worker is excessive: *Harvard/Fusion proteins* OJEPO 1992, 268(T006/890).

⁹⁸⁰ *Conor*, para.42.

⁹⁸¹ [1999] FSR 683.

- (d) How widely known was the problem and how many were likely to be seeking a solution?
- (e) What prior art would have been likely to be known to all or most of those who would have been expected to be involved in finding a solution?
- (f) What other solutions were put forward in the period leading up to the publication of the patentee's development?
- (g) To what extent were there factors which would have held back the exploitation of the solution even if it was technically obvious?
- (h) How well has the patentee's development been received?
- (i) To what extent can it be shown that the whole or much of the commercial success is due to the technical merits of the development?

The *Haberman* questions were aptly summarized into three categories by Pumfrey J in *Angiotech Pharmaceuticals Inc's Patent*,⁹⁸² saying the first question starts off with identifying what the problem was, and then those that address the wider question of why the invention was not made earlier and the last three are concerned with commercial success. The limitation of these questions is one shared with the problem-solution approach in that it is premised on the existence of a problem, and one not prescribed by law. A further challenge with assessment using the *Haberman* questions was identified by Pumfrey J., saying there is a temptation to turn the indicative list into a checklist,⁹⁸³ yet Laddie J was clear that these are factors that *may* be helpful.

In *Generics (UK) Ltd & Ors v H Lundbeck A/S*⁹⁸⁴ the court warned:

‘The commercial success may be attributable to factors other than the invention, for example effective advertising, better workmanship or more attractive presentation. Or it may be that those in the field were not aware of the prior art said to render the invention obvious or were unable to exploit any developments of it. Careful consideration must be given to all circumstances. Many of which were identified by Laddie J in *Haberman v Jackel* [1999] FSR 683.’

⁹⁸² [2006] RPC 28.

⁹⁸³ *Angiotech Pharmaceuticals Inc's Patent* [2006] RPC 28, para.36.

⁹⁸⁴ [2007] EWHC 1040 (Pat), para.238-241. Some types of technically advantageous pharmaceuticals have had limited market success: Kaufman J and Kalaitzandonakes N ‘The economic potential of plant-made pharmaceuticals in the manufacture of biologic pharmaceuticals’ (2011) *Journal of Commercial Biotechnology*, p.173-182.

In using secondary indicia like commercial success in judging non-obviousness, it is indeed difficult to identify ‘a mere commercial decision’ which is ‘matter of business judgment.’⁹⁸⁵ Concern with secondary indicia is that it has played an increasingly primary role in the actual determination of obviousness, even though the courts have cautioned that secondary evidence is no more than an aid to assessing primary evidence as to obviousness of the difference between the inventive concept and the state of the art.⁹⁸⁶ Lemley warns against this trend of judging the patentability of an invention using evidence after the invention has been conceived, for instance under the justification that further investment in improvement or commercialisation of the invention is necessary, in that it is contrary to the *ex ante* justifications of patents.⁹⁸⁷ Market considerations of the invention are thus of limited use under a conceptual framework which is pivoted on factors at the priority date and the sole statutory question being whether there is an inventive step irrespective of the reasons of the inventor to pursue the invention.⁹⁸⁸

6.3.2 South Africa

The implementation of the statutory non-obviousness criteria takes on a slightly different phraseology in South Africa. Influential academic writers have identified three summary questions that Patents Act 1978, s.25 requires of non-obviousness assessment:

‘What matter was available to the public immediately before the priority date of the patent in suit; secondly, whether the invention claimed was a step forward on the

⁹⁸⁵ *Biogen v. Medeva* [1995] RPC 25, 112-114. Indeed the pharmaceutical industry was shown to have a large number of non-significant patents, but ‘vigorously protects commercially successful products through litigation’: Bessen/Meuer, fn.1, p.11.

⁹⁸⁶ *Angiotech Pharmaceuticals Inc’s Patent* [2006] RPC 28, para.82-85.

⁹⁸⁷ Lemley M. ‘*Ex ante* versus *ex post* justifications for intellectual property’ (2004) *University of Chicago Law Review*, p.129-149.

⁹⁸⁸ The court in *Actavis*, para.119, acknowledged that ‘obviousness must be determined as of a particular date. There is at least one other well-known example showing how an invention which might be held obvious on one date, would not be so held at a later date. That is where there has been commercial success following a long-felt want. Time can indeed change one’s perspective. The perspective the court must bring to bear is that of the skilled man at the priority date.’ Cf. Sichelman T. ‘Commercializing patents’ (2010) *Stanford Law Review*, p.341-413, proposing a conceptual patentability framework that is effected only after commercialization of the invention.

matter available to the public; and thirdly, whether in the light of the matter available to the public the step was inventive, ie not obvious.’⁹⁸⁹

This series of questions is a summary of what was initially devised in the first case, *Roman Roller CC and Another v Seedmark Holdings (Pty) Ltd*,⁹⁹⁰ to come before the Appeals Court under the new Patents Act. The Court there said:

‘In order to apply the provisions to a particular case it is necessary to first determine (i) what the art is to which the invention relates; (ii) what the state of the art was at the relevant time and; (iii) who is to be regarded as ‘person skilled in the art’⁹⁹¹

‘Secondly one has to answer the question as to whether, in light of the state of the art as it was immediately prior to the priority date, the invention claimed in the patent constituted a step forward.’⁹⁹²

‘The next and final question to answer is whether the invention involves an inventive step in light of the state of the art at the time and the step forward taken by the invention.’⁹⁹³

The Court of Appeals subsequently made a reformulation of the steps in assessing non-obviousness in *Ensign-Bickford (South Africa) (Pty) Ltd and Others v AECI Explosives and Chemicals Ltd*.⁹⁹⁴ Under the reformulation, assessment of non-obviousness is divided into two broad and structured stages. These are; the preliminary assessment and the actual structured assessment of non-obviousness. The Court said that the first determination that has to be made is:

- ‘(i) what the art is to what the invention relates;
- (ii) what the state of the art was at the relevant time and;

⁹⁸⁹ Burrell, p.154-155.

⁹⁹⁰ 1996 (1) SA 405 (A); 1995 BP 199.

⁹⁹¹ *Ibid*, p.210, para.B and C.

⁹⁹² *Ibid*, p.215.

⁹⁹³ *Ibid*, p.219.

⁹⁹⁴ *Ensign-Bickford (South Africa) (Pty) Ltd and Others v AECI Explosives and Chemicals Ltd* (SCA) 1999 (1) SA 70.

(iii) who is to be regarded as ‘person skilled in the art.’

This preliminary step of questions was previously stated in *Roman Roller CC and Another v Seedmark Holdings (Pty) Ltd*⁹⁹⁵ and is the link between the statutory stipulations and actual assessment. The preliminary stage is helpful as non-obviousness assessment tends to have many points where subjectivity can be introduced. Therefore, the settling of these preliminary points acts as a parameter within which the decision maker should make the determination of the non-obviousness of the invention. It has to be noted that this stage is similar to the UK first question of the *Windsurfing/Pozzoli* approach.

From the preliminary assessment, the enquiry then broadly moves onto the actual making of the inventive concept assessment. These were derived from the UK case *Molnlycke AB v Procter & Gamble Ltd (No.5)*.⁹⁹⁶ Southwood J, sitting as Commissioner of Patents and following *Ensign-Bickford* said ‘after this step the structured enquiry described in the *Ensign-Bickford* case must be undertaken and the four matters referred to in para13 answered.’⁹⁹⁷ Southwood J in *Ausplow*,⁹⁹⁸ quoting Plewman JA in *Ensign-Bickford*,⁹⁹⁹ said these four steps are:

‘What is the inventive step said to be involved in the patent in suit?

What was, at the priority date, the state of the art (as statutory defined) relevant to that step?

In what respect does the step go beyond, or differ from, the state of the art?

Having regard to such development or difference, would the taking of the step be obvious to the skilled man?’

There seems to be tension between the cases between the two Supreme Court of Appeals cases in *Roman Roller* and *Ensign-Bickford*. Burrell argues that the earlier

⁹⁹⁵ *Roman Roller*, 1996 (1) SA 405 (A), p.413.

⁹⁹⁶ [1992] RPC 21, CA, stated in *SmithKline Beecham plc v Sandoz AG*, Case no: SA Patent no. 96/3472, p.28.

⁹⁹⁷ *Ausplow (Pty) Ltd v North Park Trading 3 (Pty) Ltd (formerly Marais Engineering CC)* 2007 BIP 1 (CP), para.57.

⁹⁹⁸ *Ibid*, para.13.

⁹⁹⁹ *Ensign-Bickford (South Africa) (Pty) Ltd and Others v AECI Explosives and Chemicals Ltd* (SCA) 1999 (1) SA 70, para.24.

‘skeletal structure’ adopted by the courts and used extensively is to be preferred over the later ‘more structured enquiry’. However, the rules of precedent would seem to support the later structured enquiry in *Ensign-Bickford*.¹⁰⁰⁰

There was a suggestion that the test or list of questions is non-exhaustive and may be taken to conveniently list the inquiries to be made.¹⁰⁰¹ The making of these steps non-exhaustive is certainly not disallowed by the statute. The point of the second stage entails establishing whether an invention has the inventive concept. Since the question on the state of the art was settled in the first stage, it may not be necessary to make the enquiry again in the second stage.

The Court in *Ensign-Bickford* gave further assistance on the restrictions to the questions one should ask in ultimately deciding obviousness. These are designed to take focus away from commercial considerations, as these usually arise after the fact. The Court said ‘[f]irstly the question to be determined is whether what is claimed as inventive would have been obvious, not whether it would have been commercially worthwhile.’¹⁰⁰²

The Court in *Ensign-Bickford* also said ‘secondly, emphasis must lie on the technical features.’¹⁰⁰³ That means overall the structured approach emphasises that the inventive concept should be found in the technical features of the invention. As such, it could be said that non-obviousness lies in the technical advance made by the invention more than just the difference in what is made available to the public and the state of the art.

The courts have also emphasised that the assessment is not of the magnitude of the non-obviousness but whether the inventive concept does exist at all. The court’s guidance under the structured approach appears to be more in line with the statute as it does not emphasise a forward step but only a difference between the inventive

¹⁰⁰⁰ The Supreme Court of Appeals approved the later approach in *Cipla Medpro (Pty) Ltd v Aventis Pharma SA, Aventis Pharma SA and Others v Cipla Life Sciences (Pty) Ltd and Others* [2012] ZASCA 108.

¹⁰⁰¹ *Ausplow (Pty) Ltd v North Park Trading 3 (Pty) Ltd (formerly Marais Engineering CC)* 2007 BIP 1 (CP), para.57.

¹⁰⁰² *Ibid*, para.58.

¹⁰⁰³ *Ibid*.

concept and the state of the state of the art, a criterion set by the statute. That means obviousness is in fact a qualitative test as intended by the statutes.¹⁰⁰⁴ It is irrelevant that the inventive concept may be small. ‘The law only requires that there be inventiveness. It is not a requirement that there be a large step forward.’¹⁰⁰⁵ This position is similar to when the courts, under the former law, would say ‘but if there is a real inventive step forward, no matter how small, that is sufficient to give subject-matter to a patent.’¹⁰⁰⁶

The structured tests between the two jurisdictions are different in their wording and number of stages or questions to be asked but they seem to achieve more or less the same result. However, a difference is noticeable in that the UK method takes into consideration secondary factors said to be indicative of non-obviousness as enunciated in *Harbeman* for instance, whilst in South Africa emphasis is on non-deviance from the statutory prescription even though the statute is expressed in abstract terms offering no practical guidance on the evaluation. In South Africa reliance on these auxiliary considerations would be useful, but limited in terms of their use by the inventors or third parties because there is no examination of patent applications at the patent office which would gather and evaluate the relevant prior art documents in order enable one to make a judgment of whether there is need to engage the secondary evidence in the non-obviousness evaluation of each case. The function of assessing whether matter is obvious is carried out effectively by patent examiners, rather than only being first considered in litigation. Difficulties in making the judgment to evoke secondary considerations have been acknowledged. The EPO Guidelines for Examination in cases where there is a long-felt need or commercial success cautions that ‘where the invention solves a technical problem which workers in the art have been attempting to solve for a long time, or otherwise fulfils a long-felt need, this may be regarded as an indication of inventive step. Commercial success alone is not to be regarded as indicative of inventive step, but evidence of immediate commercial success when coupled with evidence of a long-felt want is of relevance provided the examiner is satisfied that the success derives from the technical features

¹⁰⁰⁴ As was stated in *Molnlycke*, p.112, that ‘the statute has laid down what the criterion is to be: it is a qualitative not a quantitative test.’

¹⁰⁰⁵ *Ausplow*, para.59.

¹⁰⁰⁶ *Veasey*, p.282. Also in *Drummond-Hay v DI Fram & Co Ltd* 1963 BP 380 (A), p.388E-F; *Herculite Products Ltd v Harris* 1952 1 SA 627 (W), p.630; *Hills v Livingstone-Jackson* 1935 NPD 5, p.18; *Vine and Another v Barratt & Pillans Ltd* 1939 WLD 238, p.241.

of the invention and not from other influences.’¹⁰⁰⁷ The *Haberman* questions would therefore have to be used carefully in the South African context.

