

The Public Interest and the Construction of Exceptions to Patentee's Rights

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A comparative Study of UK and German law

by

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A Thesis Submitted for the Degree of Doctor of Philosophy

Queen Mary, University of London

2015

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Abstract

The thesis analyses the concept of public interest with regards to exceptions to patent rights. It is submitted that patent rights are generally provided for a utilitarian purpose which is to enable technological advance. This goal is meant to be achieved by providing exclusive rights over the patented invention. Often however public interest considerations also mandate a limit to the exercise of the patent right through exceptions.

The thesis maintains that whilst public interest considerations with regards to patent rights and exceptions have constantly been adopted and incorporated through legislation by national (or regional) legislators; international legal regimes are increasingly influencing these considerations. Such supra-national regimes which are relevant to patent law include the TRIPS Agreement but also fundamental rights regimes such as the ECHR or the EU Charter on Fundamental Rights.

The thesis will assess how these regimes influence and possibly restrict legislators in providing exceptions to patent rights. It makes significant contributions to the field of patent law by scrutinising what public interest consists of with regards to exceptions to patent rights and will analyse how a third party interest is factored into this process. It will analyse how supranational regimes influence this assessment and therefore identify the impact of the TRIPS Agreement along with the increasingly more relevant discourse on the fundamental rights level. The approaches provided by both of these legal regimes directly influence national legislation which leads to the question: how much flexibility remains to national legislators to provide for exceptions in the public interest without violating international law?

This analysis therefore ultimately contributes to the scholarship with regards to the increasing transnationalisation of law. The findings of the thesis will recommend an approach on how legislators can provide for an individually balanced national patent system that is consistent with international norms. This becomes even more important because patent laws have become an important element in bilateral agreements, such as the TTIP currently being negotiated by the United States and the European Union.

Acknowledgements

First, I would like to thank my supervisor for helping me complete this research. Professor Guido Westkamp has not just been a valued “Doktorvater”. Over the years I can truly say that he has become a good friend. I have always appreciated our great conversation about “the law” but more those not on the law. I look forward to many more to come. My gratitude also goes to Professor Spyros Maniatis. His leadership, generosity and constructive guidance have been a true inspiration since my days as his LL.M. student.

I would like to thank the Herchel Smith studentship that entitled me to commence this project. This research could have not been completed without the wonderful resources that I have been provided with at Queen Mary. To mention is the excellent IP Archive that has been my home for many years and Malcolm Langley is perhaps the most helpful person when it comes to research. I would also like to express my gratitude to the Max Planck Institute for Innovation and Competition and its people. It has become my second academic home while I have been squatting there over the last years.

What particularly nurtured this research was the wonderful and inspiring academic community at Queen Mary. It has truly become my home, my *alma mater*. Over the years I have been fortunate to have encountered wonderful friends and colleagues and I owe these people so much. So, I shall not pick out particular people – you know who you are!! I just wanted to mention Dr Theodora Christou for her help and constructive criticism in finishing this work and looking through numerous drafts - and the good mood she spreads.

Personally, I would also like to thank my friends who have supported me during these many years and encouraged me to carry on. A special thank you goes to Dr Vivian Mak. She has been a true inspiration and my *spiritus rector* over the years.

Finally, I would like to thank my family for their everlasting and unshaking support to get this work done. I would like to particularly thank my father, Dr Manfred Mimler who has eagerly been assisting me in my academic pursuits and is eagerly looking forward to welcoming me in the club of Doctors. Last but definitely not least; this thesis would have not been possible without the endless loving support of my mother Angela Doreen Mimler who has endlessly been storming heaven. This work is dedicated to her.

Abbreviations and Acronyms

| | |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| BGH | Bundesgerichtshof (German Federal High Court) |
| BVerfGG | Bundesverfassungsgerichtsgesetz |
| BGBI | Bundesgesetzblatt |
| Biotech Directive | Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions of 6 July 1998 on the legal protection of biotechnological inventions |
| CJEU | Court of Justice of the European Union |
| CPC | Community Patent Convention |
| DSB | Dispute Settlement Body |
| ECommHR | European Commission on Human Rights |
| ECJ | European Court of Justice |
| ECHR | European Convention on Human Rights |
| ECtHR | European Court of Human Rights |
| EC | European Community |
| EEC | European Economic Community |
| EFTA | European Free Trade Association |
| GATT | General Agreement on Trade and Tariffs |
| HRA 1998 | Human Rights Act 1998 |
| IP | Intellectual Property |
| OECD | Organisation for Economic Co-operation and Development |
| PatG | Patentgesetz (German Patent Act) 1981 (if not referred to otherwise) |
| R&D | Research and Development |

| | |
|-------|--------------------------------------------------------------------|
| RG | Reichsgericht |
| TEU | Treaty on European Union |
| TFEU | Treaty on the Functioning of the European Union |
| TRIPS | Agreement on Trade-related Aspects of Intellectual Property Rights |
| UK | United Kingdom |
| WIPO | World Intellectual Property Organisation |
| WTO | World Trade Organisation |

Journals

| | |
|-----------|-------------------------------------------------------------------|
| BIfPMZ | Blatt für Patent-, Muster- und Zeichenwesen |
| EIPR | European Intellectual Property Review |
| GRUR | Gewerblicher Rechtsschutz und Urheberrecht |
| GRUR Ausl | Gewerblicher Rechtsschutz und Urheberrecht, Ausländischer Teil |
| GRUR Int | Gewerblicher Rechtsschutz und Urheberrecht, Internationaler Teil |
| IIC | International Review of Intellectual Property and Competition Law |
| IPQ | Intellectual Property Quartely |
| OJ | Official Journal of the European Union |
| OUP | Oxford University Press |
| QMJIP | Queen Mary Journal of Intellectual Property |
| ZaöRV | Zeitschrift für ausländisches öffentliches Recht und Völkerrecht |

Table of Legislation

International

Agreement on Trade-related aspects of Intellectual Property Rights (TRIPS)

Berne Convention for the Protection of Literary and Artistic Works

Convention on International Civil Aviation (also known as Chicago Convention)

Convention Establishing the World Intellectual Property Organization (Signed at Stockholm on July 14, 1967 and as amended on September 28, 1979)

European Convention on Human Rights as amended by Protocols Nos. 11 and 14 supplemented by Protocols Nos. 1, 4, 6, 7, 12 and 13

European Patent Convention

Universal Declaration of Human Rights (UDHR)

International Covenant on Civil and Political Rights (ICCPR)

International Covenant on Economic, Social, and Cultural Rights (ICESCR)

Paris Convention for the Protection of Industrial Property

Patent Cooperation Treaty (PCT)

Understanding on Rules and Procedures Governing the Settlement of Disputes (Annex II to the Agreement establishing the World Trade Organisation)

Vienna Convention on the law of treaties

National and regional legislation

Austria

Bundesverfassungsgesetz vom 4.3.1964

Canada

Patent Act

European Union/Communities

Directive 2001/83/EC [2001] OJ EC L311/67 on the Community code for medicinal products for human use, substituted by art.1(8) of Directive 2004/27/EC of the European Parliament and of the Council [2004] OJ EC L136/34

Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products [2001] OJ EC L311/1, substituted by art.1(6) of Directive 2004/28/EC [2004] OJ EC L136/58

Directive 2004/27/EC of the European Parliament and of the Council [2004] OJ EC L136/34, and art.13(6) of Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products [2001] OJ EC L311/1, substituted by art.1(6) of Directive 2004/28/EC [2004] OJ EC L136/58

Charter of Fundamental Rights of the European Union OJ, (2010/C 83/02)EN 30.3.2010 Official Journal of the European Union C 83/389

Community Patent Convention 1975

Community Patent Convention 1989

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

Charter of Fundamental Rights of the European Union OJ, (2010/C 83/02) EN 30.3.2010 Official Journal of the European Union C 83/389

Regulation (EC) No 469/2009 of the European Parliament and the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products

Treaty on European Union

Treaty on the Functioning of the European Union

Germany

Bundesverfassungsgerichtsgesetz

Grundgesetz (Basic Law of the Federal Republic of Germany)

Gesetz über das Gemeinschaftspatent und zur Änderung patentrechtlicher Vorschriften

Patentgesetz 1981(Patent Act)

Patentgesetz 1877

Patentgesetz 1891

Urhebergesetz (Authors' Rights Act)

Weimarer Reichsverfassung (Weimar Constitution)

Italy

Constitution of the Italian Republic

Spain

Spanish Constitution

Spanish Intellectual Property Act

United Kingdom of Great Britain and Northern Ireland

Copyright and Rights in Performances (Personal copies for Private Use) Regulations 2014

Copyright and Rights in Performances (Quotation and Parody) Regulations 2014

Human Rights Act 1998

UK Patents Act 1977

Legislative Reform (Patents) Order 2014

Patents Rules 2007, SI 2007/3291

Patent Rules 1968, Schedule 4

United States of America

Copyright Act of 1976 - 17 U.S.C.

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Chapter 1: Introduction

1.1 Background to the research

Patents are exclusive rights granted once the granting patent office has concluded that the patentability- and other criteria are met. The right as such has a negative component which means that the patentee may exclude others from using his invention during the term of the patent. But not all uses that would constitute an infringement are sanctioned. Patent legislation around the world provides for certain acts to be exempted from patent infringement. Such exceptions to patentees' rights limit the patent holder's control of the invention. Practically, they provide the dividing line from which point someone needs to seek permission to use the patented invention from the patent holder:¹ As such, "(e)xceptions are in their nature limitations on rights."²

Such exceptions have been provided for a wide array of purposes. In his report for the World Intellectual Property Organisation (WIPO), Lionel Bently identifies 33 types of exceptions.³ They exempt a variety of different uses from infringement, such as prior and experimental uses, de-compilation of software and for the sake of public order. The differing rationales for which exceptions are provided lead Bently to say that legislators have either enacted exceptions intuitively as to what "was fair or sensible"⁴ or that their enactment was the outcome of compromises between different lobbying interests.⁵

Comparable to the different rationales on which exceptions are based, terminological differences can also be seen. Provisions that restrict the exercise of the patent holder's right to exclude others have been referred to as "defences", "permitted acts", "free uses", "restrictions", "limitations of effect" or even "users' rights".⁶ Their effect is however the

¹ Lionel Bently, 'Exclusions and exceptions to Patentees' Rights: Taking Exceptions seriously' [2011] Current Legal Problems 315, 319.

² *ibid* 328.

³ Lionel Bently et al, 'Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights' (WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I, World Intellectual Property Organisation 2010) 30 – 31.

⁴ *ibid* 56.

⁵ *Ibid* 56.

⁶ Lionel Bently et al, "Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights", WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I (2010) 7.

same: They imply that a certain use by a third party which would otherwise constitute an infringement is legally permitted provided that the prerequisites of the exception provision are given.⁷ As a working definition for this work, the term *exceptions* will be applied.⁸ By this, an unauthorised use of the patented invention is meant that would normally constitute an infringement of the patent but is permitted.⁹ Similarly to Annette Kur¹⁰, the use of this term is not meant to imply a particular standpoint to the issue but opts to apply the most commonly used term.

⁷ Richard Gold and Yann Joly, 'The Patent System and Research Freedom: A Comparative Study' (WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I, World Intellectual Property Organisation 2010) 1. Pires de Carvalho provides another terminological clarification with this regard: "Exceptions are factors that reduce the enforceability of rights against certain acts of infringement only, thus without affecting the general integrity of the rights. Limitations are factors that do affect the integrity of the rights – and thus their enforceability in general against all acts of infringement. Exhaustion and compulsory licenses are examples of exceptions. Term and exclusions from protection are examples of limitations." - Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (4th edn, Wolters Kluwer 2014) IN.32.

⁸ Kur notes that there is no international agreement relating to the nomenclature and highlights the problems arising when one refers to "exceptions" which could suggest that these provisions rank lower than the right. She uses the term "exceptions" interchangeably with "limitations" - Annette Kur, 'Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?' [2008-2009] *Richmond Journal of Global Law and Business* 287, 291-292.

Cook, on the other hand applies the term "defence" within his report for the Intellectual Property Institute - Trevor Cook, 'A European Perspective as to the extent to which experimental use, and certain other defences to patent infringement apply to differing types of research' (IPI Report 2006) 1 (in fn 1).

⁹ The term "exceptions" appears to be widely accepted and is also used in the study for the Standing committee on the Law of Patents (SCLP) at WIPO. The term however is problematic as it could lead to the connotation that the exercise of the patent right is the rule while a deviation thereof is "exceptional" and only permissible in such exceptional circumstances. This connotation stems from the *singularia* rule in Roman law that exceptions are to be interpreted narrowly. The rule is therefore present in such civil law jurisdictions that are based on Roman law - Henrik Holzapfel and George Werner, 'Interpreting Exceptions in Intellectual Property law' in Wolrad Prinz zu Waldeck und Pyrmont, Martin J. Adelman, Robert Brauneis, Josef Drexl and Ralph Nack, *Patents and Technological Progress in a Globalized World – Liber Amicorum Joseph Straus* (Springer 2009) pp 99. Holzapfel and Werner however conclude that the *singularia* rule would allow the application of the rule in relation to the interpretation of exceptions to infringement of an intellectual property right and that rather their interpretation needs to be conducted "in accordance with customary hermeneutics"- *ibid.* p 114. Additionally, Canaris states that in the event of an "exception" to a rule the person wishing to apply and interpret this rule needs to seek for counsel from the wording of the provision as well as making a teleological assessment of the provision - Claus-Wilhelm Canaris, *Methodenlehre der Rechtswissenschaft* (3rd edn, Springer 1995) 174 – 176. Bently mentions that exceptions are prone to a narrow interpretation, especially in countries with a civilian legal tradition since they would be perceived as derogations to general principles. He adds that "British courts have tended not to accept this logic, instead seeing exceptions as part of the legislative definition of the grant itself, the Court of Justice of the European Union has indicated its approval of the general proposition (at least with respect to exceptions to fundamental treaty freedoms)." - Lionel Bently, 'Exclusions and exceptions to Patentees' Rights: Taking Exceptions seriously' [2011] *Current Legal Problems* 315, 330.

¹⁰ Annette Kur, 'Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?' [2008-2009] *Richmond Journal of Global Law and Business* 287, 292; Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 212.

The body of patent law is commonly seen as being subject to countervailing interests.¹¹ On the one hand, patent holders seek to receive broad protection for their inventions and would like to exclude any third party use without their consent. On the other hand, competitors and the greater public at large would like to be free to use the patented invention. Aside from these individual interests surrounding patent law, it has been said that both the grant of the patent rights as well as exceptions thereof have been provided in the public interest: courts and legislators have exempted certain uses from patent infringement for a specific purpose which they found to be in the public interest. This reasoning arguably highlights a functional role that exceptions have: Together with the infringement provisions they delineate which uses fall within the exclusivity of the patent right from such that should remain exempted from its scope. However, the term “public interest” remains a blurry legal concept which warrants clarification. Such clarification is important since exceptions have an undiscovered potential as a legislative tool to provide for policy making in the public interest.¹²

1.2 Significance and scope of this study

The thesis will analyse how public interest considerations have been and are implemented and applied in relation to exceptions to patentee’s rights. The analysis will be conducted by comparing the approaches of German and UK patent law. Both countries are important countries within the European Union with regards to patent activity and litigation but have different legal traditions, one being the common law and the other being the civil law tradition. The way that public interest considerations are adopted in Germany and the United Kingdom differs. In Germany, it is submitted that constitutional law is often applied when assessing whether public interest prevails over the property right of the patent holder. In

¹¹ With regards to an exception that is commonly found throughout patent legislation worldwide, the research exception, Professor Cornish has outlined the underlying question when he states:

“Patents offer the reward of an exclusive market opportunity and thereby supply an incentive to both research and subsequent development. But they do so only under the condition that the invention be adequately disclosed in the patent specification, so that the industry concerned and the public generally can know what it is. How far may competitors thereafter perform the invention, particularly when their activities develop the invention further or provide new information about its uses? If they may engage in such experiments as they please, the initial incentive of the patent may to a degree be diminished. But if they may not, the original patentee may control the further progress of a particular technology for the duration of his exclusive right.”