6.4 The notional skilled worker

It is desirable that the assessment of non-obviousness has objective reference points. Even though in both jurisdictions the assessment relies on a case-by-case assessment,¹⁰⁰⁸ it remains important that there are fundamental points that objectively anchor the whole assessment methodology. It deserves further investigation therefore how the skilled person, who represents an objective view of the state of the art, is defined. The primary statutes are silent on the characteristics of the person skilled in the art, but case law has established various definitions that continue to evolve and play a critical role in the determination of non-obviousness.

6.4.1 United Kingdom

Assessing non-obviousness is based on the mentality or viewpoint of the skilled person in the art. It has been said that he is notional addressee of the patent. He is labelled by Lord Reid as an ‘unimaginative skilled technician.’¹⁰⁰⁹ In other words, as Aldous L.J. commented in *Beloit Technologies*¹⁰¹⁰ he has the skill and general knowledge of the practitioner of the art, but has no capacity for inventing. ‘He is a person with practical knowledge and experience of the kind of work in which the invention was intended to be used’.¹⁰¹¹ In other words he reflects the competency that would be expected from a real practical worker in the art to which the patent is addressed.

¹⁰⁰⁷ EPO Examination Guidelines, 11.10.3. In T1212/01 (*Pyrazolopyrimidinones for the treatment of impotence/Pfizer Limited*), deciding that neither technical prejudice against the invention nor commercial success establishes non-obviousness, the Board identified evidence assessment difficulties in resolving contributory factors to inventiveness.

¹⁰⁰⁸ Kitchin J opined that ‘the question of obviousness must be considered on the facts of each case’, an opinion which was approved by Lord Hoffmann in *H Lundbeck A/S v Generics (UK) Ltd* [2008] RPC 19, para.24 and *Conor*.

¹⁰⁰⁹ *Technograph Printed Circuits Ltd. v Mills & Rockley (Electronics) Ltd.* [1972] RPC 346, p.355.

¹⁰¹⁰ *Beloit Technologies Inc v Valmet Paper Machinery Inc.* [1997] RPC 489.

¹⁰¹¹ [2006] EWHC 2686 (Pat), para.75.

He is also assumed to have knowledge he would have from learning from existing literature in order to provide a solution for a problem at hand.¹⁰¹² It is said he will read the literature carefully without a limitation to assimilate the knowledge.¹⁰¹³ He obtains common general knowledge from standard documents used in industry and supplements this with knowledge from documents from industry-specific press, patent specifications and relevant scholarly journals.¹⁰¹⁴ In other words, although he is an imaginary person, his comprehension and actions reflect those of the typical practical worker, which evidently are above those of a layperson.

To decide whether the invention meets the patentability or validity standards of the inventive requirement, ‘the court or other tribunal is required to embark on an exercise in which they must first ascertain how far, if at all, the invention has advanced the state of the art and then evaluate this advance from the perspective of a notional person skilled in the relevant art.’¹⁰¹⁵ Gratwick points out that he will try what is obvious to him which has subjective elements to it,¹⁰¹⁶ while on the other hand the courts have maintained that the specified standard is objective.¹⁰¹⁷

Where the skilled worker has a particular problem in mind, it has been said that a solution to his problem would usually lead him to an obvious answer, which is not inventive as it amounts to no more than an obvious verification.¹⁰¹⁸ On the other hand when that result is unexpected, the solution is inventive. In some cases he may not have a particular problem in mind, and obtains unexpected results, which entails a non-obvious invention. The qualifying criteria seem to be the degree of expectancy in the result that entitles one to an invention.¹⁰¹⁹ Moreover, as Griffiths¹⁰²⁰ opines, the ‘mental effort which a skilled person would have to reach a patentable invention ... is therefore the crucial factor in determining inventiveness and patentability.’

¹⁰¹² Cornish/Llewelyn/Aplin, fn.955, para.5-28.

¹⁰¹³ Jacob L.J. in *Rockwater Ltd v Technip SA* [2004] WL147665 said this person is a nerd.

¹⁰¹⁴ Cornish/Llewelyn/Aplin, fn.955, para.5-37.

¹⁰¹⁵ Griffiths, fn.949, p.166.

¹⁰¹⁶ Gratwick, fn.949, p.406.

¹⁰¹⁷ *Molnlycke AB v Procter & Gamble Ltd (No.5)* [1992] RPC 21, Sir Donald Nicholls stated that the assessment was ‘wholly objective’.

¹⁰¹⁸ Cornish/Llewelyn/Aplin, fn.995, para.5-39.

¹⁰¹⁹ In *Beecham Group (Amoxycillin) Application* [1980] RPC 261, it was held that the invention was inventive as the degree of advantage possessed by the Amoxycillin as a therapeutic agent could not have been predicted even though the line of research taken in synthesizing it was obvious.

¹⁰²⁰ Griffiths, fn.949, p.169.

Authors suggest that there is a need to view the knowledge that comprises the state of the art as something which has a potential for further development as reflected in the use of the word ‘obvious’ in specifying the ultimate non-obviousness evaluation.¹⁰²¹ This implies that the notional skilled person should have some question or aim in mind when considering the state of the art. This, nevertheless, does not seem to be right, at least not in all cases. Accidental discoveries, a common occurrence in the pharmaceutical sector, are allowed, in which the skilled worker has no problem in mind or was working on a different line of research that results in a solution in another area.

The notional skilled person is assumed to have common general knowledge at the priority date. Consequently, it has to be emphasised that the notional skilled worker uses this knowledge to view the state of the art forward from the priority date. His view is not from the invention backward to the prior art, as it has been emphasised that hindsight is not allowed.¹⁰²² Hindsight would raise the patentability bar to levels where it would be improbable to have an invention that is considered inventive.¹⁰²³ Later on in this chapter, attention will be on how hindsight bias could be avoided to prevent unduly high non-obviousness standards. Unattended hindsight bias has the ability to undermine the case law postulations about the characteristics of the skilled person.

In *Conor* an issue that arose was whether the patentee is mandated to explain why the invention works. Commentators are of the view that ‘all he needs to do is to explain how it works in a manner which enables persons skilled in the art to perform it without themselves inventing anything.’¹⁰²⁴ Against the premise and justification that patents perform a public education function, it would at first glance seem this position is mistaken. However, the workability of the invention by the person skilled in the art is the only burden on the patentee. According to Lord Hoffmann ‘if the claimed invention works, it is irrelevant that you arrived at it by accident or on the basis of an

¹⁰²¹ Griffiths, fn.949, p.166.

¹⁰²² Phillips J. and Firth A. *Introduction to intellectual property law*. 4th edn (2001) Oxford: Oxford University Press, p.51.

¹⁰²³ *Ibid.*

¹⁰²⁴ Deepak J.S. ‘The elusive quest for the definition of obviousness- patent law’s holy grail’ (2010) *International Review of Intellectual Property and Competition Law*, p.410-427, p.423.

altogether mistaken theory.’¹⁰²⁵ The person skilled in the art only has to show that the invention works. That is to say the patentee discharges their duty to educate the public by showing how the invention works.

6.4.2 South Africa

Similar to English law, assessment of non-obviousness in South Africa is based on the mind-set of the skilled person in the art. The assessment seeks to establish whether the invention was inventive compared to what was available to the public immediately before the priority date. In *Gentiruco*¹⁰²⁶ the court prescribed that the relevant person would be those ‘ordinary skilled or qualified persons engaged in the art or science.’ The Court would, in *The B-M Group Pty Ltd v Beecham Group Ltd*¹⁰²⁷ later state that the specification addressee would be the notional ‘person skilled in the art or science.’

Although, it is rarely in dispute, making the actual identification of the hypothetical skilled person has proven difficult in some circumstances. In *Heineman Electric (SA) Ltd v Switch King Electrical Industries (Pty) Ltd*¹⁰²⁸ the Court acknowledged this difficulty and pronounced that ‘it is not always easy to identify the person ‘skilled in the art’ who must be visualised for the purpose of applying that test. His industrial and scientific attainments must clearly vary according to the nature of the patent whose validity is to be determined. In some of the early patent cases dealing with simple devices he has been described as ‘an ordinary workman in the trade’. At the other end of the scale dealing with complex technologies, a very different person may have to be visualised, as in *Transvaal and O.F.S Chamber of Mines v General Electric Company*,¹⁰²⁹ where the invention related to the manufacture of synthetic diamonds and where the court expressed itself in these terms:

¹⁰²⁵ UCL Institute of Brand and Innovation Law: *Conor v Angiotech* on Appeal (2011) Skeleton argument, para.(d), by Lord Hoffmann in a mock simulation of *Conor*, 23 November 2011 UCL, London. Event proceedings available, at www.ucl.ac.uk/laws/ibil/docs/Conor_v_Angiotech/skeleton_Arguments.pdf.

¹⁰²⁶ *Gentiruco*, p.196D.

¹⁰²⁷ *The B-M Group Pty Ltd v Beecham Group Ltd* 1978 BP 373 (T), p.398-399.

¹⁰²⁸ 1969 BP 297 (CP), p.299-300.

¹⁰²⁹ 1966 BP 281 (T).

‘It is obvious that there is not a class of synthetic diamond-makers which can be looked to establish the common knowledge... Our hypothetical diamond-maker would be part physicist, part mineralogist and part engineer, part chemist and part crystallographer.’

This leads to the deduction that this skilled person may sometimes be a group of people. It is an amalgamation of different skills which do not exist in reality in one person.¹⁰³⁰ This situation may somehow be seen as not portraying reality and introduces weakness in the non-obviousness criteria. In effect, this would mean that the patent specification is actually not addressed to anyone in existence.

In *Marine Construction and Design Company v Hansen’s Marine Equipment (Pty) Ltd*,¹⁰³¹ as in the UK, the Court summarised to whom the assessment is relative to and actions he would be allowed to take when acting on prior art:

‘The test whether an invention lacks subject-matter and is invalid for obviousness, has been authoritatively stated to be whether or not the ordinary person skilled in the art could, if faced with the problem solved by the invention, and having regard to what was common knowledge in the art at the relevant time, and using his intelligence, easily have produced the solution or taken the step taken by the patentee.’

However, it is the court that makes the final decision on what the skilled worker would view as obvious. In *Miller v Boxes and Shocks (Pty) Ltd*¹⁰³² the court asserted that it is was the one that ultimately makes the non-obviousness decision, although ‘it is extraordinarily difficult to avoid the evidence of experts from occasionally trenching on the province of the court.’¹⁰³³

In non-obviousness assessment, hindsight is guarded against but the decision makers must be vigilant. This is because its effect would be more severe than in the UK

¹⁰³⁰ For instance, in *Genentech Inc.’s Patent* [1989] RPC 147, p.278, the court acknowledged that the ‘successful pursuit of Genentech’s research required the deployment of techniques in more than one field’ and no such person existed in reality.

¹⁰³¹ 1971 BP 187, p.198.

¹⁰³² 1945 AD 561, p.584.

¹⁰³³ *Levin v Number Plates and Signs (Pty) Ltd* 1942 CPD 412, p.429.

because there is no patent application examination carried out in South Africa. The first time any person puts themselves in the position of the skilled worker is after the patent is sealed or when there is a dispute, which is long after the priority date and by which time the knowledge and technology would have advanced and diffused into the public domain. What would have been genuinely inventive at the priority date, could seem ordinary and mundane at the time of assessment. The role that would be played by the examiner at the Patent Office taking the position of the skilled person is thus underscored.

6.5 The inventive concept

6.5.1 United Kingdom

The objective test of non-obviousness seeks to ascertain significant differences in the state of art and what the patentee claims to have invented; the inventive concept. Unlike novelty, which is to be assembled from the whole of prior art, non-obviousness excludes prior specifications that are subsequently published.¹⁰³⁴ Non-obviousness assessment may entail the reading of prior art documents in light of each other.¹⁰³⁵ Nevertheless, this does not mean that two pieces of articles could simply be placed next to each other without any working inter-relationship.¹⁰³⁶

There are views that the objective of the evaluation is to measure the development in knowledge as advanced by the invention. For example, in *Generics (UK) Limited and others v H Lundbeck A/S*, Lord Walker said there were some discussions of whether the inventive concept is the same thing as the technical contribution to the arts.¹⁰³⁷ Knowledge has a dynamic nature which may impede proper non-obviousness evaluation. It has been said that knowledge ‘should not be viewed at a particular point in time in isolation as if it were something static since this would ignore its dynamic

¹⁰³⁴ Both Patents Act 1977, s.3 and Patents Act 1978, s.25(10) provide for disregarding of prior specifications subsequently published for inventiveness assessment.

¹⁰³⁵ Cornish/Llewelyn/Aplin, fn.995, para.5-40.

¹⁰³⁶ For example, mosaicing- collating material from different sources for comparison with the invention- is not allowed and was criticised in *Technographic Printed Circuits* [1972] RPC 346, p.355.

¹⁰³⁷ *Generics (UK) Limited and others v H Lundbeck A/S* [2009] UKHL 12, para.29 to 34.

quality and provide an inappropriate basis for evaluating change.¹⁰³⁸ However, in the context of non-obviousness assessment, this would not be the correct view to take, as the legislation requires one to freeze the state of the art the day before the priority date in making assessment of the invention concept. Later developments in knowledge are irrelevant as at that time they are not part of the state of art. This would in fact introduce hindsight bias.

There have been different approaches to establishing the inventive concept. There is the problem and solution approach, favoured in the EPO.¹⁰³⁹ The Courts and the UKIPO, however, have not fully embraced this approach.¹⁰⁴⁰ Under this approach, the invention is viewed as a solution to a pre-existing problem where the skilled man has a particular problem in mind. The inventive concept is viewed as the solution to the problem of moving from the closest prior art to the new advantage or solution. This is criticised for being impractical though, in the sense that the inventor may not be aware of the true closest prior art and the ignoring of other disclosures that may make the invention obvious.¹⁰⁴¹ It also suffers from the defect that the problem solved is not prescribed by the law and in reality is a fictitious one derived with the benefit of hindsight after invention has been developed.¹⁰⁴²

According to writers,¹⁰⁴³ the EPO approach is commendable in its emphasis on evaluating the inventive concept in terms of knowledge development, which is the classical justification foundation of the patenting system. Nevertheless, as with the *Windsurfing/Pozzolli* approach, however, this still leaves open the decisive and ultimate evaluation and the question of what quality should be present in new knowledge for the invention to be regarded as inventive.¹⁰⁴⁴ In fact, in *Alcan/Aluminium Alloys*¹⁰⁴⁵ the TBA said that EPC Rule 27(1), the foundation of this approach, deals more with formulation of the invention's description as opposed to non-obviousness assessment under Art.56 EPC. Therefore it could be said that the

¹⁰³⁸ Dutfield/Suthersanen, fn.365.

¹⁰³⁹ Cornish/Llewelyn/Aplin, fn.995, para.5-39.

¹⁰⁴⁰ Cole E. 'Towards a single pan-European standard- common concepts in UK and "continental Europe" patent law: Part 2: Obviousness' (2010) *European Intellectual Property Review*, p.259-267.

¹⁰⁴¹ At para 68 and 69, *Ranbaxy UK Ltd v Warner-Lambert Company* [2006] FSR 14.

¹⁰⁴² Phillips/Firth, fn.1022, p.51.

¹⁰⁴³ Griffiths, fn.949, p.184.

¹⁰⁴⁴ Griffiths, fn.949, p.184.

¹⁰⁴⁵ *T465/92 [1995] E.P.O.R 501*.

current approaches may need some improvement as they do not always make the legislatively required assessment of the inventive concept, even though they may achieve the appropriate result in most cases.

6.5.2 South Africa

The approach to making the step from the state of the art to the claimed invention is easy in theory, but has proven problematic in practice. The approaches suggested over the years for evaluating the inventive concept tend to make preparations for making this step but do not give clear direction of how to actually take the step, a problem similar with the UK as seen above.

In *Veasey v Denver Rockdrill and Machinery Company. Ltd*¹⁰⁴⁶ Wessels JA stated that:

‘The difference between the plaintiff’s invention and prior common knowledge must be measured and valued. If there is no difference, there is no subject matter; if there is a difference, but it calls for no inventive ingenuity to bring it about, there is also no subject-matter; but if there is a real inventive step forward, no matter how small, that is sufficient to give subject-matter to a patent.’

There have been helpful court pronouncements with regards to how the inventive concept would be established. One prominent test of conceptualising the inventive concept is directed to the attempts that could be made in finding solutions to a problem that the person skilled in the art would be faced with:

‘The duty of the judge is, so far as possible, to attempt to gain a full perception of the position at the date of the patent, not necessarily of the patentee, but of an ordinary skilled person in the art, and to give an answer to the question: “If an ordinary person skilled in the art had set himself to solve the problem which the inventor set himself to solve, would he, in the light of the

¹⁰⁴⁶ *Veasey v Denver Rockdrill and Machinery Company. Ltd* 1930 AD 243, p.282.

knowledge which he should have then have had, arrived at this solution without difficulty, or would it have required some quantum of invention.”¹⁰⁴⁷

With regard to assuming the inventive concept could be indicated through the skilled person trying to solve a problem, it could be said that the South African approach has more resemblance to the problem-solution approach used in the EPO. In this respect, therefore, the approach to the inventive concept is slightly different to that of the UK approach. As such, it bears more the criticisms and strengths of the EPO approach than the UK’s approach.

6.7 Reform needs of a structured approach

It is desirable to utilise a structured approach when making non-obviousness assessment,¹⁰⁴⁸ to assist in attaining and maintaining a consistent level of non-obviousness. The approach should not be deficient in any of the non-obviousness elements required by the statutes. Justice Laddie acknowledged in *PCME Ltd v Goyen Controls Co UK Ltd*¹⁰⁴⁹ that *Windsurfing* ‘sets out a structured approach to the question of obviousness and *sometimes* simplifies analysis.’ It is noted that the tests are not always applicable or helpful, thus an ideal structured approach that systematically integrates all the elements required by the statutes in its steps to ensure consistency in all the cases could be suggested. It has come to be expected of an approach applying a legislative ‘requirement to be clear, comprehensive and free from ambiguity.’¹⁰⁵⁰ It is on this premise that a reform could be suggested that would complement the evaluation of the non-obviousness criteria.

The assessment questions in the tests do not always properly guard against hindsight by those attacking a patent. Consistently guarding against hindsight is important especially because it is difficult to unlearn what is already known. It has been equated to the inventor using much effort completing a word puzzle, with the tests asking the

¹⁰⁴⁷ *Levin v Number Plates and Signs (Pty) Ltd* 1942 CPD 412, p.424

¹⁰⁴⁸ Cole P.G. ‘Inventive step: meaning of the EPO problem and solution approach, and implications for the United Kingdom: part 1’ (1998) *European Intellectual Property Review*, p.214-218, p.214.

¹⁰⁴⁹ [1999] EWHC 830 (Pat), para.56, emphasis added.

¹⁰⁵⁰ Griffiths, fn.949, p.170.

courts to complete the same puzzle that they already know solutions to.¹⁰⁵¹ Those attacking the validity of a patent can easily mosaic, although limitedly,¹⁰⁵² taking together pieces of prior art that would otherwise not be obvious to make a case of lack of non-obviousness.¹⁰⁵³ To some extent the South African and *Windsurfing/Pozzoli* non-obviousness approaches suffer from this defect. For these reasons suggestions could be made for improvement.

6.8 Reform proposal

In both jurisdictions, one of the underlying weaknesses of the non-obviousness tests used is that they always have the risk of allowing the assessment to be influenced by ‘the brilliance of hindsight.’¹⁰⁵⁴ It is not possible to unlearn knowledge once acquired as observed by Lord Moulton when he said ‘I confess that I view with suspicion arguments to the effect that a new combination, bringing with it new and important consequences in the shape of practical machines, is not an invention, because, when it has once been established, it is easy to show how it might be arrived at by starting from something known, and taking a series of apparently easy steps. This *ex post facto* analysis of invention is unfair to the inventors.’¹⁰⁵⁵ Judges are well trained in carrying out the non-obviousness assessment *ex ante*.¹⁰⁵⁶ Since the evaluation is carried out by cognitive beings, the risk is always there.¹⁰⁵⁷ To some extent, it then depends on the willingness of the evaluator to guard against this bias. If there is a coherent structured approach to non-obviousness in place, elimination or at least minimization of this hindsight risk seems possible.

¹⁰⁵¹ Phillips/Firth, fn.1022, p.51.

¹⁰⁵² Both South Africa and UK courts guard against mere combinations.

¹⁰⁵³ *Daesang Corporation v Ajinomoto Co Inc.* [2003] EWHC 973 (Ch), Laddie J, held that in obviousness assessment there was a danger of hindsight, as once an invention was made and understood, it could be easily arrived at from the prior art by a series of logical and apparently obvious steps if not viewed through the eyes of the skilled person in the art at that time. Gratwick, fn.901, p.403.

¹⁰⁵⁴ The court in *The B-M Group Pty Ltd v Beecham Group Ltd* 1978 BP 373 (T), p.404, warned against introducing the unshakable hindsight bias.

¹⁰⁵⁵ *British Westinghouse Electric and Manufacturing Co Ltd v Braulik*, (1910) 27 RPC 209, p.230.

¹⁰⁵⁶ Generally, Guthrie C., Rachlinski, J.J. and Wistrich A.J. ‘Inside the judicial mind’ (2001) *Cornell Law Review*, p. 777-830.

¹⁰⁵⁷ *Ibid*, p.779-780.

6.8.1 The skilled person

An approach that continuously approximates reality into the whole obviousness analysis is recommended, particularly the typical situation that would have been faced by the person skilled in the art. By definition, the skilled person is a legal construct. As we have seen, it therefore has no reflection on actual qualities or actions of real individuals in all cases. It is proposed that the skilled person should be approximated more to real situations.¹⁰⁵⁸ This approximation, however, cannot eliminate hindsight bias in itself as the person skilled in the art is usually created after the patent is challenged or infringed or to assist in resolving particular obviousness issues after the priority date. Even examination at the patent office occurs after the fact. That is to say the skilled person is identified for making a historical judgment.

6.8.2 The inventive concept

The inventive concept cannot be standardized across all fields of technology. Although it is desirable to have certainty and predictability of law, there is also the reality that the inventive concept cannot easily, if at all possible, be predetermined. This is true even within the same field of technology. This makes it harder to devise a methodology that would properly encompass the inventive concept for all cases that come to court.

6.8.3 The Recommendation

For the attainment of the ideal non-obviousness standard, a two-fold suggestion is made. The suggestion is directed at improving assessment and making the obviousness decision easier to execute. When making the proposal on an additional mechanism of conceptualizing and approaching obviousness assessment, one has to

¹⁰⁵⁸ The use of a hypothetical person to decide what a scientist in the real world would do is seen as worrisome: Durie D.J. and Lemley M.A. 'A realistic approach to the obviousness of inventions' (2008) *William and Mary Law Review*, p.989-1020, p.995. In South Africa because of non-examination of applications, this is compounded with the passage of time before the inventiveness judgment could be made.

be mindful of the words of Diplock LJ in *Johns-Manville Corporation's Patent*¹⁰⁵⁹ that:

‘The correctness of a decision upon an issue of obviousness does not depend upon whether or not the decider has paraphrased the words of the Act in some particular verbal formula. I doubt whether there is any verbal formula which is appropriate to all classes of claims.’

First of all, non-obviousness should be analyzed using a more robust structured approach, but one that is not rigid. This assists in properly sorting all evidence to the making the non-obviousness decision, emphasizing the pervasive role of the person skilled in the art and the identification of the inventive concept. Secondly, the framework or mechanism for non-obviousness analysis should prevent or at least minimize the infiltration of hindsight bias. It has been suggested that this is attainable with the proper use of secondary evidence or considerations.¹⁰⁶⁰

To begin with, the robust approach will be considered. When utilizing such a structured approach, it is not easy to mix up the division between primary and secondary considerations for obviousness. Some technologies rapidly diffuse into the public store of knowledge as common knowledge whilst some others remain obscure for some time.¹⁰⁶¹ For inventions in sectors where technology is easily integrated into the public store of knowledge, it is common that when patents are disputed, facts about the invention are easily taken for granted as having been obvious before the priority date. A structured approach stimulates the careful consideration of the different elements of the invention relative to the prior art. That is to say it enhances contextualizing of all the evidence in support or against founding of non-obviousness.

Secondly, it is proposed an analysis that prevents hindsight bias or at least mitigates against it. The basis for this assertion is that a ‘proper non-obvious decision must not take into account the *ex post* fact that the invention is actually created.’¹⁰⁶² This is because the non-obviousness analysis should only turn on the *ex ante* view of the state

¹⁰⁵⁹ [1967] RPC 479.

¹⁰⁶⁰ Durie/Lemley, fn.1058, p.1006.

¹⁰⁶¹ SCP/12/3 Rev, p.33-36.

¹⁰⁶² Mandel G.N. ‘Patently non-obvious: Empirical demonstration that the hindsight bias renders patent decisions irrational’ (2006) *Ohio State Law Journal*, p.1391-1463, p.1393.

of the art. The statutes in the UK and South Africa prescribe that obviousness should be judged against the state of the art at anytime before the priority date and immediately before the priority date, respectively. However, the assessment that has to be carried out depends heavily on *ex post* factors.

Mitigating hindsight bias is admittedly complicated, as even with a clear structured *ex post* instruction of evaluation, the hindsight influence does not immediately diminish.¹⁰⁶³ The very knowledge that the invention was attained compels analysis toward the invention, an advantage that the patentee did not have when he created the invention from the complete sea of prior art.¹⁰⁶⁴ Therefore reliance on information concerning events after the priority date should be reduced and rarely used as ‘hindsight research has revealed that individuals tend to overestimate both the likelihood a known outcome occurring and the foreseeability of that outcome.’¹⁰⁶⁵ Thus, there should be active guarding, in the courts, against the underestimation of the inventive concept in disputed inventions as a result of secondary evidence for instance.¹⁰⁶⁶ Otherwise, there would be obviousness in a lot of inventive concepts that indeed advance the state of the art.

In addition, because of hindsight bias, the person skilled in the art is usually assumed to have higher skills than they had in actuality.¹⁰⁶⁷ This, therefore, can make many borderline inventions appear more obvious than they were to a practically existing person skilled in the art. There should also be an allowance for the fact that there may have been different schools of thought in the technical field under consideration, such as in genetic sciences, biotechnology or any of the newer fields like stem cell research and nanotechnology, where there may still be no settled accepted unified scientific opinions. Courts should therefore not always prescribe or assume one acceptable wisdom of the time in the person skilled in the art, but scrutinize for an objective range of knowledge.