William Cornish, ‘Experimental use of patented inventions in European Community States’ [1998] IIC 735.

¹² Lionel Bently et al, “Exclusions from Patentability and Exceptions and Limitations to Patentees’ Rights”, WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I (2010) 69-71.

contrast, in the UK, such constitutional law in its traditional sense is absent and courts seem to follow a pragmatic rather than doctrinal approach.

However, both national approaches are subject to hierarchically superior legal provisions that national laws need to abide to since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as well as regional legislation in Europe, influence the application of public interest considerations in national legislation. In particular, the inception of fundamental rights considerations, as promoted in the EU Charter of Fundamental Rights and the European Convention on Human Rights (ECHR) have the potential to influence considerations of public interests in relation to exceptions to patentee's rights in national laws.

Considerations of public interests in exception provisions are indeed critical for policy making. The TRIPS Agreement stipulates in its Article 27 (1) that patent protection is available for any inventions in all fields of technology. *Ex ante*, this provides a very broad application for patent protection. The Agreement does provide legislators with the possibility to exclude certain subject matters from being protected as a patent. But arguably, exceptions to patentee's right that do not negate the patent right but just limit its exercise provide a more flexible tool for legislators¹³ to adopt public interest considerations¹⁴ as stipulated in a report for the Standing Committee on the Law of Patents at the World Intellectual Property Organisation (WIPO).¹⁵

It is therefore the purpose of this thesis to provide a conceptual definition of what constitutes "public interest"¹⁶ in the chosen jurisdictions and an analysis of how it is assessed and adopted in relation to exceptions. Generally, exceptions are precisely drafted and apply for a particular purpose. It is however submitted that the different rationales for providing

¹³ Ghidini labels exceptions as antidotes since they can address the anti-competitive properties that patent protection entails – Gustavo Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law* (Edward Elgar 2010) 33-34.

¹⁴ Hence, this could serve the paradigm shift that Dreier stipulates: "In general, the critical voices consider intellectual property legislation no longer as a regulation that exclusively or predominantly serves the purpose of protecting the interests of right-holders. Rather, the function of intellectual property legislation is seen in the accommodation of the interests of creators, producers, competitors and users alike, this creating an appropriate legal framework for the knowledge and innovation society." - Thomas Dreier, 'How much 'property' is there in IP?' in Helena R. Howe and Jonathan Griffiths (eds), *Concepts of Property in Intellectual Property Law* (Cambridge University Press 2013)134.

¹⁵ Lionel Bently et al, "Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights", WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I (2010) 69-71.

¹⁶ Häberle finds that the public interest surrounding a piece of legislation has often become difficult to detect due to the autonomisation and hence specialisation of a field of law - Peter Häberle, *Öffentliches Interesse als juristisches Problem* (Athenäum Verlag 1970) 289 – 290.

exceptions are based on more abstract public interest considerations. This also addresses the issue of whether third party interests in using the patented invention can be considered as being within the “public interest”. This tends to be the case in relation to exceptions to patent infringement. In this case, the exceptions excuse an unauthorised use from patent infringement of a third party. This mandates the question of whether the use of that party is within the public interest. In other words: When can such third party use be considered to be in the public interest?

The thesis will then scrutinise to what extent international and regional *meta-norms* influence or conflict with national applications and how such conflicts may be accommodated. The research in relation to how considerations of public interest have been accommodated within exceptions in national patent acts should already, in itself, provide interesting insights. The analysis however, will become even more crucial now that intellectual property (IP) rights are part of global trade regulation due to the WTO’s TRIPS Agreement. Furthermore, the competence to provide for such exceptions, and its underlying public interest, no longer lies solely with national legislators but falls under the scrutiny of WTO law. National patent laws depend to a considerable extent on their compatibility with this Agreement and its interpretation by bodies of the WTO.

1.3 Hypothesis and research questions

The thesis sets out to test the hypothesis that exceptions to patentee’s rights are based on and informed by public interest considerations that are applied by the respective legislator.

In order to examine this hypothesis, this thesis evaluates the following two research questions.

Firstly, how public interest considerations as a general principle are internalised into patent law by exceptions to patentee’s rights; what meta-norms potentially influence the legislator and had to be adhered to; and how the interests of third parties in using the patented invention inform the discourse. As mentioned above this first question will be sought to be answered by using the research exception within the patent laws of the United Kingdom and Germany.

Secondly, bearing the first question in mind, how does the shift of competence to international forums, such as the WTO that determine the scope of exceptions, influence the accommodation of public interest considerations by exceptions?

1.4 Research Methodology

The research will identify both primary and secondary sources to scrutinise the research questions and to deduce arguments and recommendations. The theoretical framework of the study involves an analysis of relevant legislation, statutes, case law and academic legal literature. Since the study encompasses a comparative analysis the theoretical tools of economics will only provide referential assistance.

The thesis has two important limitations: First, it is limited to analysing public interest considerations within exceptions where the public interest is not verbatim mentioned within the respective provision but rather serves as an underlying rationale. As a recurring case study, the thesis will analyse how researching on a patented invention has been treated in patent law in the chosen jurisdictions. Research is considered to be crucially important for technological advance and hence, widely considered to be in the public interest. This makes it a useful case study but limits its findings to this particular aspect of the public interest. But careful generalisations will be drawn where applicable in order to provide a broader picture. However, an in-depth analysis of other exceptions to patent rights would go beyond the scope of this work.

Secondly, the thesis will also not analyse compulsory licensing. While it is argued that provisions allowing the unauthorised use of the patented invention are a form of exception provision, a detailed analysis would be beyond the scope of this work. It will however refer to compulsory licensing where this is appropriate.

1.5 Structure of the thesis

The thesis proceeds by analysing the research questions in two parts. Part 1 establishes in chapters 2 and 3 what constitutes public interest considerations in relation to exceptions to patent rights. Part 2 then establishes how international law influences this assessment. Part 3 provides a synthesis of the findings and policy recommendations.

Chapters 2 & 3 provide an overview of national patent legislation and examine public interest considerations within exceptions in Germany and the United Kingdom. This analysis will be conducted in the form of a case study in relation to one particular exception to patentee's rights, being the research exception. Chapter 2 will provide a historical overview. Due to the lack of a statutory provision, the chapter will analyse how courts allowed such uses for research purposes within their judgements and to what extent public interest considerations guided them.

Chapter 3 then looks at the statutory provisions that both the UK and Germany have legislated. It will analyse the *travaux préparatoires* and case law in order to furnish how public interest was consolidated within the drafting and application of the research exception. Both Article 60(5)(b) of the UK Patents Act 1977 and § 11 Nr.2 PatG introduced statutory exceptions for experimental use in both jurisdictions and are modelled on the same provision from the Community Patent Convention (CPC) 1975. However, the application and scope of the respective provisions within each jurisdiction differs. The chapter will analyse the approaches the courts took in order to analyse how public interest consideration were applied and will reveal how fundamental rights considerations play a role in the application and interpretation of the exception within Germany.

The second part of the thesis then addresses how international legal frameworks can influence the assessment of public interest within a nation state. Chapter 4 examines the notion of public interest deviation for property rights in regional jurisdictions in Europe. It will analyse the influence that legislative measures by the European Union (including the EU Charter of Fundamental Rights, which is legally binding following the Lisbon Treaty) and the European Convention on Human Rights (ECHR), which is governed by the Council of Europe, have and may have in future. The assessment of these instruments, such as the EU Charter of Fundamental Rights and the ECHR, is important as these they are hierarchically

above national law and therefore are crucial for a comprehensive overview of national patent laws though their effect is still debated.

Human rights considerations from the ECHR are of particular relevance for the UK as the Human Rights Act 1988 (HRA 1998) stipulates that Human Rights as enacted by the ECHR are relevant in such an assessment. The case law within the UK in relation to copyright has already provided some guidance in relation to this issue and analogies, where possible, to the law of patents will be made in order to elaborate in what way fundamental rights can influence exceptions within UK patent law.

The chapter will analyse how these notions deriving from regional European law may influence the assessment of public interest in exceptions to patentee's right within national patent laws. While emphasising that patent rights are protected under the fundamental right of property, it will be argued that the fundamental rights framework provides legislators sufficient scope to provide for exceptions in the public interest and that it constitutes a viable approach to balance the interests of right holders and third parties.

Chapter 5 analyses how public interest considerations are covered within the global context of patent law. The TRIPS Agreement that was introduced in the mid-1990s sets a mandatory minimum level of protection for patents within WTO Member States. Article 30 of the TRIPS Agreement sets out how exceptions to patentee's rights have to be implemented in WTO Member States. The inception of the TRIPS Agreement therefore sets abstract but strict parameters on how exceptions within national legislation ought to be drafted.

In particular, the chapter investigates the nature of Article 30 and how it has been applied in the decisions by the WTO dispute settlement proceedings. The *EC-Canada* case¹⁷ specifically treated the compatibility of exceptions that were provided within the Canadian Patent Act. It will finally be argued that a rigorous application of the Three Step Test in Article 30 TRIPS as conducted by the Panel does not provide much leeway for public interest assessment, although it specifically mentions that third party interests would be taken into account in its overall assessment.

Chapter 6 will synthesise the findings of the previous chapters. Based on the findings of Part 2 that international law may restrict the application of public interest considerations, it will first analyse to what extent such considerations surrounding exceptions can be applied in

¹⁷ *Canada – Patent Protection of Pharmaceutical Products* 'WTO Document WT/DS114/R'.

other legislative tools. Finally, it will address the apparent difficulties in applying domestic public interest considerations with an international regime that curtails such considerations. Additionally, the arguably narrow scope that Article 30 TRIPs (and its current interpretation provide) may compromise a consistent application of fundamental rights considerations in relation to public interest. It will therefore be argued that the rigorous application of the 3-Step-Test within Article 30 of TRIPs neither provides a sufficient basis for applying public interest considerations by national legislators nor does it permit the application of fundamental rights considerations. Therefore an alternative interpretation of Article 30 TRIPs ought to be applied *de lege lata*.

Chapter 7 will conclude the work.

Part 1: Inception and application of public interest considerations within exceptions in national patent legislation

Exceptions to patent rights have nowadays become a common feature in many patent jurisdictions. This can be seen by the fact that they have been applied in an increasing number of patent acts worldwide. Furthermore, the number of purposes for which an exception provision is provided for has steadily increased over the years as the tables in Bently's report demonstrate.¹⁸ This wide application of exceptions to patent rights is arguably a result of legal evolution.

Part 1 will analyse how public interest considerations served this evolution. It will show how public interest considerations have helped to develop exceptions to patent infringement and how such considerations were applied within national legislation. The analysis will be conducted in form of a case study by analysing the inception of the research exception. For the purposes of this work this serves as a useful case study for two reasons: First, the statutory research exception, which is now available in Germany and the United Kingdom, is a prominent exception within patent laws worldwide.¹⁹ Secondly and importantly, because its underlying rationale to permit and encourage research is commonly considered to be within the public interest.²⁰

¹⁸ Lionel Bently et al, 'Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights' (WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I, World Intellectual Property Organisation 2010) 29-31.

¹⁹ According to the study conducted by Bently et al. an exception for experimental/educational use can be found in 86 jurisdictions - *ibid* 29-31.

With this regards, the EC submitted in the *EC-Canada* dispute before the WTO Dispute Settlement Panel that "[i]t could, [...], be said that practically all Members of the WTO had such an exception albeit drafted in a great variety of ways." *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R 55.

²⁰ "A strong research base is vital to the competitiveness of our economy and to promoting the well-being of society" - UK Intellectual Property Office, 'The Patent Research Exception: A Consultation' (UK Intellectual Property Office 2008) 2.

Additionally, Gilat's study on experimental use in patent law stipulates that the public interest that underlies the exception is "in improving public welfare by encouraging technological progress" which would need to be balanced with the interest of patent holders to control their market - David Gilat, *Experimental Use and Patents* (IIC Studies Vol 16, Wiley-VCH 1995) 2.

Part 1 is divided into two chapters: Chapter 2 provides a historical analysis of how research uses were perceived and addressed historically under German and British patent law before a statutory provision with this regard was introduced. Such statutory provision for experimental uses was only introduced in the late 20th century in both jurisdictions which meant that courts had to exempt such uses from patent infringement. The analysis of the case law will provide a better understanding what guided the courts to exempt some uses from patent infringement. In other words, how was the research exception conceived in both jurisdictions? And why was it initially rather narrow in scope compared to the now available research exceptions when researching is perceived to be in the public interest? The chapter importantly focuses on outlining the legal evolution of exempting uses from patent infringement in national laws endemically, i.e. before international intellectual property conventions were able to influence this development.

Chapter 3 will then focus on the currently applicable law which provides for a statutory exception for research purposes in both jurisdictions. This stipulates that legislators perceived a need to provide for such an exception provisions; a need that lies in the public interest. Interestingly, the scope of the research exception differs significantly in Germany and the United Kingdom while the text of the respective provisions is almost identical. Hence, this chapter will focus on the courts' interpretation of their respective research exception and what particular public interest considerations guided them. Particular reference is put on the fundamental rights discourse in Germany in order to establish how fundamental rights affect and even inform public interest considerations.

The Washington Declaration on Intellectual Property and the Public Interest has generally stated that limitations and exceptions serve the public interest. It states that “limitations and exceptions are positive enabling doctrines that function to ensure that intellectual property law fulfils its ultimate purpose of promoting essential aspects of the public interest. By limiting the private right, limitations and exceptions enable the public to engage in a wide range of socially beneficial uses of information otherwise covered by intellectual property rights — which in turn contribute directly to new innovation and economic development.” - The Washington Declaration on Intellectual Property and the Public Interest (August 2011)
<<http://infojustice.org/washington-declaration-html>> accessed 27 May 2015.

Chapter 2: The historical development of exempting research uses from patent infringement in the United Kingdom and Germany

2.1 Introduction

Chapter 2 assesses how activities relating to research were adopted historically within the law of patent infringement of the United Kingdom and Germany. This is because an explicit statutory provision that exempted research uses from patent infringement was only introduced late in the 20th century.²¹ Prior to the introduction of statutory provisions, both patent jurisdictions exempted certain uses relating to research from patent infringement. Due to the lack of statutory law with this regard, it was the courts that developed and shaped patent law. Based on the hypothesis that research is in the public interest it could be argued that they applied public interest considerations to permit experimental uses.

The chapter will therefore focus on what led the courts to exempt certain research focused activities from patent infringement. Furthermore, it will show how courts achieved this. In particular, the chapter will shed light on what guided the courts' judgments and to what extent they followed any public interest considerations. Ultimately, the evolution of exceptions to patentee's rights in Germany and the United Kingdom and their divergent rationale in terms of policy and doctrine will be explored. This will provide a useful basis for the analysis of exceptions *de lege lata*.

²¹ A statutory exception provision for experimental purposes was introduced in the United Kingdom by the UK Patents Act 1977 and in Germany by the German Patent Act of 1981.