¹⁰⁶³ *Ibid*, p.1395.

¹⁰⁶⁴ *Ibid*, p.1403.

¹⁰⁶⁵ *Ibid*, p.1404.

¹⁰⁶⁶ Davis J, in *Levin v Number Plates and Signs (Pty) Ltd* 1942 CPD 412, p.423-424 warns on hindsight taking the opposite extreme of overestimating the inventive concept.

¹⁰⁶⁷ Mandel, fn.1062, p.1405.

The hindsight bias is also high when the result is unexpected.¹⁰⁶⁸ This means, for instance, that the inventive concept could be judged to be lower than it actually was for inventions resulting from routine work with some surprising results. Thus preliminary determination of what was achieved by the invention at the priority date will be contaminated and judged to be lower than what it was. To diminish the influence of hindsight, what is suggested is that the preliminary issues in evidence should be settled with the assumption of no invention having occurred or with the exclusion of evidence that selectively points towards the existence or attainment of the invention. A reason to combine the prior art must come from a specific informational sources in existence at the time of the invention -the prior art, general knowledge in the art, or the nature of the problem and not be influenced by the claimed invention. Then the actual evaluation of the inventive concept will be less affected by hindsight bias. The courts are under obligation to determine obviousness, a historical judgment, through the eyes of the person skilled in the art in light only of the prior art.¹⁰⁶⁹

The UK case law pronouncement on obviousness analysis encapsulates the proposal that to some degree prevents hindsight: ‘*viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?*’¹⁰⁷⁰ It is suggested that it should thus be emphasised, more than merely mentioned. In South Africa in *Ensign-Bickford* it was only established that ‘having regard to such development or difference, would the taking of the step be obvious to the skilled man?’, without the instruction that such regard should be had with the assumption of no invention having occurred. Exercising caution is recommended to prevent hindsight bias that occurs from analysis with the knowledge that the invention was attained.

¹⁰⁶⁸ *Ibid.*

¹⁰⁶⁹ At the lower end of the expectancy scale when the invention is expected from teachings of prior art, there is no inventive concept, see *Transvaal and Orange Free State Chamber of Mines v General Electric Company* 1966 BP 281 (T), p.290.

¹⁰⁷⁰ Step 4 of *Windsurfing/Pozzoli*, para.23, emphasis added.

6.9 Conclusion

With the advent of international harmonization of the patentability standards, it is recommended that the UK and South Africa engage in a continual introspection of domestic inventiveness policies. It has been observed that ‘of course, we researchers in IP share a professional bias in favour of solving all problems with the law,’¹⁰⁷¹ but it has to be understood that industry looks for what works practically, to allow invention and innovation and to maximise profits. The law should develop to assist industry to function efficiently.¹⁰⁷² Elements in the non-obviousness assessment approach that stifle invention or are impracticable to the industrialist are undesirable. Hence, the non-obviousness criteria should appeal to a ‘practical’ skilled worker in the art.¹⁰⁷³ This is why in law, emphasis should be put on making assessments through the eyes of the skilled worker. The identified skilled workers in industry should thus be able to analyse for themselves whether their inventions are considered inventive or not in law.

It was noted that ‘in our field, legislation keeps increasing in complexity and scope, often to no purpose.’¹⁰⁷⁴ Non-obviousness reforms could however be to simplify the case law into a consolidated cohesive instrument rather than the need to wade through volumes of case law before identifying which non-obviousness test is to be applied to a particular situation. The recommendation made in this chapter has given a two-stage approach to non-obviousness, which can meet these needs. It could also serve to bring the UK and South Africa assessment methods, of common legal ancestry, closer.

Even though it is generally accepted that those seeking patent protection, do so more as a strategic decision, especially in the lucrative fields of pharmaceuticals, the non-obviousness requirement should carefully guard for technical advancement in the state of art and against hindsight. The focus of inventive concept analysis should be on the

¹⁰⁷¹ Geller P.E. ‘Dissolving intellectual property’ (2006) *European Intellectual Property Review*, p.139-145, p.144.

¹⁰⁷² Lord Irvine, fn.27. England P. ‘Towards a single pan-European standard– common concepts in UK and “continental European” patent law: Part 2: obviousness’ (2010) *European Intellectual Property Review*, p.259-267, p.261-262.

¹⁰⁷³ Szabo G.S.A. ‘The problem and solution approach to the inventive step’ (1986) *European Intellectual Property Review*, p.293-303, p.300.

¹⁰⁷⁴ Geller P.E. ‘Dissolving intellectual property’ (2006) *European Intellectual Property Review*, p.139-145.

provision of new technical solutions which are not simple variants of the state of the art, which in this chapter has been recommended as a conceptual framework for making non-obviousness assessments.

CHAPTER SEVEN

INDUSTRIAL APPLICATION

7.1 Introduction

One of the four routes identified in chapter one of this thesis by which pharmaceutical discovery occurs is through the study of disease pathway and identifying the target that is involved in the disease, a process that increasingly relies on biotechnology and genomic technologies. The science of genomics, in particular, correlates genetic information with biochemical pathways and disease mechanisms with the consequence, for instance, that in a particular disease, if a gene is under- or over expressed, then the protein for that gene may be a target for pharmaceutical molecule intervention that interferes with its function commonly through the blocking of the receptor for that protein.¹⁰⁷⁵ Such biomedical technological interventions are usually seen as helpful in the carrying out of research that result in pharmaceutical treatment of disease, but questions have been raised on the desirability of their inclusion in the ambit of patent protection.

As a result, at one end, there is great interest in the patenting of inventions of the frontier and emerging fields of biomedical technology. This is the case in the biotechnological and genomic fields which have been heralded as opening new avenues of treatment and providing the pioneering research tools in the fight against disease. On the other hand, there is concern that allowing the patenting of what could essentially be considered research tools in these fields or the products resulting thereof, would hinder further research and advance of the technology if the patenting is allowed before tangible results are observed or the science is fully understood.¹⁰⁷⁶ The requirement that an invention must be capable of industrial application is positioned in the middle of this debate and is usually cited as bringing equilibrium between the two extreme views. The germinate sciences and field of technologies will

¹⁰⁷⁵ Grubb, fn.256, p.294.

¹⁰⁷⁶ Eisenberg R.S. and Merges R.P. 'Opinion letter as to the patentability of certain inventions associated with the identification of partial cDNA sequence (1995) *American Intellectual Property Law Association Quarterly Journal*, p. 6.

therefore be used in this chapter for an expository analysis of the interpretation of the industrial application criteria.

In this chapter, the thesis turns to analyse how the criteria of industrial applicability or use has been applied in the two jurisdictions. Satisfying the industrial application criteria for the pharmaceutical molecules or processes is not considerably controversial. Thus, particular focus will be on the approach that is taken in applying this criterion in the research technologies that precede and enable the development of the medical and pharmaceutical products. That is to say particular focus will be on the ‘transforming and enabling technologies.’¹⁰⁷⁷ It should also be noted that since these are frontier technologies, their application is usually not restricted to one field of technology, but has impact on other diverse fields besides health related ones.¹⁰⁷⁸

The chapter will briefly trace the purpose of the industrial application criteria in the patentability of inventions discourse to begin with. Then the statutory nature of the criteria in the two jurisdictions will be examined and analysis of how the tests have been applied by the courts will be made. There will also be an examination of how the two jurisdictions have, by using the industrial application criteria, sought to put a balance between the unpatentability of medical treatment methods whilst allowing the patenting of the compounds of those treatments.

7.2 The purpose of the industrial application criteria

The industrial application limb to patentability is one that has rarely received attention from the courts or commentators as there have not been significant challenges to granted patents on this ground. In the UK, *Chiron Corporation and Others v Murex Diagnostics Ltd. and Others*,¹⁰⁷⁹ is one case that looked into the industrial applicability requirement, albeit briefly. However, this trend recently changed as in

¹⁰⁷⁷ ‘A framework for biotechnology statistics’ (2005) Organisation for Economic Co-operation and Development, OECD Secretariat, p.12.

¹⁰⁷⁸ Johnson D.K.N., ‘Biotechnology Inventions: What Can We Learn from Patents?’ (1999). *Wellesley College Working Paper*, <http://dx.doi.org/10.2139/ssrn.181009>.

¹⁰⁷⁹ [1996] RPC 535.

Human Genome Sciences Inc v Eli Lilly,¹⁰⁸⁰ (HGS) the assessment of the requirement reached the Supreme Court. In South Africa, the question of the assessment of the criteria has not been directly addressed by the courts.

The criteria works in tandem with the other patentability criteria in ensuring that practical technical advances and advantages are disclosed by the patent.¹⁰⁸¹ Authors state that '[t]his requirement emphasises the importance of practical application to the patent system.'¹⁰⁸² For instance, the patent application is expected to disclose or it is generally implicit from specification what the practical advantage of the invention is or for biotechnology inventions the requirement to disclose at least one practical use of the invention is testament to the fact that practical technical advances are considered important to the system.¹⁰⁸³ This function comports with the justification of the patent system that the patent is regarded as a system of disclosing advances in the state of the art in practicable ways.

The need to highlight the practical advantage of inventions is perhaps more significant in the biotechnological and genomic industries which have been shown to be vital for modern pharmaceutical industries. These inventions are in many cases radical and geminate such that their practical application in most cases is not yet fully understood or appreciated. Nonetheless, the patentees are given a monopoly with the view that they will put the invention into practice.¹⁰⁸⁴ Therefore, the purpose of the criteria emphasises practical application.

The current focus of the application of the criterion could be viewed as different to when the criterion was at its infancy. At that time, there was to a large extent a clear demarcation between different fields of technology and most inventions could be seen as to what they were intended to serve. Discerning the function of the invention was relatively straightforward. The emergence of new and complex technologies has

¹⁰⁸⁰ [2011] UKSC 51.

¹⁰⁸¹ It has to be noted that the criterion is separate to related patentability criteria. The UKIPO for instance notes that an invention that is challenged on this ground would usually fail the excluded subject matter limb to patentability, para. 4.03: <http://www.ipo.gov.uk/practice-sec-004.pdf>. In *Aerotel* [9](v), Jacob L.J. observed that the criteria may overlap with patentability exclusions.

¹⁰⁸² Phillips/Firth, fn.1022, p.57.

¹⁰⁸³ Biotechnology Directive, Art.5.3 requiring sequence or partial sequence of genes to be disclosed.

¹⁰⁸⁴ Lord Sydney Templeman 'Intellectual property' (1998) *Journal of International Economic Law*, 1998, p.603-606, p.606.

changed not only the ease of making judgment of the function of an ensuing invention in R&D, but making the distinction between research tools themselves and the resultant invention from that activity.¹⁰⁸⁵

Another purpose of the industrial application criterion developed as a legislative fiction to exclude the patenting of medical treatment methods or diagnosis on the ground of their not being capable of industrial application. This has subsequently changed in the UK as the rejection from patentability of medical treatment methods is now made as a policy exclusion. In South Africa, it remains as a bar to patentable invention under the concept that medical methods of treatment are not capable of industrial application. Although the position has changed in the UK, there will be a discussion of medical methods unpatentability and a comparison between the two jurisdictions highlighted for lessons to be had from the reasoning under this rule.

7.3 United Kingdom

7.3.1 The statutory nature of the industrial application criteria

The industrial applicability requirement is governed by the Patents Act 1977 section 4. Section 1(1)(c) provides that one of the conditions for patentability of an invention is that it must be capable of industrial application and then section 4(1) elucidates this by providing that ‘an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.’ This comports with EPC Art.57, which states that ‘an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.’ The words ‘capable’ and ‘susceptible’ seem to be used synonymously as the courts adopted an interpretation approach which accepts the two as synonymous and used Art.57 to interpret whether or not an invention is capable of industrial application.¹⁰⁸⁶

¹⁰⁸⁵ Commentators claiming that the recent trend in gene-related inventions has been the patenting of research tools blurring the line between R&D output and the indispensable research tools; Sumikura K. ‘Intellectual property rights policy for gene related inventions- toward optimum balance between public and private ownership’, in Castle, fn.40, p.77-78.

¹⁰⁸⁶ HGS, para.28.

To discern the appropriate interpretation and application of this criterion, the history of the provision is instructive. During the negotiations for the EPC, there was a suggestion made that the industrial application criterion in the original draft instrument be dispensed with, but it was decided that the criterion was necessary ‘to avoid any restrictive nature of patentable inventions.’¹⁰⁸⁷ The broad meaning of the word ‘industry’ was emphasised and also said to include the army and the professions.¹⁰⁸⁸ The intention was to extend the patentability of inventions to cover fields that could not be contemplated at that time. Interpretation was intended to be liberal and inclusive of fields that may not be readily considered to be industry.

At that time, when the industrial applicability article was under consideration in the negotiations, particular attention was also directed to holding agriculture as an industry. The express reference to agriculture in the definition was included because in the EPC negotiations the Netherland’s delegation raised reservations about technical processes applying to agriculture, to which the chairman pointed out that it would be difficult to exclude agricultural inventions from patentability because of a single member.¹⁰⁸⁹ That is one reason why the criterion in the statute specifies agriculture.

Economies and industries have advanced since that period and there is now usually the need to ascertain the industrial application of inventions in new and complex fields of technology. The interpretation of industrial applicability in the UK has been further influenced by Community law in subsequent Directives, designed to clarify the patenting of some new fields of technology, that have to be taken into account when interpreting this criterion, for instance in biotechnological inventions. This renders the assessment of industrial application of some inventions to further conditions, for instance that ‘the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.’¹⁰⁹⁰ Furthermore, the

¹⁰⁸⁷ Document IV/2767/61-E, Draft Article 13, 14 March 1961, p.11.

¹⁰⁸⁸ Document 9081/IV/63-E-Final, p.74. ‘Professions’ appear to be directed to professional fields for instance doctors.

¹⁰⁸⁹ Document IV/2767/61-E, *Discussion of Article 13 of the Preliminary Draft of 14 March 1961*, p.10.

¹⁰⁹⁰ Rule 29(3) EPC; This rule is a result of the implementation of European Parliament and Council Directive 98/44, the Biotechnology Directive.

EPC has also had revisions which have to be taken into account when evaluating industrial applicability.¹⁰⁹¹ With this statutory framework in mind, the thesis turns to analyse how the criteria has been applied in court.

7.3.1.1 The test in court

Domestically, the test for industrial applicability has been authoritatively clarified by the Supreme Court in *Human Genome Sciences (HGS)*, in an assessment which to a large extent referred to the decision of the EPO deciding on the same subject matter.¹⁰⁹² The case centred on a genes-related invention, which are increasingly useful for pharmaceutical discovery, with the genomics industry, for instance, working with and patenting at least three types of genes: those encoding therapeutic proteins, sequences with diagnostic information and receptors useful in high throughput drug discovery screenings.¹⁰⁹³ The case concerned an invention by Human Genome Sciences, which describes an encoding nucleotide, amino acid nucleotide, certain antibodies and a novel human protein Neutrokin-alpha which is a member of the tumour necrosis factor (TNF) group ligand superfamily of cytokines, which are proteins that act as inter-cellular mediators in inflammation and other immune responses.¹⁰⁹⁴ This is important to drug discovery because it is through understanding the pathway of disease that there can be the creation of new compounds that will act in desirable ways within this pathway. Indeed, the claimed Neutrokin-alpha was shown to be expressed in inflammation and in the fight against infection in a variety of diseases.¹⁰⁹⁵

The court said the methodology of assessing industrial applicability needed to be case sensitive, as there is the likelihood that inventions that are challenged on this ground

¹⁰⁹¹ The revised EPC, EPC (2000).

¹⁰⁹² The Supreme Court saw it fit to differ from the lower courts in preference to EPO, with the Lords stating reluctance in overturning a decision by highly experienced IP judges in the courts below: *HGS*, para.166, 168 and 172.

¹⁰⁹³ Ebersole T.J., Guthrie M.C. and Goldstein J.A. 'Patent pools as a solution to the licensing of diagnostic genetics' (2005) *Intellectual Property and Technology Law Journal*, p.1-5, p.5.

¹⁰⁹⁴ *HGS* [2011] UKSC 51, para.7 and 10. For instance the TNF superfamily consist of molecules that have characteristics that make them important in the treatment of acquired and genetic diseases: Bodmer J., Schneider P. and Tschopp J. 'The molecular architecture of the TNF superfamily' (2010) *Trends in Biochemical Sciences*, p.19-26.

¹⁰⁹⁵ [2011] UKSC 51, para.8.

are in a new field of technology where there is still a lot unknown about them.¹⁰⁹⁶ Hence, the court stated that it was preferable that caution be exercised in approaching the evaluation so as to balance interests of the inventor and public by not hindering subsequent research in this field.¹⁰⁹⁷ At the same time, in allowing the appeal, the court emphasised the need for consistency in arriving at results as demonstrated by the EPO.¹⁰⁹⁸ This suggests that the case-by-case sensitivity of the approach in deciding industrial applicability is to be balanced out by approaching each patentability analysis in a consistent manner. That is to say deciding on a case-by-case basis does not encroach on and derogate the need for consistency of methodology even though the fields of technology may still be new and uncertain.

The court outlined three groupings of conditions that would have to be fulfilled in establishing industrial applicability, especially for patents involving biological material. The first and general consideration stated by the court was that to satisfy EPC Article 57, the patent must specify a practical advantage and a concrete benefit and that merely speculative use will not suffice and that the patent and the common general knowledge must enable the person skilled in the art exploit and use the claimed invention.¹⁰⁹⁹ Secondly, more specifically where the patent discloses a new protein with its encoding gene, a real as opposed to a purely theoretical possibility of exploitation is needed; not attributing a clear function of the protein structure will not suffice. The absence of wet lab or experimental evidence will not be adverse to the attainment of industrial applicability and a plausible or reasonably credible claimed use or ‘educated guess’ can suffice in meeting the criteria, moreover this plausibility can be assisted by later evidence even though the later evidence on its own will not suffice.¹¹⁰⁰ The court emphasised that the requirements of plausibility and specific possibility of exploitation can be at any of three levels; namely the biochemical, cellular or biological levels and this was found to be one of the reasons the lower courts conclusion differed from that of the EPO.¹¹⁰¹ Thirdly, in cases where the novel protein is claimed to be a member of a family or superfamily, the court added that if

¹⁰⁹⁶ *HGS*, para.2.

¹⁰⁹⁷ *HGS*, para.99.

¹⁰⁹⁸ Needle J. ‘Patents: Industrial application’ (2011) *Chartered Institute of Patent Agents Journal*, p.768-769.

¹⁰⁹⁹ *HGS*, para.107.

¹¹⁰⁰ *Ibid.*

¹¹⁰¹ *Ibid.*

all the known members have a particular role to play in the disease pathway, assigning a similar role to the novel protein may be adequate and the problem to be solved in such a case would be in the disclosure of isolating a further member of the family.¹¹⁰² As ‘the disclosure is “important to the pharmaceutical industry”, the disclosure of the sequence of the protein and its gene may suffice.’¹¹⁰³ This, however, may not hold true if there is contradictory evidence as to such membership to the group or if the members of the group have different activities, although it is acceptable if the majority have a common role.¹¹⁰⁴

Noteworthy in this case is that the court was of the view that the courts below identified the appropriate facts but then made an incorrect conclusion in applying those facts.¹¹⁰⁵ This highlights the importance of assessment methods that will take one from sifting through the relevant facts in the evidence of the case to actually making the appropriate conclusion of whether the invention meets the industrial applicability benchmark. Lord Hope did not accept the view by Jacob L.J. in the Court of Appeal that the reason the decision of the trial judge differed from that of the TBA was because they were using different evidence and procedure.¹¹⁰⁶ In essence, the court was saying that the patentability evaluation carried out for identical inventions has to result in the same result.

The industrial applicability contention by HGS was that the standard was set too high by the courts below, with regards to patents for biological matter.¹¹⁰⁷ The court below had concluded that the patent’s Neutrokine-alpha function ‘at best, were a matter of expectation and then far too high a level of generality to constitute a sound or concrete for anything except a research project.’¹¹⁰⁸ Prior to this case, commentators had acknowledged that requiring specific uses of a molecule of the invention was a high standard for the industrial application criterion, which would exclude some raw biological information from patenting and, unless interpreted very narrowly, would not exclude structural genomics inventions from patenting because the gene and

¹¹⁰² *Ibid.*

¹¹⁰³ *Ibid.*

¹¹⁰⁴ *Ibid.*

¹¹⁰⁵ *Ibid.*, per Lord Neuberger, para.104, 165.

¹¹⁰⁶ *Ibid.*, para.165, per Lord Hope.

¹¹⁰⁷ *Ibid.*, para.33.

¹¹⁰⁸ [2008] RPC 29, para.234.

protein sequences and structure will in most cases be associated with function.¹¹⁰⁹ As a result in this case, some commentators have stated that the standard for industrial application has been lowered by the Supreme Court.¹¹¹⁰

Of particular impact to researchers in the field of pharmaceutical discovery is perhaps the fact that the assessment method allows industrial applicability to be established without tests to support the data. The BioIndustry Association made submissions to the effect that early patenting is favourable for the ability to attract funding.¹¹¹¹ However it is suggested that early patenting by one individual cannot override the public benefit argument that subsequent researchers must not be prevented in carrying out further desirable advances to the technology. It had been asserted before this case that the assessment has to take into consideration that mere speculations that have not been practically tested are not accepted as meeting the industrial application criteria.¹¹¹² This proposition is premised on the fact that the appropriate benchmark is one where the public is taught something and that teaching must be of something valuable and practicable.

The court addressed attainment of this delicate equilibrium by stating that caution must be exercised when the decision is made and proper weight be given to the research process of figuring out the possible use of the compounds under study. In particular, it saw it appropriate that the assessment revolve around whether the prediction could be considered plausible. The lower courts were of the view that the disclosed use was no more than speculative and did not arise to the level of showing an ‘immediate concrete benefit.’¹¹¹³ Nonetheless, the Supreme Court was of the view that concrete prediction was allowed,¹¹¹⁴ as it is an unavoidable step in knowledge generation. The root issue in *Conor* revolved on whether the inventor was mandated

¹¹⁰⁹ Barman H.M. and Dreyfuss R.C. ‘Reflections on the science and the law of structural biology, genomics and drug development’ (2006) *UCLA Law Review*, p.871-908, p.893.

¹¹¹⁰ Sharples A. ‘Industrial applicability, patents and the Supreme Court: *Human Genome Sciences Inc v Eli Lilly and Co*’ (2012) *European Intellectual Property Review*, p.284-286, p.286.

¹¹¹¹ BioIndustry Association intervened in these proceedings, *HGS*, para.100 and 101.

¹¹¹² Thambisetty S ‘Legal transplant in patent law: Why “utility” is the new “industrial applicability”’ (2009) *Jurimetrics*, p.155-201, p.182.

¹¹¹³ *HGS*, para.129, 120.

¹¹¹⁴ *HGS*, para.120, 121. A concrete prediction should be plausible, para.122, and is indeed difficult to discern: para.126 and 127.

to explain why the invention works and it was settled that he was only required to explain how it works in a manner that enables the skilled person to carry it out.¹¹¹⁵

Other factors considered important were the notional addressee and his view of the ‘common general knowledge’ which was used to assess the invention’s susceptibility of industrial application.¹¹¹⁶ Accordingly, these have a significant role to play in reaching the conclusion which the Supreme Court identified as attributable to the difference between the lower courts and the EBA. The court said:

‘There is a very obvious difference of view as to the test that the invention had to satisfy to be susceptible of industrial application. For the TBA, the question was whether, taking the common general knowledge into account, it had been plausibly shown that the molecule was usable. It was not necessary for a skilled person to undertake a research programme to conclude that the presence of Neutrokine-α in B cell and T cell lymphomas might be used to develop appropriate means and methods for their diagnosis and treatment... For the judge, this did not go far enough. For him the critical point was that neither the Patent nor the common general knowledge identified any disease or condition which Neutrokine-α could be used to diagnose or treat.’¹¹¹⁷

Assessment of the patentability standard in the UK considers judgements that do not emanate in the local authority alone; the EPO decisions being the most common relied on.¹¹¹⁸ In addition, the influence of other jurisdictions has been accepted by the courts.¹¹¹⁹ Under such customs, commentators have suggested that similar foreign rules that are not statutorily sanctioned in the UK could infiltrate case law and practice in UK tribunals.¹¹²⁰ However, the Supreme Court was clear that there has to be caution in transplanting apparently similar concepts and was not persuaded by US utility standard although its benefits were acknowledged.¹¹²¹ It is notable that the

¹¹¹⁵ Deepak J.S. ‘The elusive quest for the definition of obviousness- patent law’s holy grail’ (2010) *International Review of Intellectual Property and Competition Law*, p.410-427, p.423.

¹¹¹⁶ HGS, para.31.

¹¹¹⁷ HGS, para.161.

¹¹¹⁸ For instance Lord Neuberger said‘[h]owever, on further reflection, like Lord Hope, I have come to the conclusion that the basis upon which the Judge decided the issue was not consistent with the approach adopted by the Board...’, HGS, para.106.

¹¹¹⁹ Lower courts used and made comparisons with the American utility standard.

¹¹²⁰ Thambisetty, fn.158.

¹¹²¹ HGS, para.40.

industrial applicability in *HGS* had two sources of external persuasive influence, one from the US and the other from the TBA and the court preferred the TBA jurisprudence in overturning the lower courts. That is to say the court was at liberty to flexibly choose external law deemed more effective for appropriate legal development, a contrast to a situation where there is an obligation to follow external law historically prevalent in developing countries. Writers have said ‘where law develops internally through a process of trial and error, innovation and correction,...legal institutions tend to be highly effective. By contrast, where foreign law is imposed and legal evolution is external rather than internal, legal institutions tend to be much weaker.’¹¹²²

7.4 South Africa

7.4.1 The statutory nature of the industrial application criteria

The Patents Act s.25(1) *inter alia*, provides that a patent may be granted for an invention ‘which is capable of being used or applied in trade or industry or agriculture.’ This is unlike the UK Act, which initially prescribes that the invention must be capable of industrial application in one section and then defines that capability as subsisting if the invention ‘can be made or used in any kind of industry, including agriculture’ in another section. This seems to be a superfluous difference in statute drafting and would result in identical outcomes in terms of the statutory requirements for industrial application.