2.2 Historical development in the United Kingdom

2.2.1 Introduction

The importance of case law in the development of exempting activities is based on the fact that English and later British patent legislation²² did not provide for an express statutory provision exempting research uses from patent infringement until the 1977 Act. The lack of a statutory exception may be correlated to the fact that there equally was no statutory provision²³ nor definition²⁴ of what would constitute an infringement of a patent until their introduction with the 1977 Act.²⁵ Previously, patent infringement was treated as a tort under common law.²⁶ Cook explains that the lack of a statutory provision regarding patent infringement could explain the lack of statutory exceptions thereof: An infringement provision could have worked as a counterpart to an exception provision.²⁷

2.2.2. The law of infringement

The lack of a statutory provision that specifically exempted a particular use from infringement forced courts to assess whether such use would be considered an infringement of the patent in suit. Before the 1977 Act, an infringement occurred where the alleged infringer did something which the letter patent prohibits after publication of the entire specification. This is reflected by the Royal Command that provided the applicant with his letter patent and which stated:

We do by these presents for Us, our heirs and successors, strictly command all our subjects whatsoever within our United Kingdom of Great Britain and Northern Ireland, and the Isle of Man, that they do not at any time during the continuance of the said term either directly or indirectly make use of or put in practice the said invention, nor in anywise imitate the same, without the written consent, licence or agreement of the patentee, on pain of incurring such penalties as may be justly

²² The 1852 Patents Act replaced the separate patent systems for England, Scotland and Ireland with a UK patent - Klaus Boehm and Aubrey Silberston, *The British Patent System – I. Administration* (University of Cambridge Press 1967) 28.

²³ Paul G. Cole and Stephen F. Jones (eds), *CIPA Guide to the Patent Act 1977* (7th edn, Sweet & Maxwell 2011) [60.03].

²⁴ Simon Thorley, Richard Miller, Guy Burkill, Colin Birss, Douglas Campbell, *Terrell on the Law of Patents* (17th edn, Sweet & Maxwell 2011) [14-01].

²⁵ Within Article 60 (1) and (2) of the UK Patents Act 1977.

²⁶ Paul G. Cole and Stephen F. Jones (eds), *CIPA Guide to the Patent Act 1977* (7th edn, Sweet & Maxwell 2011) [60.03].

²⁷ Trevor Cook, 'A European Perspective as to the extent to which experimental use, and certain other defences to patent infringement apply to differing types of research' (IPI Report 2006) 12. A statutory provision (and therefore definition) was provided by the Patents Act 1977 in Sec. 60 (1) and (2).

inflicted on such offenders for their contempt of this our Royal Command, and of being answerable to the patentee according to the law for damages thereby occasioned.²⁸

The act of experimenting inevitably “makes use” of the patented invention or “puts it into practice” and therefore would *ex ante* constitute an infringing act. While the courts developed case law that would permit experimenting with such an invention to a certain degree,²⁹ they had to address the doctrinal difficulty how such otherwise infringing acts would be permissive. The options that can be applied with this regard were, on the one hand, not to regard experimenting as an infringing act. This raises the problem that a literal interpretation of “making use” or “putting into practice” would often encompass the activities surrounding experiments and research. The other option was to permit or excuse experimental use from patent infringement while still regarding such use as an infringing use. This would create a judge-made exception or limitation to the right of the patent holder.

2.2.3. The case law in relation to experimental uses

A general basis for allowing experimental uses with patented inventions was made possible when it was held that the manufacture of the invention could in some cases not constitute an infringement of that patent. Such an approach can be seen in an early case, *Jones v Pearce*³⁰ where it was held that to “make a thing merely for the defendant’s amusement or as a model was not an infringement”.³¹ This importantly implies that the court was looking at the subjective reason or purpose for the defendant’s use of manufacture of the patented invention rather than just looking at the objective act. In other words, the purpose of the defendant’s use would become relevant in assessing infringement.³²

The approach taken in *Jones v Pearce* affected the courts’ assessment of experimental use as patent infringement. An early case relating to how particularly experimental uses of a patented invention were treated by the courts was *Muntz v Foster*³³ in 1843. The case related to a patent in relation to improved metal plates which were used in sheathing the bottoms of

²⁸ Patent Rules 1968, Schedule 4.

²⁹ *Infra* 2.2.3.

³⁰ *Jones v Pearce* [1832] 1 W.P.C. 122.

³¹ *ibid* 125; James Johnson and J Henry Johnson, *The patentee's manual: being a treatise on the law and practice of letters patent, especially intended for the use of patentees and inventors* (3rd edn, Longmans Green, Reader & Dyer 1866) 221.

³² This is highlighted in the case *Proctor v Bailey and Son* where the judge noted while commenting on *Frearson v Loe* that no infringement would occur where “a person takes a patented article for *the purpose* of seeing whether he can improve upon that patented article (emphasis added)” - *Proctor v Bayley and Son* [1889] 6 RPC 106, 109.

³³ *Muntz v Foster* [1844] 2 W.P.C. 96.

ships and were made by the defendants. With respect to how such use would be regarded, Tindall C.J. stated to the jury:

If they had actually made any small experiment for the purpose of ascertaining what the proportions or properties of the different alloys would come to, that would scarcely have been said to be a making in violation of the patent; but you must ask yourselves whether the making of a quantity which amounts to ten tons, I think, and of which the cost would be something like the sum of between £700 or £800, could have been made for any other purpose at the time than for the purpose of sale, although on second thoughts and on further consideration it may have been deemed to be not a safe nor a proper thing to have used it as it then was made. If such were the case there is no doubt that would be an infringement of the patent.³⁴

The court acknowledged in this case that some uses do not constitute patent infringement. It then applied a rationale where it differentiated between experiments on a small scale which would not conflict with the patent right and those conducted on a large scale which would. This particular finding was acknowledged by the Court of Appeal in the contemporary decision by the High Court in *Monsanto v Stauffer*.³⁵

This stipulates that the court in *Muntz v Foster* was looking at the potential impact that the manufacture would have on the patent holder: while a small scale experiment would not have any effect on the commercial interest of the patent holder, a large scale experiment may have. The Court had the difficulty in *Muntz v Foster* to assess whether the manufacture of the amount of the patented sheathing by the defendant could still be seen as experimental and not already conducted for further commercialisation by the defendant.

The leading case on experimental use before the inception of the 1977 Act, *Frearson v Loe*,³⁶ followed the approach in *Muntz v Foster*. In *Frearson v Loe* it stipulated that experimental use was such that had no further commercialisation of the experimental pursuits in mind. In relation to exempting experimental uses, this precedent was considered to be good law for decades to come³⁷ and remained to be of relevance until the enactment of the 1977 Act.³⁸

The claimant in the case sought relief for an alleged patent infringement conducted by the defendant. Among other defences, the defendant argued that his use would not constitute

³⁴ *Muntz v Foster* [1844] 2 W.P.C. 96, 101.

³⁵ Falconer J stated that “[i]n that passage Tindall C.J. was clearly drawing a distinction between a “small experiment” relating to the subject-matter of the invention (the properties and proportions of the alloys used in the sheathings) and the making of a quantity of 10 tons for the purposes of sale.” - *Monsanto v Stauffer Chemical* [1985] RPC 515, 528-529.

³⁶ *Frearson v Loe* [1878] L.R. 9 Ch.D. 48 (George Jessel M.R.).

³⁷ So for instance Blanco White in relation to the 1949 Act - T. A. Blanco White, *Patents for Inventions and the registration of Industrial Designs* (4th edn, Stevens & Sons Limited 1974) 3-216 in footnote 13.

³⁸ Robin Jacob, ‘Interpretation of Claims and Infringement’ in Mary Vitoria (ed), *Queen Mary College Patent Conference Papers* (Sweet & Maxwell 1978) 73 within fn 26.

patent infringement as what he was doing was "merely for the purpose of experiment, and not for the purpose of sale"³⁹ and that "[t]his would give the Plaintiff no right of relief."⁴⁰ "The machine also was only made for experimental purposes".⁴¹ He also relied on a set of preceding case law such as *Jones v Pearce*, *Higgs v Godwin* and *Muntz v Foster* which stipulated that "[m]anufacture for the purpose of experiment is not an infringement."⁴² The court handed down an assessment on whether experimental uses would be considered as patent infringement or not in its decision by stating:

[A]nd no doubt if a man makes things merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither using or vending of the invention for profit, the mere making for purposes of experiment and not for fraudulent purpose, ought to be considered within the meaning of the prohibition, and if it were, it is certainly not the subject of an injunction.⁴³

The court found that the defendant was at times making the patented invention in suit, i.e. the screws, holding that this could amount to an infringement of the patent. The court went on to specifically note that the use of the defendant would not constitute experimental use and therefore an infringement. It held that:

It does not appear to me, when I consider the circumstances under which the Defendant made these alleged experiments, that I ought to treat this as coming within the rule which prevents mere experiments being subject to the liability of action being brought against those who make them, and to the costs of an injunction being granted against them.⁴⁴

While having come to the finding that the defendant's use constituted an infringement, the court's elaborations in *Frearson v Loe* on when experimental uses would be exempted from patent infringement are of utter importance. This would be the case where such uses were merely conducted for *bona fide* experiments. The approach applies the normative term of *bona fide* which warrants interpretation.

Thankfully, the court provided some guidance as to what it considered to be *bona fide* experiments by providing both positive and negative definitions of the term. As a positive definition, it held that *bona fide* experiments would be such uses with "the view of improving upon the invention the subject of the patent, or with the view of seeing whether an

³⁹ *Frearson v Loe* [1878] L.R. 9 Ch.D. 48, 57 (George Jessel M.R.).

⁴⁰ *ibid* 57.

⁴¹ *ibid* 57.

⁴² *ibid* 57.

⁴³ *ibid* 66-67.

⁴⁴ *ibid* 67.

improvement can be made or not.”⁴⁵ The Court of Chancery of the County Palatine of Lancaster elaborated on this notion when it established that the activities of the experimenter would relate to “testing and trying from the patented article whether he can invent a better thing for the public.”⁴⁶ Importantly, the court said that this would not be possible without actually using the patented invention.⁴⁷

By means of a negatively formulated definition, it stipulated that such *bona fide* use would not be given where the experiments were conducted “with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted.”⁴⁸ The Chancery Court of Palatine again elaborated on this and gave a short definition by holding that no infringement occurs where the invention is not used practically but in order to test and try the article in order to assess whether it could be improved.⁴⁹ *Bona fide* experiments were given where this meant “neither using nor vending of the invention for profit.”⁵⁰

The courts had the chance to elaborate on what they considered to be non-infringing experimental use in *United Telephone Company v Sharples*⁵¹. The case related to the use of patented telephone and transistors which the defendant imported from the Netherlands. He admitted that, if sold within the UK, this would constitute patent infringement. He, however, stated that the patented items were for experimental use by his pupils. The court found this still to be patent infringement. This is based on the particular facts of the case: The pupils were paid by the business of the defendant but arguably less than an assistant that did not need to acquire the skills anymore the pupils attempted to gain. The court held that the user “would be getting the advantage of instructing his pupils by means of this cheaper instead of the more expensive instruments.”⁵²

The fact that the defendant saved on expenses was the crucial issue for the court. Although not mentioned by the court, this could be regarded as not falling within the *bona fide* experiment assessment developed in *Frearson v Loe*. This is the conclusion reached by the Vice Chancellor in *Proctor v Bayley and Son* when he linked the *Sharples* case with the

⁴⁵ *Frearson v Loe* [1878] L.R. 9 Ch.D. 48 (George Jessel M.R.).

⁴⁶ *Proctor v Bayley and Son* [1889] 6 RPC 106, 109.

⁴⁷ *ibid* 109.

⁴⁸ *Frearson v Loe* [1878] L.R. 9 Ch.D. 48 (George Jessel M.R.).

⁴⁹ *Proctor v Bayley and Son* [1889] 6 RPC 106, 109.

⁵⁰ *Frearson v Loe* [1878] L.R. 9 Ch.D. 48 (George Jessel M.R.).

⁵¹ *United Telephone Company v Sharples* [1885] 29 Ch.D. 164.

⁵² *ibid* 168.

precedent of *Frearson v Loe*.⁵³ Whether experimental use was accepted as non-infringing therefore depends on the motives of the user. Where this is clearly done to improve on the invention then patent law should not stop the user. Where a more immediate practical or real use⁵⁴, or where “pecuniary benefit is obtained thereby”⁵⁵, then this would be disallowed.

United Telephone Corporation v Sharples therefore provides two important elements: First, it appears that the court did regard experimental uses as being potentially liable for infringement. This is supported by the fact that the court was willing to regard any advantageous use as infringing. *Bona fide* experiments are then regarded as an exception which is excused from infringement rather than not *ex ante* constituting an infringing act.⁵⁶ Secondly, the case does not only stipulate that direct pecuniary advantage through the commercialisation would amount to patent infringement; also an advantage in saving costs, i.e. an indirect pecuniary advantage, can taint experiments as not being in *bona fide*.

This general line that a commercial orientation would taint experiments as not being *bona fide* in the understanding of *Frearson v Loe* was followed by the courts. A good example of this approach is *Molins and Molins Machine Co. Ld v Industrial Machine Co Ld*.⁵⁷ The decision relates to the alleged infringement of the patent in suit, an improved cigarette-making machine. The defendants were also producing cigarette-making machine and argued against the alleged infringement, stating that they had conducted experiments which would not amount to infringement of the patent as the invention was just being demonstrated for use which would amount to mere experimental use.⁵⁸ The court held:

What happened was that certain machines were supplied by the defendants to a firm of cigarette makers in Belfast. Those machines had this device in question, that is to say this helical device, and

⁵³ *Proctor v Bayley and Son* [1889] 6 RPC 106, 109.

⁵⁴ David Fulton, *The law and practice relating to patents and designs (Patents and Designs Acts, 1907-8)* (4th edn, Jordan & Sons 1910) 178.

⁵⁵ Henry Cunynghame, *English patent practice: with acts, rules, forms and precedents* (William Clowes & Sons 1894) 318.

⁵⁶ Such notion can also be derived by the pleading of the defendant in *Proctor v Bayley and Son* [1889] 6 RPC 106, 107. The defendant denied that their use of the patented invention would constitute an infringement while admitting the validity of the patent. Alternatively, the defendant pled that if the use would be considered an infringement it would constitute permitted experimental use. This makes experimental use come across as an exemption or defence of patent infringement and hence a limitation to the patent right rather than not being considered an infringement in the first place.

⁵⁷ *Molins and Molins Machine Co. Ld v Industrial Machine Co Ld* [1937] 54 RPC 94.

⁵⁸ The Court initially found that “[t]he mere possession of a machine is not infringement; there must be use-use commercially” - *ibid* [103]. It however dismissed the argument by the defendant’s counsel that the operation of the patented invention (a cigarette machine) was only used on the premises of another company in form of a trial and that no cigarettes were sold - “But they were also clearly being introduced into the factory in Belfast in the hope that the persons who owned the factory in Belfast might see fit to acquire such machines from the Defendant company.” - *ibid* 108.

with the machines were sent two men who were in the employ of the defendant company. They went to Belfast, they were there for some time, and they ran the machines with a view to testing the machines and seeing what the nature of the cigarettes was that they produced and how far they were proved satisfactory; but they were also clearly being introduced into the factory in Belfast in the hope that the persons who owned the factory in Belfast might see fit to acquire such machines from the defendant company. Moreover, the machines were used for making cigarettes and making cigarettes in large numbers; those cigarettes certainly found their way, when made, into the packing department of the Belfast manufacturer and, I have little doubt, were ultimately sold to the public. I am quite incapable myself of seeing how it can seriously be suggested that there was not such a user of the defendants' machine as amounts to an infringement if the patent itself be a valid patent.⁵⁹

Although the defendants were testing whether the apparatus would be satisfactory, the fact that this was done in hope to eventually sell the device rendered the alleged experiments as not being conducted in *bona fide*. This highlights a consistent approach by the courts to disallow such experiments which had a further commercial intent. It however, has to be noted that the case is also specific about the fact that cigarettes were produced in commercial scale which has made the court come to its finding.