There is not much substantive discussion on the criteria in South Africa. Academic authors in South Africa have sought to resolve the difference between the words ‘used or applied’ in defining industrial applicability under the current law. The previous South African Patents Act provided protection for ‘any useful...composition of matter capable of being *used* or *applied* in trade or industry’, but omitted the word ‘used’ from the grounds of opposition, revocation and defence for infringement under this

¹¹²² Berkowitz D., Pistor K and Richard J.F ‘The Transplant Effect’ (2003) *American Journal of Comparative Law*, p.164-204, p.189.

limb.¹¹²³ On one end, authors have stated that the inclusion of both words in the current Act is *ex abundante cautela* while on the other end there are those who favour the retention of both.¹¹²⁴ In practice, this seems unlikely to result in significant differences in applying the criterion. At the same time, one could suggest that this is in line with the expansive interpretation for industrial application that was intended in the negotiations of the EPC and Strasbourg Conventions. Moreover, in South Africa, the statute explicitly refers to trade, in addition to industry and agriculture as found in the UK statute. This is indicative of an intention for an even wider ambit of the statute by the legislature compared to the UK.

7.4.2 Test in court

The test has not been applied by the courts. Some parallels could be drawn with the test as applied in the UK. Flowing from the statutory framework discussed above for the UK, the interpretation could be said to be similar. This is based not only on the fact that South Africa and UK have common sources of the criterion, but because of the reliance on EPO and UKIPO guidance documents when South African courts assess patentability generally.

Significant difference between the two jurisdictions is perhaps in the area of biological inventions. In the UK, reliance has had to be placed on the Biotechnology Directive, stating that the industrial application must be disclosed in the application.¹¹²⁵ South Africa does not have to follow this instrument. At the same time, there is no local instrument that addresses these, yet the technologies have advanced since the current Patents Act came into force. Commentators have asserted that the policy makers or tribunals that interpret a particular concept before others gain a position of influencing over other jurisdictions later on when they encounter similar situations.¹¹²⁶ The South African jurisdiction is likely to follow the position in UK on the strength of the commonality of the origins and foundations of the industrial

¹¹²³ Patents Act 1952, s.23(1)(c), s.43(1), s.53(a).

¹¹²⁴ Gertholtz R.O.P. 'Are medical methods patentable?' (1969) *Tydskrif vir Hedendaagse Romeins-Hollandse Reg*, p.242-262, p.254; Burrell, p.42.

¹¹²⁵ Art.5.

¹¹²⁶ Thambisetty, fn.1112, p.155-156.

provisions and also the influence of the jurisdiction and seniority of the court that has already decided this issue. However, this could not be assumed as certain.

7.5 United Kingdom and South Africa

7.5.1 Summary of the industrial application criteria

There appears to be a similarity in the statutory framework that requires the invention to be capable of industrial application between the UK and South Africa. Even though the UK has the elaboration of how industrial application is defined in another section of the statute, there is internal consistency that makes it similar to the South African statute.¹¹²⁷

The major difference between the UK and South Africa is in how the statutory framework has been adapted to the patenting of the new fields of technology, especially biosciences, which carry the potential to alleviate some of the burdens of disease which cannot easily be dealt with under the traditional pharmaceutical interventions. In the UK, there is the additional requirement, for instance, that the ‘industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application as filed’¹¹²⁸ for the specification to be considered to have attained the requisite patentability benchmark. Essentially, the requirement prevents speculative claiming in new fields, where patentees usually seek to cover a wide scope for the invention for possible harnessing of future developments in the field.¹¹²⁹ In South Africa, the law is silent on this point and there is no guidance on how genomic related inventions would be assessed for industrial applicability.

¹¹²⁷ The UKIPO was of the view that since the requisite changes to the Patents Acts due to the EPC 2000 were to be made through an amendment, it was not possible to completely re-arrange the existing structure and text of the legislation: para.20, <http://www.ipo.gov.uk/patact-response.pdf>.

¹¹²⁸ Patents Act 1977 c.37, Schedule A2 Biotechnological Inventions, added by Patents Regulations 2000/2037 Sch.2 para.1 (July 28, 2000).

¹¹²⁹ HGS, para.56, 58.

7.6 United Kingdom

7.6.1 Methods of treatment and diagnosis

Before the commencement of the Patents Act 1977, the Court of Appeal was of the view that medical treatment methods were not within the ambit of patent law, although the precise grounds were not entirely clear. One view was as articulated by Russell L.J. in *Upjohn Co. (Robert's) Application*¹¹³⁰ that 'it had always been the view of those professionally concerned with patent law that a method of medical treatment of a human being is not within the definition of invention as meaning 'any manner of new manufacture' within s.6 of the Statute of Monopolies.'

After the 1977 statute came into force, these medical inventions were statutorily explicitly excluded from patentability on a more clear ground. Methods of treatment or diagnosis of the human and animal body were prevented from being the subject matter of a patent by the expedient of stating that they were not capable of industrial application under the Patents Act 1977, s.4(2):

'An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.'

This exclusion was so designed to prevent veterinarians and doctors from being sued directly for treating their patients using patented medication¹¹³¹ but this did not prevent the patenting of the medication itself. In other words this did not prevent the patenting of a product consisting of a substance or compound for use in any such method as:

¹¹³⁰ [1977] RPC 94, p.96.

¹¹³¹ Department of Trade and Industry (DTI) Consultation Paper on the Proposed Patents Amendment Bill, issued 29 November 2002, p.9. Also, it has been said that 'the policy behind the exclusion of such methods is clearly to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents.' Decision of TBA: T 964/99-3.4.1, *Device and Method for Sampling of Substances using Alternating Polarity/CYGNUS, Inc.*, [2002] O.J.E.P.O 4, 10 (point 3.7 of the Reasons).

‘Subsection (2) above shall not prevent a product consisting of a substance or composition being treated as capable of industrial application merely because it is invented for use in any such method.’¹¹³²

These instruments indicated that medical treatment methods may actually constitute an ‘invention’ but due to arbitrary legal creation they are to be regarded as incapable of industrial application even if they were.¹¹³³ This legal fiction was said to be directed toward preserving public policy, although there were criticisms of whether it was justified or even logical.¹¹³⁴ Others opine that when the EPC was drafted, the medical profession was not regarded as a trade, a contrast to current prevailing opinion.¹¹³⁵ It is difficult to envisage a justifiable situation where the performance of a medical method is reserved for a select few practitioners as a result of the existence of a patent. In *Wellcome /Pigs*,¹¹³⁶ the Board was of the view that policy should prevent the reach of patents into the treatment of humans or animals. Nonetheless, promoting this point under the notion of the underlying invention not being capable of industrial application remained unconvincing.

The basis of holding methods of treatment as not capable of industrial application whilst holding that the compounds are patentable also caused difficulties in the way the inventions could be claimed.¹¹³⁷ The then DTI issued a Consultation Paper¹¹³⁸ to clarify the position on the patentability of medicaments. Subsequently, on 15 January 2004 the Patents Bill was introduced in the House of Lords, which inserted a new section 4A provision to the 1977 Act to emphasise that although methods of treatment or diagnosis are not patentable, the substances or compounds used in such methods

¹¹³² 1977 Patents Act, s.4(3).

¹¹³³ Paterson, fn.464, p.421.

¹¹³⁴ Pila J. ‘Methods of Medical Treatment in Australian and United Kingdom Patents Law’ (2001) *University of New South Wales Law Journal*, p.421-444, p.422.

¹¹³⁵ Bostyn S.J.R. ‘No cure without pay? Referral to the Enlarged Board of Appeal concerning the patentability of diagnostic methods’ (2005) *European International Property Review*, p.412-419, p.413

¹¹³⁶ T116/85 *Wellcome/Pigs* I O.J. EPO 1989 13.

¹¹³⁷ This had impact not only in the claiming of compounds used in medical treatment, but also in second medical use. For instance see Ventose E.D. ‘Patent protection for second and further medical uses under the European Patent Convention’ (2009) *Scripted*, p.57-74. DOI:10.2966/scrip.060109.57.

¹¹³⁸ Department of Trade and Industry Consultation Paper on the Proposed Patents (Amendment) Bill on 29 November 2002. ‘The primary reason for the consultation was to set out proposals for amending the Patents Act 1977 in order to give effect to the revised EPC, which was agreed in November 2000. The consultation aimed to inform the public of the effect of EPC 2000 on the Act, and to seek views on the proposed changes which followed from that effect: para.2, <http://www.ipo.gov.uk/patact-response.pdf>.

are patentable, regardless of form of the claim. Traditionally, only ‘Swiss’ type claims were generally accepted for claims to new use of known compositions or substances, for example in the form; the use of compound X for the manufacture of medicament to treat Y. The resulting Patents Act, s4A(4)¹¹³⁹ had the effect of removing the requirement of Swiss type claims, thus pharmaceutical substances can now be claimed as: substance X for use in treatment of disease Y.

The reasoning preventing the patenting of medicament has consequently also now changed from lack of industrial application to an exception.¹¹⁴⁰ This is the major point of difference between the UK and South Africa, whereby the UK has moved into preventing patentability of methods of treatment as an exception whilst in South Africa it is done on the industrial applicability ground. Authors, doubting the wisdom of the change, have said ‘removing the lack of industrial applicability language from Section 4 removes the ethical or public policy dimension of this criterion in the only statutory instance where it was used to represent such interests, however poorly interpreted’¹¹⁴¹ and this undermines the criterion as a ‘gate-keeper’ criterion and weakens the public policy principles which the previous law sought to address. However, in a closer examination of the EPC *travaux preparatoires* this does not seem to have been the intended direct function of the criterion. For example, when delegations enquired whether earlier versions of the industrial application criterion would be wide enough to cover all possible applications, the Chairman, supported by other delegations, explained that the subject matter of an invention could even be a new application of a known substance obtained by a process already known, with the practical implementation of a new application constituting a new use of the subject matter of an invention.¹¹⁴² The industrial application was intended to allow for the widest possible interpretation and to cover wide industrial activity within the ambit of this criterion and no ethical obligations were imposed.

¹¹³⁹ Inserted by s.1 of Patents Act 2004.

¹¹⁴⁰ The Patents Act 1977, Ch. 37, Section 4A(1) (2007), reflecting EPC, Art.53(c) (2000). The UKIPO is of the view that this did not result in a significant change in practice: UKIPO, Examination guidelines for applications relating to medical inventions in the UKIPO, <http://www.ipo.gov.uk/medicalguidelines.pdf> (9 January 2012) para.4. Also, indeed TRIPS Art 27.3(a) provides that ‘medical treatment and diagnostic techniques for humans and animals can be exempted from patentable subject material.’

¹¹⁴¹ Thambisetty, fn.1044, p.166.

¹¹⁴² Document IV/2767/61-E, p.46. This is particularly significant for further or second medical use claims.

The assertion that industrial application is not intended to directly deal with public interest as a gate-keeper further finds support in that when the industrial application was discussed expressly with regards to pharmaceutical products, the Working Party concluded that each member state ‘could cause compulsory licences to be granted for a European patent protecting such a product if public interest so required.’¹¹⁴³ The framers of the EPC sought to remove public policy considerations from the industrial applicability of pharmaceutical products patentability. Even in the Strasbourg Convention, which was frequently referred to in the EPC negotiations, under the article dealing with industrial character, it was agreed that “‘susceptible of industrial application’ shall be understood in the widest sense’ and exclusions and exceptions to patentability were only made optional for members and not on an incapable of industrial application grounding.¹¹⁴⁴ There was a question as to whether therapeutic methods should be regarded as inventions, and, after some discussion, it was agreed that they were not patentable under the laws of six members and none of the Working Party delegations wanted to depart from that principle.¹¹⁴⁵ That is to say, the framers preferred not discussing the reasoning and basis of their exclusion from patentability nor whether they were inventions.¹¹⁴⁶

Even currently, the EPC 2000 changes indirectly acknowledges that the industrial application criteria was not designed to act as a direct public policy gate-keeper preventing the patentability of medical inventions, but rather serving the public interest by encouraging patenting of the widest array of invention types. Proposals for the change stated that:

‘While these surgical or therapeutic methods constitute inventions, they have been excluded from patentability by the fiction of their lack of industrial applicability. It is undesirable to uphold this fiction since methods of treatment and diagnostic methods are excluded from patentability in the interests of public health. It is therefore preferable to include these inventions in the

¹¹⁴³ Document 3076/IV/62-E, 22 May 1962, p.138.

¹¹⁴⁴ Document EXP/Brov (61)2 Revised, *Preliminary Draft Convention on the Unification of Certain Points of Substantive Law on Patents*, 8 May 1961, Appendix v, p.26.

¹¹⁴⁵ Document 2632/IV/64-E-Final, *Proceedings of the 12th meeting of the Patents Working Party held at Brussels from 26 March to 6 March 1964, Minutes*, p.22.

¹¹⁴⁶ Ventose E.D. ‘In the footsteps of the framers of the European Patent Convention: examining the *travaux préparatoires*’ (2009) *European Intellectual Property Review*, p.353-363, p.354.

exceptions to patentability in order to group the three categories of exceptions to patentability together in Article 53(a), (b) and (c) EPC.’¹¹⁴⁷

The reclassification of the patentability of the medical treatment methods was said to be a cosmetic exercise and did not change the substance of the law.¹¹⁴⁸ The switch does not seem to diminish the argument by pharmaceutical firms that patents provide the incentive to invest in finding new or improved treatment. Court judges questioned the logic in excluding methods of medical treatment, saying ‘[t]he thinking behind the exception is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not apply also to methods of medical treatment.’¹¹⁴⁹ In many cases, it is difficult to differentiate between the methods of treatment *per se* and a treatment course utilising a specific sequence of treatment compounds.