2.2.4 Analysis

The court in *Frearson v Loe* highlighted the rationale for the approach to allowing experimental uses when it stated: “Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way.”⁶⁰ The court made the important finding that patent rights should not hamper researching on the invention. By this, it delineated the extent of the patent holder’s right and exempted such acts where its purpose would relate to improving the patented invention. It additionally limited the defence to such experiments that were considered to be fair. The intention to gain profit, i.e. commercialise the experiments, would taint the *bona fide* use and render the experiments unfair. What is generally remarkable is the emphasis of the courts with regards to the purpose of the third party use which would become a “litmus test” of whether infringement was found or not.

This division of infringing to non-infringing uses can be based on the purpose of patent protection, as a commentator states: Cunynghame holds that the rationale of patent infringement applies where the manufacture of the patented item by the defendant is done to “directly or indirectly [...] obtain profit.”⁶¹ He deduces this from the fact that “the power of

⁵⁹ *Molins and Molins Machine Co. Ld v Industrial Machine Co Ld* [1937] 54 RPC 94, 108.

⁶⁰ *Frearson v Loe* [1878] L.R. 9 Ch.D. 48, 67 (George Jessel M.R.).

⁶¹ Henry Cunynghame, *English patent practice: with acts, rules, forms and precedents* (William Clowes & Sons 1894) 317.

the Crown to grant monopolies depends on its position as protector of trade.”⁶² Cunynghame expands from this notion and states that “merely to make a thing is no infringement unless in some way the trade in the thing is affected.”⁶³ His purposive interpretation of patent law arguably expands the scope for non-infringing uses considerably in comparison to a rigorously literal understanding of infringing uses.

The public interest that was enunciated by the courts claims that where experimental use was conducted in order to improve or test the patented invention, then the defence would apply. By this, the courts, though not explicitly but tacitly, acknowledged that the patent right was not meant to hinder further improvements of the patented invention but rather to permit this.⁶⁴ From this point, one can deduce that the right of the patent holder does not extend to instances where the purpose of the use of the third party related to improving or testing the patented invention. The courts held that such use must be allowed and should not be restricted by the patent right in order to “invent a better thing for the public.”⁶⁵ This means that the purpose of the third party use is paramount. With these words, the court has directly elevated this purpose and indirectly the third party interest in using the invention to being in the public interest.

The courts however, limited the scope of the defence where the defendant was using or selling the invention for profit on the basis that this would otherwise be unfair. It appears that the courts meant that the commercialisation of the patented product should exclusively remain with the patent holder by declaring such intent to be fraudulent. This is an observation that Cook identifies. He states that the decision indicates that the patent bargain⁶⁶ would mean that “experimentation with a view to devising improvements on the patented invention did not infringe” even long before its expiry.⁶⁷

This could mean that the patent holder should not be deprived from the invention’s commercialisation potential which eventually relates back to the rationale that patents serve

⁶² Henry Cunynghame, *English patent practice: with acts, rules, forms and precedents* (William Clowes & Sons 1894) 317. See also - *Caldwell v Vanvlissengen* [1851] 68 E.R. 571.

⁶³ Henry Cunynghame, *English patent practice: with acts, rules, forms and precedents* (William Clowes & Sons 1894) 317.

⁶⁴ Amiram Benyamini, *Patent Infringement in the European Communities* (IIC Studies 1993) 266.

⁶⁵ *Proctor v Bayley and Son* [1889] 6 RPC 106, 109.

⁶⁶ i.e. the disclosure of the patented invention and dissemination of the information it contains in return for its grant.

⁶⁷ Trevor Cook, ‘A European Perspective as to the extent to which experimental use, and certain other defences to patent infringement apply to differing types of research’ (IPI Report 2006) 11.

as a reward for disclosing the invention.⁶⁸ The notion arguably acknowledges the causation between the disclosure and the improvement: without the disclosure, there would not be an improvement thereof *in strictu sensu*. Additionally, this notion also relates back to the incentive function of the patent system which would be hampered where the exclusive right is weakened to the degree that it does not serve to overcome the public goods dilemma.⁶⁹ Ultimately, this fits with the rationale of the patent monopoly and the Crown's duty to protect trade which Cunynghame mentions⁷⁰ and highlights the functional or utilitarian nature of the patent right in the UK.

The court in *Freason v Loe* provides a classic example of the intrinsic tension that patent protection has on innovation and tacitly applies some economic theory of patent law. While the patent right serves to overcome the public goods dilemma, its nature as an exclusive right may hamper follow-on invention. Economic theory holds that the wider the economic good "information" is disseminated and used, the more it would serve perfect competition. This is because the use of third parties which is often referred to as "free riding" is considered to be a positive externality.⁷¹ Such externalities are generally advantageous as they can create spill overs in multiplying the information. Therefore, from a welfare point of view, information

⁶⁸ Based on Machlup's study of 1958 'An Economic Review of the Patent System' there are usually 4 theories applied to justify the grant of patents: The property (or natural law) theory, the reward theory, the incentive theory and the disclosure theory - Fritz Machlup, 'An Economic Review of the Patent System, Study No.15 of Committee on Judiciary, Subcommittee on Patents, Trademarks, and Copyrights', 85th Cong., 2d Sess. (Comm. Print 1958) pp 21; see also - Frank Fechner, *Geistiges Eigentum und Verfassung* (Mohr Siebeck 1999) 141.

⁶⁹ The Public Goods dilemma is one of the frequently applied economic explanations of patent rights. While there is no overarching legal definition of what constitutes this subject matter they constitute works of the intellect. As such they are knowledge or information. Translated into economic terms information then constitutes a good. Information however provides for a particular form of economic good through its similarity to public goods. (See Stiglitz who states that information is a public good - Joseph E. Stiglitz, 'Economic Foundations of Intellectual Property Rights' [2007-2008] *Duke Law Journal* 1693, 1699).

Economic theory defines such public goods as having two characteristics: they are (1) non-rivalrous, as well as (2) non-excludable (Robert B. Cooter and Thomas Ulen, *Law and Economics* (5th edn, Pearson 2004) 46; Graham Dutfield and Uma Suthersanen, *Global Intellectual Property Law* (Edward Elgar 2008) 49).

Information shares with public goods that its use is non-rivalrous - Matthew Fisher, *Fundamentals of Patent Law* (Hart Publishing 2007) 64; Peter Drahos, 'Intellectual property rights in the knowledge economy' in David Rooney, Greg Hearn, Abraham Ninan (eds), *Handbook on the knowledge economy* (Edward Elgar 2005) 139. This means that it cannot be exhausted by someone's use but may be used simultaneously as others are able to use it - Robert B. Cooter and Thomas Ulen, *Law and Economics* (5th edn, Pearson 2004) 120; Ansgar Ohly, 'Geistiges Eigentum und Wettbewerbsrecht - Konflikt oder Symbiose?' in Peter Oberender (ed), *Wettbewerb und geistiges Eigentum* (Duncker & Humblot 2007) 52; Suzanne Scotchmer, *Innovation and Incentives* (The MIT Press 2004) 31.

Public goods are also held to be non-excludable. This means that it is very difficult if not impossible to exclude a third party from using that good. Unlike tangible property that can be it is significantly more difficult to achieve this with regards to information.

⁷⁰ *supra* fn 63.

⁷¹ A positive externality occurs when "the benefits of an exchange may spill over onto other parties than those explicitly engaged in the exchange." - Robert B. Cooter and Thomas Ulen, *Law and Economics* (5th edn, Pearson 2004) 44.

should be freely available:⁷² the more users are able to utilise the good information, the better for social welfare.⁷³

This is where the defence for experimental use, as laid out in *Frearson v Loe*, attempts to strike the balance between allocative and dynamic efficiency⁷⁴ and permits such uses that improve on the patent which serve technological advance. This balancing exercise done by the court fosters the general public interest in technological advance. First, by leaving enough reward for the patent holder's disclosure of a useful invention while simultaneously not significantly diminishing the incentive function of the patent right; then by not extending the patent right to *bona fide* experiments which have the purpose of improving the patented invention. This stipulates that such third party uses are welcomed and are accommodated by the law while not verbatim being declared as being in the public interest. It could however, be regarded as the underlying rationale for exempting experiments from patent infringement.⁷⁵

2.3 Historical development in Germany

2.3.1 Introduction

German patent law did not provide for a specific statutory research exception before the introduction of § 11 Nr. 2 PatG. This, albeit the fact that the German legislator already introduced the concept of statutory exceptions to patentee's rights in its 1877 Act.⁷⁶ Additionally, the subsequent revisions and amendments of the German Patent Act provided for a wider ambit of compulsory licensing.⁷⁷ With regards to how experimental uses of a patented invention were treated by patent law, it was the courts that dealt with this issue, similarly to the development in the United Kingdom: German courts directly linked

⁷² Kenneth J. Arrow, 'Economic Welfare and the Allocation of Resources of Invention' in National Bureau of Economic Research, *The Rate and Direction of Inventive Activity* (Princeton University Press 1962) 616-617.

⁷³ Dominique Foray, *Economics of Knowledge* (The MIT Press 2004) 16.

⁷⁴ Drahos states that "[m]any cases in intellectual property law present judges with a choice about whether to tilt the property right in favour of dynamic or allocative efficiency." - Peter Drahos, 'Regulating Property: Problems of Efficiency and Regulatory Capture' in Christine Parker, Colin Scott, Nicola Lacey and John Braithwaite (eds), *Regulating Law* (OUP 2004)172.

⁷⁵ Chartered Institute of Patent Agents, *CIPA Guide to the Patent Act 1977* (Sweet & Maxwell 1980) 188.

⁷⁶ § 5 of the Patent Act of 1877 provided an exception for prior use (sub-section 1), a remunerated licence for government use and exempted use within a vessel entering German territory (Sub-section 3).

⁷⁷ In the years between 1923 and 1943, 296 compulsory licences have been applied for and 25 were granted. This number decreased in post Second World War Germany - Kung-Chung Liu, 'Rationalising the Regime of Compulsory Patent Licensing by the Essential Facilities Doctrine' [2008] IIC 757, 759.

experimental uses to the question whether such third party use was considered to be an infringement or not.

2.3.2. The law of infringement

Unlike the United Kingdom, German patent legislation always provided for a statutory provision relating to patent infringement.⁷⁸ The primary right of the patent holder in the original 1877 Act was formulated negatively. It stated that the effect of the patent was that no one was permitted to make or use the patent commercially without the permission of the patent holder.⁷⁹ This negative formulation of the right of the patent holder only lasted until the first revision of the Patent Act in 1891 when the right was formulated positively. This positive formulation of the patent holder's right was maintained until the revision of the Patent Act in 1981. Importantly, the 1891 revision limited the patent holders' exclusive right to commercially produce, to dispose of, to offer to dispose and use of the patented item. The legislator found that the extension of the patent right to all uses should not extend to domestic uses which explains that only commercial uses would fall under the patent right.⁸⁰

The wording of these provisions differs significantly from the current one.⁸¹ Since the 1891 revision of the Act, the patent right was formulated solely positively and provided the patent owner with the exclusive right to use the patented invention commercially – which remained until the 1981 revision.⁸² Therefore, the question of whether the use by a third party was commercial was paramount for a finding of infringement since such use would constitute patent infringement. Conversely, where the use of a third party was non-commercial⁸³ the

⁷⁸ The following analyses German patent law from the foundation of the German empire in 1877. Previously, the individual states of the German empire had 29 pieces of “patent” laws respectively - Edmund Kloeppel, *Patent und Gebrauchsmusterrecht*, (Carl Heymanns 1908) 8.

⁷⁹ § 4 PatG 1877.

⁸⁰ See Legislative reasoning of the PatG 1891 (‘Entwurf eines Gesetzes betreffend die Abänderung des Patentgesetzes’ Reichstagsdrucksache der 8. Legislaturperiode I. Session, Aktenstück Nr. 152, pp. 964).

⁸¹ The current § 9 PatG refers to both the positive side as well as the negative side of the patent right, i.e. to use it exclusively and exclude others from using the patented invention.

⁸² It was argued that, albeit the positive formulation of the patent right, the provisions rather emphasised its negative aspect as an right to exclude - Günther Wilde in Klauer/Möhring (eds), *Patentrechtskommentar, Band I* (3rd edn, Verlag Franz Vahlen 1971) § 6 [1].

⁸³ While arguing in favour of a deletion of the term “commercial”, Isay stated that the patent jurisdictions of France, the United States and the United Kingdom do not require a commercial use in their infringement provisions – Hermann Isay, ‘Zur bevorstehenden Änderung der Patentgesetzes’ [1926] GRUR 549. He bases the motivation of requiring commercial use within the patent acts of 1877 and 1891 with a reference to Kohler that the exercise of private rights should not encroach onto “the sanctuary of the family” - Josef Kohler, *Handbuch des deutschen Patentrechts in rechtsvergleichender Darstellung* (Bensheimer 1900) 432.

exclusive right of the patent owner was not infringed.⁸⁴ This made the assessment of what constituted commercial or non-commercial use the crucial question as to whether a particular use was liable for patent infringement.

The Imperial court of Justice (*Reichsgericht*) defined “commercial activity” as “an activity for continuous earning” in a criminal case from 1894 in relation to a utility model.⁸⁵ It elaborated that a “commercial” use of an invention would be any such use in the course of a commercial operation.⁸⁶ The court, however, did not follow this finding for long. In a decision from 1897, it held that a commercial activity is given when “the item of an invention was used *within* a commercial operation” (emphasis added).⁸⁷ This approach widened the scope of the definition of commercial activity. This was due to the fact that a commercial use was already given where such use was conducted within the ambit of a business establishment; not just such use that was intended to benefit and be advantageous for the commercial operation.

Based on the assessment of what would constitute a commercial use, the court held that where the use was solely conducted for private purposes, it would not be perceived as a commercial purpose.⁸⁸ By this, the court defined private and personal uses as an antonym for use for commercial purposes.⁸⁹ It held that while commercial use would need to be understood in the broadest sense, the legislator did not want patent protection to extend to the

⁸⁴ Gaul and Bartenbach state that the law does not clearly state whether missing commercial purpose of the third party use would not be considered to fall within the infringement provision of § 6 PatG 1968 as such or whether non-commercial use would be addressed in form of a justification - Dieter Gaul and Kurt Bartenbach, ‘Nutzung von Schutzrechten in der Industrieforschung als Patentverletzung?’ [1968] GRUR 281, 281.

⁸⁵ “Unter Gewerbsmäßigkeit ist auch bei Auslegung dieses Gesetzes eine auf fortgesetzten Erwerb gerichtete Tätigkeit,..., zu verstehen” - Reichsgericht, BIPMZ, 1894/1895 (231).

⁸⁶ “demnach aber unter gewerbsmäßigem Gebrauch jede Benutzung *bei dem* Betriebe eines Gewerbes” (emphasis added) - *ibid* 231.

⁸⁷ “Der Gegenstand einer Erfindung wird “gewerbsmäßig” gebraucht, wenn er in einem Gewerbebetrieb gebraucht wird.” - Reichsgericht, BIPMZ 1897, 148, 150.

The Court emphasised that the invention does not necessarily need to be used for a specific purpose within the commercial operation such as to foster or to facilitate its operation. This statement stands in stark contrast to its previous findings where a commercial use was found where the invention was used in the course of running the commercial operation. It continued that this was not the purpose of the law. It added that a commercial operation warrants respecting the exclusive rights of others. Hence, the use of a patented invention within a commercial operation would then appropriate its economic advantage.

⁸⁸ “Die nicht gewerbsmäßige Nutzung der Erfindung ist daher erlaubt. Es kann also Jeder den Apparat behufs Verwendung für seinen persönlichen Gebrauch herstellen und in der Sphäre seines Haushaltes gebrauchen.” - Reichsgericht, BIPMZ 1894/95, 201 (203).

⁸⁹ Arnold Seligsohn, *Patentgesetz und Gesetz, betreffend den Schutz von Gebrauchsmustern* (7th edn, Walter de Gruyter 1932) § 4 [5].

domestic sphere.⁹⁰ So any use of the patented invention that was kept within the personal, private sphere of the user, such as his household, would be considered as non-commercial.

This assessment of what constituted commercial use became extreme when the Reichsgericht started applying a negative definition of the term. It held that commercial use is not only such use that would fall within the commercial sphere of the user. Rather, the patent right would already apply where the use did not clearly fall within the personal sphere.⁹¹ The decision where the court applied this reasoning related to patented hooks that were applied in an accommodation which the alleged infringer rented out. The court stipulated that commercial use would apply where the use would not only serve the purposes of the infringer but also those of others.⁹² It applied the legislative reasoning that patent rights should not extend to the private or domestic sphere.⁹³ This definition of ‘commercial’ made any use conducted in a commercial entity or sphere being commercial, i.e. that any such use of the patented invention would constitute an infringement. Later court decisions of the Reichsgericht stuck to this approach for defining “commercial”.⁹⁴

2.3.3. The case law in relation to experimental uses

Based on the emphasis of commercial use that the court gradually developed, the question arose whether research uses by third parties were considered as being commercial uses for the purposes of patent infringement. The development of the case law with this regard starts with the Reichsgericht holding that use for study purposes would not constitute patent infringement.⁹⁵ The court came to this finding by following the private use/commercial use dichotomy, holding study purposes as being conducted privately and therefore not being of

⁹⁰ The decision of the Reichsgericht (Reichsgericht, BIPMZ 1907, 217) embraces the legislative explanatory statement of the Reichstag on the 1891 Act. (‘Entwurf eines Gesetzes betreffend die Abänderung des Patentgesetzes’ Reichstagsdrucksache der 8. Legislaturperiode I. Session, 964). In this decision the Reichsgericht held that the use of the patented invention for the purposes of church service would still be considered as being commercial use in the reasoning of § 4 PatG 1891 in its broad interpretation of the term “commercial” while acknowledging that this is not the customary use of that term - Reichsgericht, BIPMZ 1907, 217 (218).

⁹¹ Dieter Gaul and Kurt Bartenbach, ‘Nutzung von Schutzrechten in der Industrieforschung als Patentverletzung?’ [1968] GRUR 281, 282, referring to the Reichsgericht decision RGZ 66, 164 (= Reichsgericht, BIPMZ 1907, 217).

The Reichsgericht has held that a commercial use is then given where the use did not relate to the direct satisfaction of one’s own, in particular domestic needs - Reichsgericht, BIPMZ 1912, 219 (220).

⁹² Reichsgericht, BIPMZ 1912, 219 (220).

⁹³ *ibid* 220.

⁹⁴ Volkmar Tetzner, ‘Patentverletzung durch Forschung’ [1966] GRUR 604, 605.

⁹⁵ The court held that “[t]he opposite of commercial use is use for study purposes or for personal or domestic use”. (“Den Gegensatz zum gewerbsmäßigen Gebrauch bildet die Benutzung zu Studienzwecken oder für den persönlichen oder häuslichen Bedarf”) Reichsgericht, BIPMZ 1897, 148 (150).

commercial nature. While this decision regarded use for study purposes as a case group aside private and personal uses, another decision from the Reichsgericht regarded them as a sub-category of a non-infringing private use.⁹⁶ Thus, the court emphasised that studies are the opposite of commercial uses. This finding seems to highlight that the question was not whether the use would be considered as non-commercial but rather whether it was conducted for study purposes.⁹⁷

The courts have clarified what would constitute use for study purposes as non-commercial and hence non-infringing use. In a decision from 1929, the defendant argued that the use of the protected invention was permissible non-commercial use as it related to checking its aptitude.⁹⁸ The court, however, found that the production of 20 coal ovens incorporating the patented concept was not deemed to be merely testing the invention's technical viability.⁹⁹ This stipulates that uses may be permitted where merely the technical aptitude is being tested. Similarly, a decision by the same court from 1933 held a use that was undertaken to investigate whether the patented invention actually works was exempted from patent infringement.¹⁰⁰ The court, however, distinguished these uses, which merely assessed the aptitude, from those assessing the invention's potential for further commercialisation or economic viability.¹⁰¹

Court decisions after the Second World War maintained this approach.¹⁰² The German Federal High Court has held in its *Ethofumesate* decision¹⁰³ that experimental use is only exempted under narrow premises.¹⁰⁴ The case was decided when the new act, and with it the

⁹⁶ Reichsgericht, BIPMZ 1907, 217 (218).

Chrocziel elaborates that this notion of study purpose constitutes a sub category of private uses. He derives this finding from the wording of the Courts' decision. The Court held that purely personal and private uses, *in particular such uses for study purposes* are exempted from the effect of a patent (emphasis added). The wording in 'particular' in relation to private uses would then stipulate study purposes as being a particular sub-category of private uses - Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 127.

⁹⁷ Wolfgang Vomhof, 'Die Forschung ist frei!' [1967] GRUR 278, 278.

⁹⁸ Reichsgericht, GRUR 1929, 1199 (1200).

⁹⁹ The facts of the case clearly were that the coal produced by the 20 ovens were used commercially - *ibid* 1200. The court did not discuss the defendant's point that he was not able to the research in a laboratory were not possible.

¹⁰⁰ Reichsgericht, GRUR 1933, (294-295).

¹⁰¹ *ibid* 294-295.

¹⁰² So for instance - BGH, GRUR 1968, 142 (146) – Glatzenoperation: The court held that only use within the domestic, i.e. personal and private sphere were exempted from patent infringement and that this was considered to be the opposite of commercial use.

¹⁰³ BGH, GRUR 1990, 997 - Ethofumesat = BGH, IIC 1991, 542 - Ethofumesate.

¹⁰⁴ The *Ethofumesate* decision corrected a more lenient approach provided by the court in the *Rundfunkübertragungssystem* decision (BGH, GRUR 1987, 375) as Chrocziel states. This decision regarded that use in order to receive regulatory approval (in the case for a telecommunication permission in relation to car

specific research exception in § 11 Nr. 2 PatG, was legislated while the patent in suit related to the old law before 1981. The case related to the infringement of an herbicide that was known under the name “Ethofumesate”. The defendant imported the active ingredient of the herbicide and provided the relevant authorities with samples in order for it to be used for regulatory approval. The defendant ultimately planned to market the herbicide after the patent expired. The court followed the existing case law on experimental uses and the precedents handed down by the Reichsgericht.¹⁰⁵ Hence, experiments on the invention would not constitute patent infringement where its mere purpose was to assess whether the protected item or process would work.¹⁰⁶

The court, however, decided that the trials were commercially orientated as they were aimed at marketing the herbicide as soon as possible after the patent lapsed and so held that they would not amount to privileged use.¹⁰⁷ The case endorsed the case law provided by the Reichsgericht that only where the patent is used in “the cases of a mere test of operability and the technical improvement”,¹⁰⁸ would it be exempted from patent infringement. Importantly, however, the court extended the ambit of what was considered privileged experiments, including uses based on “the purpose of technically perfecting and further developing the patented subject matter.”¹⁰⁹

Due to the facts of the case, the public interest in technological advance was not so prevalent in this case. The experiments that the defendant conducted related to using them for regulatory approval. This generally produces knowledge that is already available and not necessarily new information. In the opinion of the court, the experiments were primarily conducted to obtain regulatory approval and hence, related to further commercialisation and not to obtaining knowledge. This is probably the reason why the court discarded any public interest with regards to the experiments in question.

In relation to the old law, the courts have allowed such uses that were conducted to test the technical viability of the invention but would fall foul of § 6 PatG when the tests were used in order to assess the economic viability. They also were excluded where they were used as a

stereos) would not constitute an infringement of the patent but would rather be a preparatory act - Peter Chrocziel, ‘Benutzung zu Versuchszwecken als Einwand gegenüber einem Anspruch wegen Patentverletzung (Q 105)’ [1992] GRUR Int 203, 203-204.

¹⁰⁵ BGH, GRUR 1990, 997 (1000) - Ethofumesat = BGH, IIC 1991, 541 (545-546) – Ethofumesate.

¹⁰⁶ Reichsgericht, GRUR 1933, 292 (294).

¹⁰⁷ BGH, GRUR 1990, 997 (1000) - Ethofumesat = BGH, IIC 1991, 541 (546) – Ethofumesate.

¹⁰⁸ BGH, GRUR 1990, 997 (1000) - Ethofumesat = BGH, IIC 1991, 541 (546) – Ethofumesate.

¹⁰⁹ BGH, GRUR 1990, 997 (1000) - Ethofumesat = BGH, IIC 1991, 541 (546) – Ethofumesate.

tool to assist the commercial operation by using it as an instrument on other subject matter.¹¹⁰ According to Gaul and Bartenbach, the jurisprudence was clear about the fact that any use for commercial purposes was not allowed and that it is irrelevant whether the user wanted to benefit financially from such use.¹¹¹ Hence, only a small scope for study purposes within the personal sphere would not fall foul of § 6 PatG.¹¹²

The mediation centre of the German Patent Office (*Schiedsstelle beim Deutschen Patentamt*) held in an intermediary decision that the decisions of the Reichsgericht were still good law.¹¹³ It held that personal or domestic use, as well as study purposes, will not be considered as commercial, i.e. infringing use.¹¹⁴ However, as Chrocziel states, it applied a modern approach by subtly stipulating that uses are not exempted from patent infringement where the invention was used as a means for conducting the research rather than being the item of research.¹¹⁵ The mediation centre held that the use in question would relate to applying the advantageous utilities of the invention.¹¹⁶ It added that applying the invention in its intended way of operation could not be deemed as research that escapes patent infringement. Otherwise, the reward deriving from the patent right would dissolve where using the patent invention in its intended way would be exempted from infringement. This would run afoul of the *ratio legis* of patent law.¹¹⁷ What the mediation centre basically did was to consider the impact of allowing such use on the patent holder. It then came to the finding that this would jeopardise the rationale of rewarding the inventor. The centre, however, did not discuss a lessened incentive to invent.

The mediation centre also considered fundamental rights in its decision. It discussed both the freedom of science as well as the social function of property.¹¹⁸ It held that the freedom of

¹¹⁰ Chrocziel finds this assessment not coherent with the general private/commercial sphere dichotomy. He argues that the acts done in these cases were all conducted within the commercial sphere of the users. He summarises, that based on this case law, experimental uses are exempted from patent infringement when they were either conducted within the personal sphere of the user or were conducted to test the technical functioning of the invention - Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 131-132.

¹¹¹ Dieter Gaul and Kurt Bartenbach, 'Nutzung von Schutzrechten in der Industrieforschung als Patentverletzung' [1968] GRUR 281, 283.

¹¹² *ibid* 283.

¹¹³ *Schiedsstelle beim Deutschen Patentamt*, BIPMZ 1973, 205.

¹¹⁴ *Schiedsstelle beim Deutschen Patentamt*, BIPMZ 1973, 205 (206).

¹¹⁵ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 142.

¹¹⁶ *Schiedsstelle beim Deutschen Patentamt*, BIPMZ 1973, 205 (206).

¹¹⁷ *ibid* 206.

¹¹⁸ *ibid* 206.

science would not be a higher ranking right in relation to the fundamental right of property.¹¹⁹ Neither would the social function of property mandate an unremunerated use of the invention.¹²⁰ The centre came to this finding by applying a systematic interpretation of the exception provisions of the German Patent Act 1968. Since both § 8 PatG 1968 as well as § 15 PatG 1968 would entail a remuneration for the unauthorised use, the centre concluded that research that is within the public interest is made possible according to §§ 8 and 15 Patent Act 1968. It would, however, mandate a remuneration of the patent holder, because an unremunerated use could neither be derived from the Patent Act nor constitutional considerations in relation to the social function of property.¹²¹

In summary, the question of whether research is exempted from patent infringement was decided by assessment of whether a commercial purpose surrounded the use. The same applied to experiments; where they were conducted within the commercial sphere and for commercial purposes, the use would constitute an infringement. Only such experiments that were conducted for personal and private purposes were exempted. The courts did exempt such experiments from patent infringement which aimed to assess the technical viability of a patented invention; as Chrocziel stipulates, even though these experiments can be clearly attributed to the commercial sphere without providing an explanation on why this is the case.¹²² It was, however, argued that other jurisdictions would allow experimental use and any further restriction would curtail scientific research and technological progress.¹²³

2.3.4 Analysis

German patent law before the 1981 Act was not very permissive with regards to allowing research uses on the patented invention. Experiments with the patented invention were only possible in very narrow premises. This narrow approach can be based on various reasons: What stands out first and foremost is the narrow conception of what would constitute allowed private studies¹²⁴ on the patented invention. Any use transcending the private sphere would

¹¹⁹ Schiedsstelle beim Deutschen Patentamt, BIPMZ 1973, 205 206.

¹²⁰ *ibid* 206.

¹²¹ *ibid* 206.

¹²² Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 131-132.

¹²³ H. Herzfeld, 'Die Gewerbsmäßigkeit als Tatbestandsmerkmal der Patentverletzung' (1927) GRUR 151, 152-153 in relation to Isay's suggestion to eliminate the "commercial use" requirement in § 4 PatG - *supra* fn 83 .

¹²⁴ Kent holds that such private uses are justified since patents should only secure the industrial application of the invention. Private uses would then not interfere significantly the patent holder's interest – Paul Kent, *Das Patentgesetz – Band I* (Carl Heymanns 1906) § 6 [189].

be likely to be considered a patent infringement. The question as to what would constitute a commercial use proved to be a crucial and arguably insurmountable threshold for courts. The courts simply applied the statutory provisions. As they were bound by the written law they could not readily discard the “commercial” requirement.¹²⁵ This narrow approach is criticised by Witte who finds that the purpose of patents should be to foster science and research which would require researching on patented inventions.¹²⁶ He adds that the courts would curtail the ability to research by limiting the possible scope for researching through an interpretation of the infringement provision further than its wording requires.¹²⁷

What also led to the very broad interpretation of a commercial use of the invention was the fact that a different interpretation was difficult to achieve. There were no other explicit exception provisions that would allow for an unauthorised and unremunerated use of the patented invention. Only provisions regarding compulsory licensing, prior use and governmental use were available in previous German Patent Acts. This lack of other unremunerated exception provisions may explain why it was difficult for courts to create such a provision. It rather made courts assume by means of a systematic interpretation that the legislator would not foresee for an unremunerated use of the invention except in the other remunerated and explicitly legislated cases.

This explains the finding of the German Federal High Court in *Ethofumesate*, which specifically held that public interest in using the patented invention without the owners’ consent was only available when public welfare as stipulated within § 8 (1) PatG 1968 could be found.¹²⁸ Only in these narrow cases would the patent act permit public interest

¹²⁵ Although it appears that they seemed to have pushed the notion of commerciality slightly backwards when allowing experiments even where these could clearly be regarded as being located within the commercial sphere.

¹²⁶ „Dieser Zweck erfordert es geradezu zwingend, daß Forschung und Industrie nicht auf ein Schreibtischstudium von Patentschriften beschränkt werden. Die von *Tetzner* für unzulässig gehaltenen Versuche mit der geschützten Erfindung "mit dem Ziel, hierbei Umgehungslösungen zu finden oder Verbesserungserfindungen zu machen", sind Handlungen, welche die Veröffentlichung von Patentschriften geradezu provozieren soll. Die Durchsetzung dieses Anliegens darf nicht an begriffsjuristischen Auslegungen scheitern.“ - Jürgen Witte, 'Zur gewerblichen Benutzung eines Patentgegenstandes [1967] GRUR 128, 129.

¹²⁷ *ibid* 129.

¹²⁸ BGH, GRUR 1990, 997 (999) - *Ethofumesat*.