7.7 South Africa

7.7.1 Methods of treatment and diagnosis

Patents Act 1978, s.25(11) prevents the patenting of human and animal treatment methods. It states ‘an invention of method of treatment of the human or animal body by surgery or therapy or diagnosis practiced on the human body or animal body shall be deemed not to be capable of being used or applied in trade or industry or agriculture.’ This however ‘shall not prevent a product consisting of a substance or composition being deemed to be capable of being used or applied in trade or industry or agriculture merely because it is invented for use in any such method.’¹¹⁵⁰ This is a position similar to the UK before the amendment of 2004. The statute is unsurprising,

¹¹⁴⁷ The Basic Proposal for the Revision of the European Patent Convention, October 13, 2000, Explanatory Remarks, Art.53, para.3.

¹¹⁴⁸ It was stated that the change was ‘a purely editorial change’, Opinion of the EBA: *Diagnostic methods* G1/04, p.359.

¹¹⁴⁹ *Bristol Myers Squibb Co. v. Baker Norton Pharm. Inc.* [1999] RPC 253, p.274. In *Eli Lilly & Co.'s Application* [1975] RPC 438, p.438, the Justices referred to the exclusion as an exception ‘based in ethics rather than logic.’

¹¹⁵⁰ Patents Act 1978, s.25(12).

given that the rider for the industrial applicability for methods of treatment as stated in s.25(11) and (12) is derived from the EPC.¹¹⁵¹

The difference now in the South African statute from the UK legislation lies in the fact that although methods of medical treatment are expressly recognised as inventions in both jurisdictions, in South Africa, the unpatentability lies in holding these inventions as incapable of industrial application. This is expected given the fact that during the EPC negotiations, the negotiations focused on the drafting of the provision fitting the prevailing conditions in some of the member states, rather than any significant debate on the property or characteristics of making treatment methods an exclusion.¹¹⁵² When the question of whether a therapeutic method should be regarded as an invention, the Chairman of the Working Party stated that six of the Member States did not consider it so and none of the delegates wanted to depart from that principle.¹¹⁵³ South Africa adopted the text into the 1978 Act and this has remained the law without much discussion by the law makers or policy makers on the desirability of its qualities in this regard.

However, the opinion of academics has been to question the desirability of the current statutory position. They have pointed that when the Minister of Economic Affairs introduced the Patents Bill for the second reading in Parliament he stated that ‘...the principle of this Bill...(is) that all inventions are clearly in the public interest’¹¹⁵⁴ and therefore have asserted that ‘there can be no doubt that it was the intention of the legislature, when passing the Patents Act, to grant the privileges of patent rights to all types of practical inventions’ thus ‘why should there be no “inventions” in the field of medical science?...why should patentable invention only include medicines and curative devices and exclude medical methods?’¹¹⁵⁵ Viewing methods of treatment as not capable of industrial application has been shown to be illogical, a lesson that could be learnt from the UK case law. Nevertheless, the fact remains that the South African statute does provide for their exclusion from patentability on the industrial

¹¹⁵¹ Domanski, fn.544, p.316.

¹¹⁵² Ventose, fn.1146, p.354.

¹¹⁵³ *Ibid.*

¹¹⁵⁴ South African Parliament, Assembly Debates 1952, 3007.

¹¹⁵⁵ Gertholtz, fn.190, p.258.

applicability ground. Since this has not been tested in court, the desirability of the provision has not been convincingly or authoritatively critiqued.

7.8 United Kingdom and South Africa

7.8.1 Summary of the methods of treatment diagnosis

The practical interpretation of patentability of an invention under the industrial application limb is intended to be wide, whilst exclusions from patentability are said to be approached in a balanced fashion. This puts South Africa and the UK on opposite ends in current statutory terms dealing with the regulation of the patenting of methods of treatment. It is perhaps difficult to accept the reasoning by some authors that the patentability of methods of treatment should have continued to be under the industrial application criteria.¹¹⁵⁶ This assertion is based on the fact that generally, industrial application is interpreted widely and yet an exception is construed in a more balanced approach. The difference in approach between the two positions is irreconcilable to the opposing functions of these two levers. Jacob J rejecting a challenge that a claim was to method of treatment rather than method of manufacture, stated that:

‘I am reinforced in that view by the consideration that the Article 52(4) provision about methods of treatment is an exception to patentability and as an exception should be construed narrowly.... There is also the limited purpose of the exception to be considered. It is not so broad as to stop doctors using whatever they feel they need to treat patients. If that were the purpose then one would not allow patents for medicines or medical implements at all. The purpose of the limitation is much narrower, merely to keep patent law from interfering directly with what the doctor actually does to the patient.’¹¹⁵⁷

Conflation of the reasoning behind the industrial application criterion with purely public policy consideration under exceptions can lead to erroneous conclusions. This

¹¹⁵⁶ Thambisetty, fn.1044, p.167.

¹¹⁵⁷ *Bristol-Myers Squibb Co. v Baker Norton Pharmaceuticals Inc.* [1999] RPC 253, para.50-51.

could also possibly open up the introduction of emotive interpretation and assessment of the patentability limb under industrial applicability. Making an exception for methods of treatment is allowed and recommendable. However, doing so under the industrial application seems to be a strained approach.

7.9 Discussion of the overall industrial criteria for the UK and South Africa

The first time significant discussions between countries on the industrial application criterion were carried out, the main focus was on whether or not there should be inclusion of agriculture within the patent system and also resulted in artificially holding that methods of treatment were not capable of industrial application. The susceptibility of industrial application of the typical invention then was not very contentious. There are now concerns that the patent standards may no longer be responsive to the technologies that have developed and advanced since then.¹¹⁵⁸ For example, the main concern is that the industrial application when assessed, should be considered established only downstream at the R&D stage when there is discernible or tangible conversion of genomic and proteomic information into practical and feasible outcomes rather than far upstream where the researcher at the forefront of the knowledge would be granted a patent that prevents further engagement in the field by subsequent scientists.¹¹⁵⁹ It is argued, though, that the criteria serves its purpose of evaluating whether an invention is capable of industrial application through its practical implementation; the result that the public interest is served by the prevention of patenting of germinate technologies is served as a separate and perhaps derivative purpose. Focusing on the susceptibility of the practical manifestation of the claimed invention confers objectivity in the assessment method, without the need for bringing other considerations into the criteria that are better served by other patentability requirements.

¹¹⁵⁸ Berman H.M. and Dryfuss R.C. 'Reflections on the science and law of structural biology, genomics and drug development' (2005) *UCLA Law Review*, p.871-908. Also, Prais R. 'Blacklight, or the patentability of wrong inventions' (2009) *European Intellectual property Review*, p.269-272.

¹¹⁵⁹ Eisenberg/Merges, fn.1076, p.6, claiming the criteria serves a timing function, leaving basic research discoveries in the public domain until they have yielded tangible benefits and have thereby left 'the realm of philosophy' and entered 'the world of commerce'.

The use of history in benchmarking the application of a principle over time or to extract principles to be learnt for current frameworks is useful but delicate as was suggested in chapter two. If caution is not exercised, we extract from it meaning of what we may erroneously assume the criteria represented historically and misapply it to our contemporary situation. It is advisable that we do not overstretch some concepts into what we perceive to be the truth or the reality from the perspective of our current environment or conditions. It is indeed important to protect public health; however, to do it directly under industrial applicability limb could be illogical and inconsistent as shown in this chapter. The reform to remove the non-industrial applicability of medical methods of treatment is one way the legislature recalibrated the criteria in the UK. For South Africa, it could be suggested that it may be untenable to hold that methods of treatment are incapable of industrial application, and rather that this be made a proper exclusion on policy grounds. With this framework in place, it becomes easier to make an assessment of whether a purported invention is capable of industrial application rather than trying to artificially fit the evaluation into illogical historical models.

7.10 Conclusion

The continued relevance of the industrial application requirement has been analysed in this chapter. The criterion has shifted from its focus on whether inventions in agriculture are to be considered capable of industrial application, wherein the transition abandoning the ‘manner of manufacture’ in defining the invention was made. Inventions relating to health have come under the spotlight when this criterion is discussed. The limb has become a benchmark that brings about balance as to when the research output in some of the radical fields leading to health related inventions should be patentable with due regard for space for subsequent improvement by the competitors or third parties who may have already spent a considerable amount of resources and time working towards the solution in the yet to be fully understood or immature industries. The tests that the tribunals tasked with assessing the patentability of these are therefore crucial to a vibrant research clusters resulting in inventions that meet medical and pharmaceutical needs.

Industry conditions have significantly changed since the initial introduction of the criteria. Interpretation that attempts to retrieve from history what the intention of the framers of the original instruments was is difficult to achieve. Focus would rather shift into what the policy makers and legislatures now intend to do to in adjusting the system to fit with evolving technology. In the UK, there have been legislative interventions which clarify the positions with regard to the criteria whilst, in South Africa, there has not been statutory activity dealing with this concept. It is possible to extend this reform movement to South Africa, but without appropriate modifications in light of prevailing domestic constitutional or legal frameworks, the extension would lead to a flawed model. Therefore it is recommended that it is imperative for the South African legislature to consider statutory reforms of this patentability limb to align it with technological developments.

CHAPTER EIGHT

CONCLUSION

8.1 Introduction

The objective of this concluding chapter is to integrate and streamline the conclusions and suggestions made throughout the thesis. Each chapter of the thesis addressed specific aspects relating to the patentability standards as applied to pharmaceutical inventions in the UK and South Africa. In so doing, each chapter analysed a dimension that impacts on the overall patentability of inventions in the two jurisdictions. This chapter seeks to make a concluding reflection, at a holistic level, on the principles established throughout the thesis regarding the patentability standards and whether the methods used for assessing them achieve their intended purpose.

8.2 The thesis outlook

The research carried out in this thesis sought to compare the patentability of inventions as applied in the UK and South Africa. The comparison was done at various levels and from different viewpoints that impact upon the patentability standard, with the statute as existing in the two countries being central to the analysis. The influence of policy, the international instruments and debates thereof, the opinion of various and diverse stakeholders of economic or technical nature, as well as the critique of academic commentators informing the patentability setting and assessment were critically analysed. However, the statute maintained primacy as it is the final determinant of which inventions will be considered legitimately patented in reality.

The thesis, being on the patentability of pharmaceutical inventions, inherently attracts controversy. These range from opponents of the system who tend to deploy rhetoric portraying patents in bad light, to the misconception about the pharmaceutical patent that occurs within discussions and debates on the system, sometimes with inadequate

understanding of the features of the system.¹¹⁶⁰ This is understandable, as the thesis acknowledged that the system has a wide array of stakeholders due to the impact of pharmaceutical patenting on society at large. The recent trend has indeed been the inclusion of more non-technically inclined participants within the patentability discourse and the awakening, especially of developing country policy-makers, to the impact of patents for pharmaceuticals.¹¹⁶¹ Nonetheless, the need for specialist or technical knowledge of the regime cannot be avoided because whatever inclusive patentability instrument is developed and agreed upon, it will have to be interpreted in specific terms and the subject matter that is usually contested in court is in most cases of a technical nature. The value of the thesis therefore manifests itself in those complex circumstances where the assessment to establish patentability is carried out and the question of whether the appropriate equilibrium sought by the policy and the law is attained.

A theme throughout the thesis has been to ground the discussion of the law of patentability on the science at issue. As a matter of observation, the science and technology is increasingly becoming more complex and there are constantly new derivative fields of knowledge and technology. A point that has been emphasised throughout the thesis is that pharmaceutical inventions have multiple sources and the misunderstanding of what the typical invention in this field is assumed to be were highlighted, pointing out that carrying out pharmaceutical R&D is not such a straightforward venture. Each of the four general sources of pharmaceuticals were highlighted in relation to the different limbs to patentability and the associated and underlying technologies that have become integral to the industry.

This research has been a comparative enterprise and, as such, had to conform to some general rules for a systematic analysis as dictated in the first chapter. However, even with those boundaries in place, there were some hurdles to overcome as some patentability issues in one jurisdiction would not necessarily have corresponding features in the other or there being other variables that could not be identically assessed in the other jurisdiction, such as further internal rules that have an impact in

¹¹⁶⁰ Deere C. *The implementation game: The TRIPS Agreement and the global politics of intellectual property reform in developing countries* (2009) Oxford: Oxford University Press, p.118-120.