§ 8 PatG 1968 allowed the Federal Government to permit the use of the invention for the purposes of public welfare. § 13 (1) PatG 1968 allowed the higher federal authorities to permit the use of the invention in the interest of the security of the federal state.

considerations to prevail over the patent holder's right, the court added.¹²⁹ Hence, the courts did not perceive a considerable interest in allowing research uses on the patented invention.

This may be based on their interpretation of the function of patent law: The court in *Ethofumesate* mentioned that the interest in technological advance would not require third parties to use the patented invention to assess the commercial viability and applicability without the patent holders consent.¹³⁰ This speaks of an economic understanding which would attempt to achieve allocative efficiency.¹³¹ It further noted that technological advance is not assisted by trials to allow a faster commercial entry of competing products after expiry of the patent.¹³² What the *Ethofumesate* decision particularly highlights is the strength of the patent holder's right that § 6 PatG 1968 provides. It even prevails in relation to public authorities that are operating in the public interest.¹³³

What might have also led to the missing notion of enabling research on the patented invention as a tool to enhance the public interest in German case law may be attributed to the protection by the fundamental right in Article 158 of the Weimar Constitution, at least while it was applicable, as Isay states.¹³⁴ This would lead to patent law being applied and interpreted in a manner which would provide the strongest possible protection of the inventor.¹³⁵ The interest of competitors would be safeguarded by provisions within the patent act such as, *inter alia*, the limited patent term and compulsory licenses.¹³⁶ This finding is supported by Nastelski who states that the legislator has delineated the exclusive right of the patent holder for the public interest through the provisions of §§ 8 and 15 of the Patent Act.¹³⁷

¹²⁹ "Nur in diesen engen Grenzen nimmt das PatG die Benutzung des Gegenstandes einer Erfindung im öffentlichen Interesse von dem Ausschließlichkeitsrecht des § 6 PatG 1968 aus." – BGH, GRUR 1990, 997, 999 - Ethofumesat.

¹³⁰ BGH, GRUR 1990, 997 (1000) - Ethofumesat = BGH, IIC 1991, 541 (546) - Ethofumesate.

It based its finding indirectly on a previous decision by the BGH in *Erythronolid* where it was held that the rationale of patent law is to reward the inventor for his disclosure with a temporary exclusive right. Additionally, this enables third parties to further develop the invention during patent protection by permissible experiments." - BGH, GRUR 1981, 734 (734) - Erythronolid.

¹³¹ See with this regards the approach of UK courts - supra 2.2.4.

¹³² BGH, GRUR 1990, 997 (1000-1001) – Ethofumesat = BGH, IIC 1991, 541 (546) - Ethofumesate.

¹³³ In this case the defendant argued that the authority providing regulatory approval for herbicides could not be an infringing party – BGH, GRUR 1990, 997 (999) - Ethofumesat.

¹³⁴ Hermann Isay, *Patentgesetz und Gesetz, betreffend den Schutz von Gebrauchsmustern* (6th edn, Franz Vahlen 1932) 23-24.

¹³⁵ *ibid* 24.

¹³⁶ *ibid* 24

¹³⁷ Karl Nastelski in Eduard Reimer (ed), *Patentgesetz und Gebrauchsmustergesetz* (3rd edn, Carl Heymanns 1968) § 6 [1].

This finding is supported by the decision of the mediation centre from 1973.¹³⁸ The public interest in using the patented invention in relation to research would be served provisions of the Patent Act 1968.¹³⁹

2.4 Comparative analysis and conclusion

The courts in both jurisdictions distinguished “between research and market-orientated experiments for the purpose of establishing patent infringement liability”¹⁴⁰ when exempting some uses from patent infringement for an experimental purpose. While UK courts placed its findings on the fact that a *bona fide* experiment would not constitute patent infringement, the German courts applied experimental use within its commercial/non-commercial use dichotomy. In practice, it is likely that the scope of both exceptions might have been comparable since both jurisdictions focussed on whether the experiments were commercially beneficial to the user.¹⁴¹ Conversely, the exempted experiments related to assessing the invention’s aptitude or the possibility in improving on the patented invention as these purposes were considered not to be a commercial use.¹⁴² What, however, may be the dividing line between the two jurisdictions is the fact that British patent law does not “exclude from the exemption experiments conducted as a business by commercial concerns.”¹⁴³ Conversely, in Germany, any use that was not conducted in the private sphere was considered as being commercial, i.e. infringing.

What is striking about the comparison between the two jurisdiction are the contrary views on whether exempting experimental uses from patent infringement was in the public interest. UK courts positively acknowledged that the patent law must allow experimental uses on the invention. They argued with the purpose of patent law in not hindering technological advance. They also positively acknowledged that such use by third parties would foster

¹³⁸ Schiedsstelle beim Deutschen Patentamt, BIPMZ 1973, 205.

¹³⁹ *ibid* 206.

¹⁴⁰ David Gilat, *Experimental Use and Patents* (IIC Studies Vol 16, Wiley-VCH 1995) 12.

¹⁴¹ Henry Cunynghame, *English patent practice: with acts, rules, forms and precedents* (William Clowes & Sons 1894) 318.

¹⁴² BGH, GRUR 1990, 997 (1000) – Ethofumesat = BGH, IIC 1991, 541 (546) - Ethofumesate; Frearson v Loe [1878] L.R. 9 Ch.D. 48, 66-67 (George Jessel M.R.).

¹⁴³ Amiram Benyamini, *Patent Infringement in the European Communities* (IIC Studies 1993) 268. Similarly, Trevor Cook who states that the case law in the England would “make no distinction as between commercial and non-commercial experimentation” - Trevor Cook, ‘A European Perspective as to the extent to which experimental use, and certain other defences to patent infringement apply to differing types of research’ (IPI Report 2006) 11.

technological advance. This directly links the third party interest in using the patented invention for the purposes of experimenting to being in the public interest.

The German courts, on the other hand, did not positively acknowledge this. Rather, it appears that such a balanced approach to patent policy as adopted in UK courts was formerly not well developed in Germany. This can be derived from the fact that the courts strongly emphasised the patent holder's contribution while ignoring that access to the patented invention may need to be established in order to promote technological advance. The German courts additionally were forced to subsume experimental uses under the notion of commercial use and developed its narrow doctrine of privileged experiments. The reason for its insertion in the 1891 Act was already being criticised by Isay in 1926.¹⁴⁴ In his opinion, such an explanation is obsolete and solicited a deletion of the requirement of commercial use for the infringer.¹⁴⁵

The more permissive British approach taken by the courts might be explained by the lack of a statutory provision that defining patent infringement before the enactment of the 1977 Act. This, perhaps, gave the courts the sufficient flexibility to apply their reasoning. The German courts, on the other hand, appeared to have been trapped in an interpretative dilemma with the term "commercial" of the infringement provision. The adherence to a strictly literal interpretation¹⁴⁶ led to a narrow approach to experimental uses and it remained dubious whether laboratories or research departments of commercial entities could use the patented invention for experimental purposes under the old law in Germany.¹⁴⁷

This point can additionally be explained from an institutional design perspective. It can be argued that the British courts were able to specifically address the public interest issues surrounding experiments in comparison to the German Courts that were bound to work with a statutory provision. Ho argues that common law systems, as systems of open institutional design are able to accommodate "the changing values and circumstances of society."¹⁴⁸ Civil law systems would lack this flexibility.¹⁴⁹ The analysis of the German approach towards experimental uses highlights this.

¹⁴⁴ Hermann Isay, 'Zur bevorstehenden Änderung der Patentgesetzes' [1926] GRUR 549.

¹⁴⁵ *ibid* 550.

¹⁴⁶ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 128.

¹⁴⁷ Joseph Straus, 'Zur Zulässigkeit klinischer Untersuchungen am Gegenstand abhängiger Verbesserungserfindungen' [1993] GRUR 308, 310.

¹⁴⁸ Lok-sang Ho, *Public Policy and the Public Interest* (Routledge 2011) 54.

¹⁴⁹ *ibid* 54.

The limited scope might also relate to the cases that were adjudicated with regards to research: the alleged infringers were to a certain degree appropriating the patent for their purposes.¹⁵⁰ In other words, they were using the patented invention in its proposed way and made the patented products in the course of the experiments.¹⁵¹ The courts felt inclined to have such uses remain under the exclusive right of the patent holder and his interest to receive remuneration.

As a more general observation, the probably most important factor for the restricted scope of the research exception in hindsight, however, may be the fact that research activities were normally not conducted by commercially orientated enterprises which is now the case.¹⁵² In other words, there was no major need for providing an *en bloc* research exception. Research was conducted on a smaller scale which would explain the courts' sympathy to the solitary private researcher who wishes to quench his thirst for knowledge.¹⁵³ And it also served competitors to assess whether the invention worked or could be opposed and invalidated.

The institutional framework in which research is nowadays conducted has changed dramatically. The expenditure that is devoted to R&D is heavily conducted by the private business sector.¹⁵⁴ European countries that have a high expenditure in R&D tend to have the highest percentage of business involvement.¹⁵⁵ The fact that research is conducted by the private sector means that an approach that disallowed any commercial orientation would not be tenable. Research increasingly became conducted by the private sector which had a commercial orientation in mind which arguably guided legislators.¹⁵⁶ The fact that both the United Kingdom and Germany have introduced statutory exceptions permitting uses on the patented invention for experimental purposes stipulates that there was a need to allow such uses and to clarify the situation.

¹⁵⁰ *United Telephone Company v Sharples* (1885) 29 Ch.D. 164; *Muntz v. Foster* (1844) 2 W.P.C. 96; Reichsgericht, BIPMZ 1907, 217; Reichsgericht, GRUR 1929, 1199.

¹⁵¹ Amiram Benyamini, *Patent Infringement in the European Communities* (IIC Studies 1993) 267-268.

¹⁵² Amiram Benyamini, *Patent Infringement in the European Communities* (IIC Studies 1993) 272.

¹⁵³ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 193.

¹⁵⁴ See the table provided by the OECD that shows that expenditure on R&D amounts to more than 60% of the entire expenditure in the EU states in the year 2009 - OECD 'R&D expenditure' in *OECD Science, Technology and Industry Scoreboard 2011* (OECD Publishing 2011) 77 <http://dx.doi.org/10.1787/sti_scoreboard-2011-16-en> accessed 23 May 2015.

¹⁵⁵ Susana Borrás, *The Innovation Policy of the European Union – From Government to Governance* (Edward Elgar 2003) 55.

¹⁵⁶ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 193 See also Beier, who wrote in 1972 that scientific research on a patented invention must also be possible for industrial research – Friedrich-Karl Beier, 'Zukunftsprobleme des Patentrechts' [1972] GRUR 214, 222.

The point of actual third party interest and need is utmost important. The increasingly changing business realities needed to be accommodated within the law. This lead to generally permitting research uses as the following chapter will discuss. Two consequences can be deduced from the assumption that research is in the public interest: First, the public interest is a concept that reflects some third party interest.¹⁵⁷ An exception provision permits an otherwise infringing use which means that there must be an interest on behalf of third parties to use this provision. If there was not any third party interest then the exception provision would be futile. In this context, the third party interest relates to permitting experimental uses by commercially orientated entities and a law that focused on the sole experimenter would not be feasible anymore to fit the realities of research.

Importantly, this notion does not suggest that the public interest can simply be derived by summing up individually held interests. The public interest cannot be derived from the sum of individual interests.¹⁵⁸ Such an approach focuses on the interest of majorities; the danger with this approach then laying in the fact that minorities' interest would too readily be omitted.¹⁵⁹ What this approach however, might assist with is to locate where a majority interest lies which could point towards what may lie in the public interest.¹⁶⁰

The public interest with regards to exceptions to patent law, at least with regards to permitting experimental uses, presents itself as a reflection of third party interests.¹⁶¹ The public interest "must not be divorced from the private interest" as it is the individual interest of people in a society that constitutes the public interest.¹⁶² The third party interest in this context is the interest to use the patented invention without authorisation of the patent holder. What is important, however, is that not every use would be perceived to be within the public

¹⁵⁷ This links back to a preponderance theory of public interest as summarised by Held. According to her approach the public interest may consist of a preponderant interest that is constituted of the majority of individually held interests - Virginia Held, *The Public Interest and Individual Interest* (Basic Books 1970) pp. 49; see also - Aileen McHarg, 'Reconciling Human Rights and the Public Interest: Conceptual Problems and Doctrinal Uncertainty in the Jurisprudence of the European Court of Human Rights' [1999] *The Modern Law Review* 671, 674-675.

¹⁵⁸ Robert Uerpman, *Das öffentliche Interesse: seine Bedeutung als Tatbestandsmerkmal und als dogmatischer Begriff* (Mohr Siebeck 1999) 36.

¹⁵⁹ Mike Feintuck, *The Public Interest in Regulation* (Oxford University Press 2004) 11-12; Aileen McHarg, 'Reconciling Human Rights and the Public Interest: Conceptual Problems and Doctrinal Uncertainty in the Jurisprudence of the European Court of Human Rights' [1999] *The Modern Law Review* 671, 675.

¹⁶⁰ Mike Feintuck, *The Public Interest in Regulation* (Oxford University Press 2004) 11.

¹⁶¹ *supra* 2.2.4 where the purpose of the unauthorised use of the patented invention was scrutinised by the courts which acknowledges that these purposes and their underlying interest were taken into account by courts in the UK.

¹⁶² Lok-sang Ho, *Public Policy and the Public Interest* (Routledge 2011) 19.

interest: Only such uses with regards to experimental purposes would be excluded from patent infringement because they serve the public interest.

The fact that public interest is linked to third party interest is important for another aspect with regards to public interest: It is a concept that requires adjustment by the changing interest of third parties which are the foundation of public interest. Since such third party interest may change over time, public interest considerations also necessarily have change to reflect current realities. The example discussed in this context was the growing shift from private experiments to commercially orientated research which underlines this phenomenon well. This then has one important consequence: If the law wishes to be in the public interest it needs to adapt to these underlying third party interests. As mentioned, both the United Kingdom and Germany now have statutory provisions exempting experimental uses from patent infringement. This shows that the circumstances changed and that this required the means, i.e. patent law, to be adapted to the end, i.e. the technological advance.¹⁶³ It however, also emphasises that legislative intervention was needed to positively acknowledge this issue. The next chapter will analyse how public interest considerations have been applied both by the legislator and the courts to allow research on patented inventions.

¹⁶³ This finding is supported by the view of the German Federal High Court in *Ethofumesate* that came to the finding that technological advance would be served by strong patent rights, hence sole control of the patent owner - BGH, GRUR 1990, 997 (1000) - Ethofumesat = BGH, IIC 1991, 541 (546) - Ethofumesate. This perspective has arguably changed as the introduction of statutory research exceptions in both the UK and Germany was regarded in serving the public interest in technological advance.

Chapter 3: The research exception in the United Kingdom and Germany – *De lege lata*

3.1. Introduction

As already mentioned, both the United Kingdom and Germany nowadays provide for unremunerated statutory exceptions for experimental purposes. The introduction of such a statutory instrument is arguably based on considerations of public interest to enable research on the patented invention through legislation. Importantly, the emergence of statutory exceptions within these jurisdictions was generally not solely a result of national legislation. It was heavily influenced by European legislation, like current patent law is as a whole. The texts of the contemporary patent acts of the United Kingdom and Germany are therefore a product of the influence of European law. For the current law in relation to exceptions to patentees' rights in national laws, it is one measure that is of utter importance: The Community Patent Convention (CPC) 1975 and its Article 31 which was transposed into British and German patent legislation.¹⁶⁴

An analysis of how public interest considerations are currently applied within national laws in relation to research exceptions warrants an analysis of what guided the drafters of the template, Article 31 (b) CPC 1975. Indeed, drafting an unremunerated statutory exception for research purposes was not a straightforward task for the drafters: An exception provision had to permit experimenting and researching of patented inventions, which was deemed to be crucially important for the public interest of technological advance. However, research nowadays is being conducted by commercially orientated companies. Additionally, universities have shifted their research focus on commercially viable topics.¹⁶⁵ Hence, the

¹⁶⁴ The CPC 1975 itself was originally conceived to establish a unitary patent within the then EEC. Some provisions within this Convention however were applied to harmonise national patent laws of EEC Member States. Article 31 of the CPC 1975 (Art 27 of the CPC1989) which regulates the "Limitation of the effects of the Community patent" has been transposed into the national patents acts of EC Member States in one way or the other. In most cases the wording hardly differs from this template. In relation to experimental uses, Section 60(5)(b) of the UK Patents Act 1977 as well as § 11 Nr. 2 mirror Article 31 (b) of the CPC 1975.

¹⁶⁵ Vincenzo di Cataldo, 'The Experimental Use of the Patented Invention: A free Use of and Infringing Use?' in Wolrad Prinz zu Waldeck und Pyrmont, Martin J. Adelman, Robert Brauneis, Josef Drexl and Ralph Nack (eds), *Patents and Technological Progress in a Globalized World – Liber Amicorum Joseph Straus* (Springer 2009) 94.

traditional approach to regard all commercially orientated uses of the patented invention as an infringement could remain a viable approach.¹⁶⁶ On the other hand, allowing such uses would have to consider a possible decrease in incentives that the patent right is supposed to provide for. Hence, an experimental use provision needs to be carefully drafted in order not to carve out too much of the patent holder's exclusivity.

This chapter will analyse how Article 31 CPC 1975 was conceived historically and what motives were applied. It will then show how national legislators have implemented the template. Having been positively affirmed by the legislator the analysis of how courts in Germany and the United Kingdom have interpreted the exception and how considerations of public interest were hereto applied becomes particularly important. The analysis of any divergences will be crucial if one bears in mind that the template's aim was to harmonise national laws and therefore the extent of the right held by the patentee.

3.2 The template of Article 31 Community Patent Convention 1975

The manner how Article 31 CPC 1975 was conceived is important for an understanding of national exception provisions. This is not only because the wording of the research exceptions in British and Germany is modelled upon the template of the Community Patent Convention. Rather, such a historical analysis is mandated since Sec 130 (7) UK Patents Act 1977¹⁶⁷ and decided case law in both jurisdictions¹⁶⁸ highlight the Community Patent Convention's impact on interpreting national provisions.¹⁶⁹ Courts therefore need to consider the historical template when interpreting their national exceptions.

¹⁶⁶ Di Cataldo holds a rule that would only allow purely experimental uses on the patented invention as "useless" - *ibid* 94.

¹⁶⁷ The provision stipulates that Sec. 60 (among other provisions) "are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty have in the territories to which those Conventions apply."

¹⁶⁸ See for instance the High Court decision in *Monsanto v Stauffer* where the judge acknowledged that pre-Patents Act 1977 (UK) case law was not applicable due to the legislative history of Section 60(5)(b) which would make such approach not be possible anymore - *Monsanto v. Stauffer Chemical* [1985] RPC 515, 537-538. For the situation in Germany see - BGH, GRUR 1996, 109 - Klinische Versuche I = BGH, RPC 1997, 623 - Clinical Trials I; BGH, NJW 1997, 3092 - Klinische Versuche II = BGH, RPC 1998, 423 - Clinical Trials II.

¹⁶⁹ This provision has had substantive effect on the interpretation of statutory provisions as the CIPA commentary on the UK Patents Act 1977 notes: "At the time of its enactment, the provision of subs.(7) was unique in United Kingdom statute law, but other examples are arising as the strict interpretation of United Kingdom statutes comes to be adapted to the interpretation of Continental civil law which is often expressed in terms of principles rather than means." - Paul G. Cole and Stephen F. Jones (eds), *CIPA Guide to the Patent Act 1977* (7th edn, Sweet & Maxwell 2011) [130.02].

The final provision of Article 31 of CPC 1975¹⁷⁰ regulated the “Limitation to the Effects of the Community Patent”:

“The rights conferred by a Community patent shall not extend to:

- (a) acts done privately and for non-commercial purposes;
- (b) acts done for experimental purposes relating to the subject-matter of the patented invention;
- (c) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription nor acts concerning the medicine so prepared;
- (d) the use on board vessels of the countries of the Union of Paris for the Protection of Industrial Property, other than the Contracting States, of the patented invention, in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of Contracting States, provided that the invention is used there exclusively for the needs of the vessel;
- (e) the use of the patented invention in the construction or operation of aircraft or land vehicles of countries of the Union of Paris for the Protection of Industrial Property, other than the Contracting States, or of accessories to such aircraft or land vehicles, when these temporarily or accidentally enter the territory of Contracting States;
- (f) the acts specified in Article 27 of the Convention on International Civil Aviation of 7 December 1944, where these acts concern the aircraft of a State, other than the Contracting States, benefiting from the provisions of that Article.”

Earlier versions of this provision date back to discussions held by the Working Group Patents which was established under the auspices of the EEC in 1959.¹⁷¹ It was formed of experts from the then 6 EEC countries and had the ultimate aim to propose a framework for a unitary patent right within EEC countries.¹⁷² The United Kingdom did not participate in this exercise since it only became a Member State of the European Economic Community (EEC) in 1973.¹⁷³

The final provision of Article 31CPC 1975 was initially based on a proposal by the Benelux Working group patents. This proposal importantly foresaw a European rather than a national

¹⁷⁰ Corresponds to Article 27 (b) of the Community Patent Convention 1989.

¹⁷¹ Kurt Haertel ‘Die geschichtliche Entwicklung des europäischen Patentrecht’ in Friedrich-Karl Beier, Kurt Haertel and Gerhard Schrickler (eds), *Europäisches Patentübereinkommen, Münchner Gemeinschaftskommentar* (Carl Heymanns Verlag 1984) [38].

¹⁷² A Working Group Patents was established under the auspices of the EEC in 1959 formed of experts from the then 6 EEC countries. Its ultimate aim was to elaborate a framework for a unitary patent right within EEC countries - Draft Convention relating to a European Patent Law [1963] Journal of the Patent Office Society pp. 182; Kurt Haertel, ‘Die Entwürfe der Übereinkommen über ein europäisches System der Erteilung von Patenten und über ein Patent für den Gemeinsamen Markt [1970] GRUR Int 95.

¹⁷³ The twofold approach of integration of European patent law can be partly explained by the UKs late entry into the EEC. The developments in the 1950ies and 60ies show that EEC countries on the one side strived for more integration within the Community while on the other hand wishing to have the participation of countries outside the EEC such as the UK - Erika Ellyne, ‘European unitary patent: are we there yet?’ [2014] QMJIP 57, 59.

solution for the effects of the proposed European patent right.¹⁷⁴ In contrast, the initial Draft Convention on a European Patent provided that the effect of the European Patent should have the effect as a nationally granted patent.¹⁷⁵ The proposition of the Benelux-Group on the Patent Working Group however, favoured a European solution. The representative from the Netherlands, Bob van Benthem (later to become the first president of the European Patent Office) argued that European Patent Law would need to be a point of reference for national laws. Otherwise, a different scope of protection in the Member States would be applied.

Van Benthem also noted that a national solution would enable national legislators to limit the effect of a European Patent by altering their legislation:¹⁷⁶ If national laws would regulate the effect of a European Patent then neither the patent owner nor the public would be able to assess the scope of its protection easily.¹⁷⁷ Importantly, van Benthem remarked in a response that a European solution was being favoured in relation to the patentability criteria in order to force national legislators to harmonise their corresponding provisions.¹⁷⁸ This would also mandate a European solution for an important question such as the effect of a European Patent.¹⁷⁹

It also appears that an underlying current within the drafting exercise of the European Patent Convention in the 1960ies related to the drafters' wish for a European Patent to have at least the same, if not a higher level of protection in relation to national rights. The drafters aimed at creating an attractive European patent in comparison to national patents.¹⁸⁰ The European solution had an additional effect, although this might have not been the intention of the original drafters then. The promoted European option with regards to the effects of European patents enabled such European provisions to serve as templates for harmonising national law in relation to the law of infringement and exceptions thereof.

¹⁷⁴ Ergebnisse der Sitzungen der EWG-Arbeitsgruppe "Patente", Dokument IV/6365/61-F, pages 1, 5.

¹⁷⁵ The first draft text on a Convention on the European Patent read that the European Patent should have the same effect in every Member States as a patent granted under national rules - Ergebnisse der Sitzungen der EWG-Arbeitsgruppe "Patente", Dokument IV/2498/1/61-D,13.

¹⁷⁶ Ergebnisse der Sitzungen der EWG-Arbeitsgruppe "Patente", Dokument IV/6514/61-D, 35.

¹⁷⁷ *ibid* 36.

¹⁷⁸ *ibid* 39.

¹⁷⁹ Ergebnisse der Sitzungen der EWG-Arbeitsgruppe "Patente", Dokument IV/6514/61-D, 39.

The main points of criticism on the Benelux proposal related to the lacking European jurisprudence and the fact that national legislators would alter national legislation would be a theoretical problem (pages 37-38). One important point that was also raised by Kurt Haertel was the fact that national law would apply with regards to remedies to patent infringement. (Kurt Haertel pages 40-41). Similar concerns were raised by the French Member of the Patents Working group, Mr Fressonet (page 42).

¹⁸⁰ See remarks from van Benthem (*ibid* 39), Kurt Haertel (*ibid* 41) and of the Italian delegate, Professor M Roscioni, who stated that the protection that a European Patent provides should be stronger than national protection in order not to favour national patent protection. (page 39).

Importantly, the Benelux proposal proved to be a milestone in the evolution of the research exception in European patent law. The proposal provided that the effect of the patent right would extend to such third party uses which are committed for commercial purposes.¹⁸¹ The provision, however, did not extend to acts for private purposes or such of experiments.¹⁸² This proposal was further discussed by the Patents Working group. Van Benthem stated that “experimental use” would need to be understood as covering “scientific purposes”.¹⁸³ He added that technical progress would make purely scientific experiments conducted by private persons and by tradesmen permissible.¹⁸⁴ The remark – that research conducted by tradesmen could be permissible - marks an important deviation from the traditional approach in how experimenting was perceived within patent law in Europe.¹⁸⁵

The Benelux proposal was finally adopted in Article 20 (3) of the Draft proposal:¹⁸⁶

“The Rights attached to a European patent shall extend only to acts done for industrial or commercial purposes. In particular, acts done for private or experimental purposes, shall not be deemed to be done for industrial or commercial purposes.”¹⁸⁷

This marks an important step to the present provision since the linkage between experimental and private uses as excluded uses was severed for the first time. The wording of the provision stipulates that private or experimental uses are not considered to be for industrial or commercial purposes. The fact that the purposes could be either for experimental or private purposes meant that experimental purposes would not necessarily have to be private. This wording would allow commercially orientated experiments. The provision opened the door

¹⁸¹ Ergebnisse der Sitzungen der EWG-Arbeitsgruppe “Patente”, Dokument IV/5569/1/61-D.

¹⁸² *ibid* 49.

¹⁸³ *ibid* 49.

¹⁸⁴ *ibid* 49.

¹⁸⁵ *supra* chapter 2.

¹⁸⁶ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag, 1986) 161.

¹⁸⁷ Vorentwurf eines Abkommens über ein europäisches Patentrecht [1962] GRUR Ausl 561, 565; Draft Convention relating to a European Patent Law [1963] Journal of the Patent Office Society 182, 199.

Additionally, the alternative proposal (which was provided within an alternative version of Article 20) was put forward and stipulated that the European patent would have the same effect as a national patent within this Member State. (see - Vorentwurf eines Abkommens über ein europäisches Patentrecht [1962] GRUR Ausl 561, 565; Draft Convention relating to a European Patent Law [1963] Journal of the Patent Office Society 182, 200;).

(It has to be noted that the translation provided in the Journal of the Patent Society errs in the translation of Article 20(3). The German original text reads as follows: „Als Handlungen, die zu solchen Zwecken vorgenommen werden, gelten insbesondere nicht Handlungen zu privaten oder Versuchszwecken.“ This translates to the translation provided while the translation in the Journal of the Patent Society speaks of “acts done for private **and** experimental purposes” (emphasis added). This translation stipulates that the purpose would have to be private and experimental cumulatively in order not to be deemed non-commercial, and therefore within the exception.

for other uses to be exempted from infringement. The reference that acts for private and experimental purposes were exempted *in particular* highlights that these acts are not considered to be exhaustive list of exempted uses. This approach is additionally emphasised by the fact that the patent rights should *only* extend “to acts done for industrial or commercial purposes.”

This intermediary proposal, however, underwent certain revisions. The following discussions of the Working Group Patents led to a pre-draft of 1965 and saw an amendment of the Benelux proposal, whereby the use of the patented invention for experimental purposes was now permitted where they would relate to the subject matter of the invention.¹⁸⁸ The Working Groups efforts, were however, halted since works of the EEC Patent finally seized due to the lack of agreement on the United Kingdoms’ involvement with the project as non-EEC Member in mid-1965.¹⁸⁹

The European Free Trade Association (EFTA) saw to reconcile the issue between EEC and non-EEC members and the EFTA Council established a Working Group under the auspices of Edward Armitage to review the 1962 proposal.¹⁹⁰ The EFTA approach took a different avenue as it commenced work on a European granting procedure which would allow participation of as many European states as possible¹⁹¹ while leaving an option for EEC states to create a unitary patent right.¹⁹²

The French Government restarted the initiative to devise a European patent law in 1969 and adopted the two conventions approach taken by the EFTA proposal.¹⁹³ This meant that EEC

¹⁸⁸ Vorentwurf eines Abkommens über ein europäisches Patentrecht, Dokument 2235/IV/65.

¹⁸⁹ Friedrich-Karl Beier, ‘Stand und Aussichten der europäischen Rechtsvereinheitlichung auf dem Gebiete des gewerblichen Rechtsschutzes’ [1969] GRUR Int 145, 146; Otto Bossung, ‘The Return of European Patent Law to the European Union’ [1996] IIC 287, 288; Peter Drahos, *The Global Governance of Knowledge – Patent Offices and their clients* (Cambridge University Press 2010) 120.

Haertel states that “the standstill was caused exclusively for political reasons. Power politics affected this special area; one Member State, the Netherlands, wanted to have Great Britain included in the work, while another, France, was opposed.” - Kurt Haertel, ‘The Draft Conventions for a European System for the Grant of Patents and for the European Patent for the Common Market’ [1970] IIC 289, 290.

¹⁹⁰ Draft of an open European Patent Convention forming the first convention in the two-part Scheme (EFTA Document 4/67); Dennis Thompson, ‘The draft Convention for a European Patent’ [1973] International and Comparative Law Quarterly 54-55.

¹⁹¹ The work on this culminated in the signing of the European Patent Convention of 1973 which was signed in Munich - Kurt Haertel, ‘Die Luxemburger Konferenz und ihre wesentlichen Ergebnisse’ [1976] GRUR Int 188.

¹⁹² Gérard Curzon and Victoria Curzon, ‘EFTA Experience with Non-Tariff Barriers’ in Hugh Corbet and David Robertson (eds), *Europe’s Free Trade Area Experiment: EFTA and Economic Regulation* (Pergamon Press 1970) 140.

¹⁹³ Kurt Haertel, ‘Die geschichtliche Entwicklung des europäischen Patentrecht’ in Friedrich-Karl Beier, Kurt Haertel and Gerhard Schrickler (eds), *Europäisches Patentübereinkommen, Münchner Gemeinschaftskommentar* (Carl Heymanns Verlag 1984) [50]-[54].