¹¹⁶¹ Drahos P. 'Developing countries and international intellectual property standard-setting' (2002) *The Journal of World Intellectual Property*, p.765-789.

only one of the jurisdiction under study. The Biotechnology Directive or the origin disclosure rules for all South Africa patent applications are illustrations of these unique features which complicated the analysis. Moreover, the comparative analysis could be significantly affected when equivalent rules in the patentability statutes are compromised by whether or not they have actually been applied at all in reality and also how they have been applied in reality. One theme that emerged in this regard is that in South Africa, for some of the patentability limbs although stated in the statutes book, there were no corresponding cases in practice, which would have given a more detailed illustrated guidance on how the courts have dealt with the various limbs to patentability.¹¹⁶²

As a result, where there was no application of the law in practice or in the courts, there are lessons to be learnt from a comparable foreign authority where a particular issue has been comprehensively addressed. Since this is a comparative study premised on careful learning of legal principles from other jurisdictions but without blind legal transplant, a suggestion could be made to address this shortage in case law. A recommendation is made that the South African Patent Office could produce a manual that would clarify the deficient legislative framework from the suggestions made from the comparative enterprise in this thesis for the different limbs. This would also compensate for the lack of examination and consolidate the law of patentability into one source. The finding in this thesis is that the lack of the law in practice has been manifested in the criteria for excluded subject matter and industrial application limbs, which nevertheless attracted public pronouncements by policy makers on the criteria without any corresponding law to supporting those assertions.¹¹⁶³

¹¹⁶² Commentators assert that a broad judge made rule will require a series of judicial decisions before inference could be made to similar situations; therefore it was difficult to definitively discern the *ratio decidendi* of some of the limited number of litigated South African cases: Landes W.M. and Posner R.A. 'Legal precedent: A theoretical and empirical analysis' (1976) *NBER Working Paper Series*, p.2.

¹¹⁶³ Justice Harms condemns those pronouncements which have no legal basis and the tendency to oppose concerns by pharmaceutical firms and any IP law reforms advanced at international stage: Harms, fn.504. *cf* Regarding negotiations at WTO or WIPO it has been said that 'the key to getting agreement is getting the right mix of issues on the table, even if they are previously unrelated, so that they can be linked for bargaining purposes', Ryan M.P. *Knowledge diplomacy: Global competition and the politics of intellectual property* (1998) Washington: The Brookings Institution, p.92.

8.3 The thesis foundation

As it has already been alluded to, the view-point adopted in this thesis finds grounding in the law. The thesis is anchored on the notion that even though the legislature is notionally free to prescribe the domestic patentability frameworks, it is helpful to do so mindful of the lessons to be learnt from the historical models of the system or from foreign jurisdictions. As the system does not exist in isolation immune from external influences, the historical models of patent justifications present a valuable source of instructive discourse on how to refine the patentability standards to attain particular ends. It was shown that the UK has a wealth of history in setting various patentability levels and these are helpful in adjusting present and future standards. Prudence was stressed in doing so, as there are outcomes of legislative interventions that are not automatically repeatable, predictable or even applicable to later situations.¹¹⁶⁴

Historically, South Africa followed the UK in most of the historical statutory promulgations. It was observed in this thesis that some of these statute imports seemed to be unconsidered and no clearly formulated basis for their adoption was discernible. The thesis then suggested that from this history, South Africa could in some instances extract the principles to be mindful of when appropriately formulating reforms and that these are to be directed to particular internal needs. The patentability standard must serve a clear domestic need. The argument advanced by this thesis is that the lessons are derivable from the historical and classical justifications of the system and its evolution.

A limitation to the recasting of patentability standards from any historical or foreign source is that the UK and South Africa are bound or at least persuaded by external obligations that impact on how they could manoeuvre their domestic models of patentability. The TRIPS Agreement has affected the extent of how both jurisdictions could adjust their laws.¹¹⁶⁵ For both countries, the influence of external forces is from both international and regional centres and increasingly plays a role in the setting of

¹¹⁶⁴ As pertinently stated by Mustill LJ in *Genentech Inc's Patent (Human Growth Hormone)* [1989] RPC 147, p.258-259.

¹¹⁶⁵ Reichman J.H. 'The TRIPS Agreement comes of age: Conflict or cooperation with developing countries' (2000) *Case Western Reserve Journal of International Law*, p.441-470.

the patentability standard. More crucial is that interpretation and assessment of the patentability limbs can rely on external authority for both jurisdictions. For example, the UK takes note of patentability interpretation in the EPO, a point illustrated by the Supreme Court in *HGS* overturning the domestic lower courts because the approach they used was different to that used by the TBA.¹¹⁶⁶ South Africa's influence by foreign jurisdictions is demonstrated by the constant use of EPO and UKIPO examination manuals for deciding patentability cases.

In respect of the dynamics within the international forum, the UK and South Africa were noted to differ in their relative positions at the international arena. The UK is one of the members of what can be called the powerful or influential grouping that persuades the direction of patentability discourse and general IP law. Not only is it through the wealth of patentability case law that other jurisdictions rely on or at least tend to refer to, but also in making reasoned and often strategic contribution at this level.¹¹⁶⁷ South Africa is usually seen to be amongst the group that has traditionally been considered the recipients of the laws from the international arena or foreign sources. However, in this thesis it was shown that on the provisions that deal with patentability, South Africa already had statutory patentability standards similar to those that were prescribed by the TRIPS Agreement.¹¹⁶⁸

The thesis proposed that even though the conditions or other variables that can impact on pharmaceutical patentability may exist, the patentability at the international level could advisably be approximated to a universal standard. This is grounded on the basis that science is universal and there is an increase in cross-jurisdictional use or flow of scientific knowledge. An argument was put forward that there is benefit to be had in setting the patentability standard at globalised levels based on the universality of knowledge.¹¹⁶⁹ There certainly are differences in knowledge systems and economies between the developed and developing countries, but the scientist to whom

¹¹⁶⁶ *HGS*, para.129 and 171.

¹¹⁶⁷ Helfer, fn.169.

¹¹⁶⁸ In South Africa the patentability limbs were introduced in colonial times and tended to readily follow UK statutory changes. In addition, the patenting of pharmaceutical products, a controversial TRIPS provision, had been allowed previously.

¹¹⁶⁹ Youde notes that 'it is not scientific knowledge on its own that influences policy: it is the interaction between knowledge and broader cultural contexts in which that knowledge exist', Youde J.R. *AIDS, South Africa and the politics of knowledge* (2007) Hampshire: Ashgate Publishing Limited, p.30.

the specification is addressed is universal. A patentability assessment that would require consideration of the personal and subjective circumstances of the researcher is rejected.

8.4 The model building

The four justifications developed from the history of the patent were useful for deployment into how each of the patentability limbs is set or evaluated. The thesis suggested that the tests designed for the assessment of each of the limbs should reflect this. It is also important to verify whether the tests that are utilised in court are attuned to the purpose of the patent system.¹¹⁷⁰

In chapter one, the four justifications were relied on to build what was laid out as an optimal standard. The justifications are that there must be recognition of the inventor's right to the invention, the patent is a monopoly reward, the patent is an incentive to invent and innovate and the patent performs an information function and therefore the patentability assessor has to be mindful of these. The justifications all have a vital contribution to make in setting the appropriate patentability standards. Thus, it was proposed that when setting policy or making assessment of whether an invention meets the patentability standards, regard should be taken of all of them as they affect how far the balance between private interest and the public is struck.

In chapter four, it was shown that the limb of excluded subject matter not only provides a lever for balancing between the private and public interests, but it also provides a systematic mechanism of deciding whether subject matter falls within the realm of categories the legislature deem unsuitable for patenting.

Building particularly on the classical justification that the patent acts as an information source, the assessment under the novelty limb sought to evaluate whether inventions disclose anything that was not available to the public before. Overall the evaluation methods were found to identify objective integers to use in the assessment.

¹¹⁷⁰ As suggested in the thesis, in order to improve on fact-specific patentability judgments, policy-based decision-making has been identified as a viable approach: Rai A.K 'Engaging facts and policy: A multi-institutional approach to patent system reform' (2003) *Columbia Law Review*, p.1035-1135 generally and particularly, p.1101-1103.

However, there are some aspects that have the potential of introducing some subjectivity, such as relying on the common general knowledge which can be subjective or the enablement concept which can sometimes allow experimentation by the skilled person.

The sixth chapter is largely grounded on the premise that patents provide an incentive to invent and innovate resulting in an improvement in the state of the art in non-obvious ways. The thesis found that the patentability assessment methods could be carried out in a way that prevents hindsight, a factor that increases with passage of time from the point of invention or absorption of the invention into general use.

The industrial application criteria was seen as one that is important for safeguarding that claimed inventions for which a patent is granted are practical. It was emphasised that it seems unnecessary to add other obligations on this criteria, for instance ones that are directed toward ethical or public policy considerations.

8.5 Recommendations

In addition to suggestions made throughout the thesis, this section seeks to combine principles applicable on a general level to the patentability limbs into a unified proposal.

A

The patentability limbs are distinct and separate, however, they often have overlapping elements. For instance, for the industrial application and excluded subject matter limbs it was observed that a purported invention that is caught out by one limb is likely to be caught out by the other¹¹⁷¹ or the fact that a court challenge on non-obviousness usually accompanies novelty.¹¹⁷² Thus, in order to maintain the distinction between the patentability limbs and the principles applicable thereof, it is necessary for commentators and courts to remain vigilant when testing under each separate limb.

¹¹⁷¹ *Melia's Application*, UK Patent No. BL O/153/92.

¹¹⁷² For instance in *Synthon*.

This builds onto another premise, that the assessment test must make it clear as to which evidence is to be captured for evaluation. For example, non-obviousness must be forward looking from the priority date without allowing hindsight or accounting for development after the priority date. This maintains objectivity in the assessment. Understanding this is not only useful for courts, which were found to be mindful of this, but perhaps more crucially for policy makers. Patent policy discussions especially at the international level can sometimes be rather charged and the advancing of stakeholder positions and interests is usually accomplished by tactical negotiation means. In the end, the assertions that are made at these political forums may be of limited use for the inventors in the domestic regimes wherein it becomes difficult to establish the accurate applicable standard.

For instance, South Africa has pursued the agenda on origin disclosure in multiple international forums for some time now in the quest to protect its resources.¹¹⁷³ However, this agenda has now been superimposed in undesirable ways on the domestic patentability requirement that patent practitioners and judges alike have lamented.¹¹⁷⁴ The domestic discourse is increasingly being informed and governed by the discourse from the international arena, which seems to be mainly directed at warning on the disadvantages of the patent. As a result, internally, the question of what constitutes prior art has become uncertain and eroded such that it is becoming increasingly difficult to properly judge prior art for patentability assessments.

The overarching theme and recommendation is that the assessment methods must be clear and accurately identify the appropriate elements for assessment under each limb without undue influence from third parties.

B

The premise in this thesis is that the optimal patentability standard is one that has characteristics that are compatible with both the needs of industry and the dictates of public interest. These needs are difficult to ascertain objectively and are subjective to the opinion of the participant concerned. The views of industry players on what

¹¹⁷³ Visser C. 'Some thoughts on making intellectual property work for traditional Knowledge' (2002) *South African Mercantile Law Journal*, p.656-687.

¹¹⁷⁴ Harms L.T.C 'A few negative trends in the field of intellectual property rights' (2009) *THRHR*, p.175-191.

should be patentable are varied, but perhaps can be encapsulated by what the president of the EPO said; that the interests of patentees or their competitors or third parties is best served when the patent application is treated consistently and independently of who in one occasion is the applicant, such that even when they are third parties they equally benefit.¹¹⁷⁵

The assessment methods used in courts can be said to achieve this benchmark of objectivity or at least approximate it and are independent of subjectivity that could otherwise be introduced by looking into the identity or circumstances of the patentee rather than the claimed invention. Lord Hoffmann has aptly summed up that the claimed invention must be judged according to what the patentee claims ‘and not to some vague paraphrase based upon the extent of his disclosure in the description’.¹¹⁷⁶ In doing so, he has allowed patentees to be held only to their claims and not any other perceptions outside of the claims under scrutiny.

The interest of the public was found to be served in this equation through the benefit of the disclosed information accruing to the public, the patentee exploiting their patented invention and through third parties either being clear on how to invent around the patent or use the invention at the expiry of the patent. The success of serving the public interest is dependent on the repeatability of the tests used by the courts and the enabling of third parties to predict how they could legitimately work around the invention without infringing.

Ultimately, robust patentability assessment methods are necessary to achieve the goal of objective and consistent analysis of the claimed invention.

A future outlook from this research is that patentability standards can and do evolve and their refining to allow adaptation to new technologies. As new technology comes about and the debate on truly global patent regime rages on, the law-makers have a difficult task whereby they have to make decisions on how the standards have to be

¹¹⁷⁵ Referring to the Patents Office’s task of always striking an equilibrium in the examination of patent applications for its multiple stakeholders: EPO President Benoît Battistelli ‘*How Can Europe Be a Key Player at Global Level in the Patent Field? What is the Role of the EPO?*’, 8 November, London: UCL.

¹¹⁷⁶ *Conor*, para.19, Lord Hoffmann, allowing the claim for invention which only had limited experimental data.

structured such that pharmaceutical research is not hindered. Whatever legislative framework they adopt, it would have to be one that applies equally amongst the users of the system and provides safeguards that the framework chosen meets its intended purpose.

8.6 Conclusion

In conclusion, it is important that the patentability standards are attuned to their designed purpose. The veracity of standards as set by the statutes is vindicated only if it also applies in reality. This is important because there is little point in having a patent that will, in all likelihood, be invalidated in practice. Admittedly, there is a case to be made for patents that are completely adjusted for local circumstances, as currently litigation and patentability assessment is made territorially. Nonetheless, if the patent offers no protection beyond the jurisdictional borders, it will be of less value in more globalised knowledge economies.

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