Member States continued the work on a unitary patent right for the Common Market.¹⁹⁴ The provision relating to exempting uses for research purposes remained the same within the First pre-draft on the Convention on the European Patent for the Common Market.¹⁹⁵ It was only positioned within Article 10 (3) of the Draft Convention¹⁹⁶ and remained untouched in the Second Draft:

The effects of a Community patent shall extend only to acts done for industrial or commercial purposes. In particular, acts done privately and for private ends and acts done for experimental purposes with a bearing on the subject matter of the patented invention shall not be deemed to be done for industrial or commercial purposes and both uses.¹⁹⁷

The wording stipulates that experimental and private uses are not considered to be industrial or commercial. It also clearly separates between private uses and those conducted for research purposes. In comparison to the final version within the Luxembourg Convention, research was still organised under the effects of patent protection within Article 10, rather than as a separate exception provision which this draft included within its Article 11. The final version of the Luxembourg Convention however placed researching within a separate exception provision. Article 31 CPC 1975 made the division of uses for private and uses for experimental even more visible. The provision now separates private and non-commercial uses in its letter (a) from acts done for experimental purposes in letter (b).

The importance of the final version for national legislation is based on the fact that the Records of the Luxembourg Conference on the Community Patent 1975 contained a Resolution on the Adjustment of National Patent Law.¹⁹⁸

There, the decision was taken:

[T]o commence the work, as soon as the Convention has been signed, to adjust their laws relating to national patents as soon as possible so as to permit ratification of the Strasbourg Convention on the unification of certain points of substantive law on patents for inventions, and so as to bring their laws

¹⁹⁴ Dennis Thompson, 'The draft Convention for a European Patent' [1973] *International and Comparative Law Quarterly* 57.

¹⁹⁵ Erster Vorentwurf eines Übereinkommens über das europäische Patent für den Gemeinsamen Markt [1970] GRUR Int 127.

¹⁹⁶ The following discussions with regards to the provision saw no necessity to delete the limitation within Article 10 (3) that stipulated that the research needed to be in relation to the subject matter of the invention. An expert committee held that a deletion of this requirement would otherwise curtail the patent right excessively since any use for experimental purposes would then be permitted - Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 162-163.

¹⁹⁷ Department of Trade and Industry, 'Patents in the Common Market' (HMSO 1972).

¹⁹⁸ The need to adjust national patents laws with regards to the effect of patent protection to a European provision hereto was already mentioned by van Benthem in the discussion of the Patents Working Group on the European Patent Convention in 1961 - Ergebnisse der Sitzungen der EWG-Arbeitsgruppe "Patente", Dokument IV/6514/61-D, 42.

into conformity, as far as practicable, with corresponding provisions of the European Patent Convention, Community Patent Convention and the Patent Cooperation Treaty.¹⁹⁹

The transposition of the provisions regarding infringement and exceptions into the national patent laws had two effects: First, the European Patent Conventions' (EPC) lack of model provisions regarding substantive law in relation to the effect of the patent right and limitations thereof was overcome with the provisions within the CPC.²⁰⁰ Second and ultimately, Article 64 of the EPC foresees that a European patent granted by the EPO has the same effect in the designated country as patents granted by national offices in that country. Since the Community Patent would also be a European patent, the effect of such a European (Community) patent needed to be identical to that in the individual Member States.²⁰¹

While the Community Patent Convention failed to be adopted as a whole, most European countries incorporated the CPC provisions into national law in anticipation of the Convention coming into force.²⁰² Article 31 CPC 1975 was finally both transposed in the patent acts of the United Kingdom and Germany.²⁰³ The provisions resemble their CPC template so there are no major differences in wording.²⁰⁴

The historical analysis of Article 31 CPC 1975 implies that the European legislator wished to allow experiments conducted by commercially orientated researchers.²⁰⁵ This was made possible by providing distinct provisions for private and non-commercial uses and use for experimental purposes. Additionally, the Memorandum on the Community Patent elaborates on what was considered to be as experimental purposes within Article 31 b CPC 1975. These are, *inter alia*, such uses assessing the invention's applicability and whether the invention can

¹⁹⁹ 'Resolution on the Adjustment of National Patent Law Records of the Luxembourg Conference on the Community patent 1975' in *Records of the Luxembourg Conference on the Community patent 1975* (Office for Official Publications of the European Communities 1982) 332.

²⁰⁰ The German legislator specifically regarded the adaptation of the German Patent Act to the provisions of 29, 30 and 31 CPC as imperative - Begründung zum Entwurf eines Gesetzes über das Gemeinschaftspatent und zur Änderung patentrechtlicher Vorschriften (Gemeinschaftspatentgesetz) BlfPMZ 1979, 276, 279.

²⁰¹ This for instance was the clear intention of the German legislator when amending its patent act – *ibid* 279; Albrecht Krieger, 'Das neue deutsche Patentrecht nach der Harmonisierung mit dem europäischen Patentrecht - eine Übersicht' [1981] GRUR Int 273, 278.

²⁰² Vincenzo di Cataldo, 'The experimental use of the patented invention: a free use of an infringing use?' in Emanuela Arezzo and Gustavo Ghidini (eds), *Biotechnology And Software Patent Law – A Comparative Review of New Developments* (Edward Elgar) 92.

²⁰³ *Infra* 3.3.1 and 3.4.1.

²⁰⁴ Fiona Bor, 'Exemptions to patent infringement applied to biotechnology research tools' [2006] EIPR 5, 6.

²⁰⁵ It has to be noted that van Benthem later wrote that that experiments within the understanding of Article 31 (b) CPC 1975 "must be purely scientific and may not serve any commercial purpose." - Johannes Bob van Benthem, 'The Rights conferred by a Community Patent under the Community Patent Convention' in Robert R. Pennington (ed), *European Patents at the Crossroads* (Oyez Publishing 1976) 129.

be further developed.²⁰⁶ Thus, the template of Article 31 b CPC 1975 provided for a new approach with regards to experimental uses of a patented invention. The historical context can therefore serve as a basis for interpreting domestic exception provisions in light of its historical template.

Article 31 (b) CPC 1975 emphasises the legislators' desire to discard a lack of a "strategic distinction between academic research and research in industry."²⁰⁷ This is justified according to Benyamini because "a considerable amount of experimental work is performed by non-private (though not necessarily commercial) bodies, such as universities and research institutions."²⁰⁸ The negotiating documents relating to Article 31 (b) CPC 1975 however, do not clearly acknowledge this. Cornish, however, states that this guided the negotiations:

Until the last two decades, when that Article began to be incorporated into national law, the scope of any exception to patent infringement for experimentation was in most systems ill-defined; in some, certainly, it was confined to the private and personal use of a scientific experimenter. The changing nature of research among industrial competitors and in academic-industrial relationships has led to a step-wise expansion of the experimental use exception and this was apparently the intention of the governments which negotiated the CPC. No longer is any exception confined to the strictly non-commercial, because frequently scientific curiosity operates in conjunction with the desire to turn successful work to account. It has long been a major objective of the patent system that the latter should follow from the former.²⁰⁹

3.3 The Law in the United Kingdom

3.3.1. Introduction

The law of patents in the United Kingdom is enacted in the Patents Act 1977²¹⁰ and the Patent Rules 2007.²¹¹ One reason for its enactment was the required assimilation of UK patent law with three international conventions, namely the EPC, the CPC and the Patent

²⁰⁶ Denkschrift zum Übereinkommen über das europäische Patent für den gemeinsamen Markt (Gemeinschaftspatentübereinkommen) [1979] BlfPMZ 325, 333.

²⁰⁷ William R. Cornish, 'Experimental Use of Patented Inventions in European Community States' [1998] IIC 735, 736.

²⁰⁸ Amiram Benyamini, *Patent Infringement in the European Communities* (IIC Studies 1993) 272.

²⁰⁹ William Cornish, 'Experimental use of patented inventions in European Community states' [1998] IIC 735, 752.

²¹⁰ The Patents Act 1977 came into force on 01st of June 1978.

²¹¹ The Patents Rules 2007, SI 2007/3291.

Cooperation Treaty (PCT).²¹² The 1977 Act provides for statutory exceptions to patent infringement within its Section 60 (5).²¹³

With regards to the research exception that was included in Section 60(5)(b) UK Patents Act 1977, the important question arose whether previous case law would apply to interpret the current provision.²¹⁴ The application of this case law would have an effect on the court's interpretation and therefore the public interest considerations surrounding it. In *Monsanto v Stauffer*, the Court of Appeal however, held in rather lapidary words that this was not the case.²¹⁵

3.3.2. Section 60(5)(b) UK Patents Act 1977

Section 60(5)(b) of the Patents Act 1977 follows the template of Article 31 CPC 1975 and exempts otherwise infringing uses from patent infringement when two requirements are cumulatively met: First, the act undertaken by the defendant must have been done for commercial purposes and secondly, this use must relate to the subject matter of the invention.

As to what constituted experimental use it held that this would be such use in trials that aim at discovering “something unknown or to test a hypothesis.”²¹⁶ This would also be the case where it is carried out “in order to find out whether something which is known to work in specific conditions, e.g. soil or weather, will work in different conditions...” However, where such trials would only relate to demonstrating the viability of the product or gather information for a third party then such use could not be considered as experimental use.²¹⁷ In the latter case, the experimenter would not be seeking to test a hypothesis.

Importantly, the Court of Appeal in *Monsanto v Stauffer* expressly discarded the argument made by the High Court in the appealed decision (and brought forward by the plaintiff's

²¹² Simon Thorley, Richard Miller, Guy Burkill, Colin Birss, Douglas Campbell, *Terrell on the Law of Patents* (17th edn, Sweet & Maxwell 2011) [1-25].

²¹³ While most of the statutory exceptions are modelled upon Article 27 CPC 1975 some additions were made after the enactment of the Patents Act 1977. Article 11 of the Biotechnology Directive has been implemented within paragraphs (g) and (h) of subsection (5). Paragraph (i) was added to subsection (5) to implement certain provisions of Directives 2001/82/EC and 2001/83/EC.

²¹⁴ The Counsel for the plaintiffs in the appeal in the *Monsanto v Stauffer* case before the Court of Appeal, Stephen Gratwick QC, has argued “that Parliament, by using the phrase “for experimental purposes” must be taken to have endorsed the earlier decisions of the English Court.” - *Monsanto v. Stauffer Chemical* [1985] RPC 515, 537.

²¹⁵ The judge held: “...I have no reason to suppose that the signatories of that Convention were concerning themselves with the minutiae of earlier U.K. patent law.” - *ibid* 537-538.

²¹⁶ *Monsanto v. Stauffer Chemical* [1985] RPC 515, 542.

²¹⁷ *ibid* 542.

counsel in the appeal) that the notion “relating to experimental purposes” ought to be construed narrowly as to exclude such experiments of the invention that are focus on the commercial exploitation of the results.²¹⁸ The Court of Appeal accepted that experiments can be conducted with “a commercial end in view”.²¹⁹ The court came to this finding by applying a systematic interpretation by looking at Sec 60 (5) of the UK Patents Act 1977 where non-commercial use was specifically mentioned while not within Sec. 60(5)(b) UK Patents Act 1977.²²⁰ This omission by the legislator meant that use for experimental purposes would not necessarily need to be non-commercial.

With this approach the Court of Appeal appears to denote a dividing line of what could be considered constituting experiments within the meaning of section 60(5) of the Patents Act 1977 (UK). It however, did not provide for enough clarity with regards to whether a commercial intention surrounded the experimental use. This can be seen in the succeeding decision in *Smith Kline & French Laboratories Limited v Evans Medical Limited* where Mr. Justice Aldous sitting in the Patents Court elaborated that the dividing line would be drawn “between trials which were experimental and those which were in truth a matter of amassing statistics to further commercial exploitation”²²¹. This arguably revisits the old case law which would not prohibit such experiments which were conducted to commercialise from these uses. This notion was refined in *Inhale Therapeutic Systems Inc. v Quadrant Healthcare Plc* where Laddie J found that an experimental use could not be found where the use relates to the defendant’s “own purposes (emphasis added)”²²² but to using it “to exploit and sell its technology to third parties.”²²³

What these court decisions seem to suggest is that while experimental purposes may be commercially motivated, this must not be the predominant motive of the experimenter when using the patented invention.²²⁴ Since the motives of experiments may be based on various motives, the courts seem to look at which is the “preponderant purpose”²²⁵ of the

²¹⁸ *Monsanto v. Stauffer Chemical* [1985] RPC 515, 538.

²¹⁹ *ibid* 538.

²²⁰ *ibid* 538. This can be derived from the context of the submission of the court.

²²¹ *Smith Kline & French Laboratories Limited v Evans Medical Limited* [1989] 1 F.S.R. 513, 522.

²²² *Inhale Therapeutic Systems Inc. v Quadrant Healthcare Plc* [2002] R.P.C. 21, 419,463

²²³ *ibid* 463.

²²⁴ *Corevalve Inc v Edwards Lifesciences AG* [2009] F.S.R 8, 367, 388

²²⁵ *ibid* 388.

experiments. Hence, where they are motivated in order to generate “immediate revenue”²²⁶ the courts will discard the use from being exempted from patent infringement.

This sits awkwardly because this approach suggests that, while acknowledging that experiments can be conducted where further commercialisation is intended, they would be disallowed where this is their preponderant purpose. The statutory provision however, does not reveal such a differentiation at all. The courts arguably still would refer to the rationale of the pre-1977 Act case law with regards to exempting experimental uses of the patented invention.

What this approach also suggests is that the courts are exempting experimental uses based on a condition which is not mandated nor stipulated by the text of the provision or its legislative history. What could have led to this approach is a rather literal approach to the term “experimental” that might be informed by the *bona fide* approach in *Frearson v Loe*²²⁷: In *Monsanto v Stauffer* the court specifically mentioned that Jessel’s definition of what constituted a bona fide experiment would be “what is intended by the wording of paragraph (b) of section 60(5) of the Patents Act 1977.”²²⁸ The statutory provision however does not mandate an analysis of the experimenter’s intention in any way and is not in line with the historical roots of Article 31(b) CPC 1975. Rather, the Court of Appeal is contradicting itself whether old case law would be applicable or not.

In defining what the meaning of “relating to the subject matter of the invention” would be, the High Court submitted in *Monsanto v Stauffer* that this should have a narrow meaning.²²⁹ It held that experiments that were aimed “to test or evaluate *some other* product or process”²³⁰ (emphasis added) would not relate to the subject matter of the invention. These would then not relate to the subject matter of the invention. Additionally, the court held that this limitation would “exclude tests or trials having as their purpose in achieving or extending the commercial acceptance of some commercial embodiment of the patented invention”.²³¹

²²⁶ *Corevalve Inc v Edwards Lifesciences AG* [2009] F.S.R 8, 367, 388.

²²⁷ *supra* 2.2.3.

²²⁸ *Monsanto v. Stauffer Chemical* [1985] RPC 515, 530.

²²⁹ So the assessment of the courts’ interpretation in Simon Thorley, Richard Miller, Guy Burkill, Colin Birss, Douglas Campbell, *Terrell on the Law of Patents* (17th edn, Sweet & Maxwell 2011) [14-79].

²³⁰ *Monsanto v. Stauffer Chemical* [1985] RPC 515, 522.

²³¹ *ibid* 522.

According to the court, this could not be derived from a literal interpretation of the provision.²³²

To strengthen his argument, Falconer J, applied a teleological interpretation by holding that it could not be the purpose of the provision to allow tests or trials that are directed to the future marketability of a hypothetically infringing product.²³³ This finding of the court may have been based on its application of the pre-1977 Act case law which took such an approach. The High Court specifically stated that “Parliament...was intending to continue in statutory form the prior United Kingdom law as to experimental use of a patented invention.”²³⁴

The Court of Appeal did not discuss the notion of relating to the subject matter of the invention in the appeal of *Monsanto v Stauffer*.²³⁵ This was because it already concluded that the trials in question were not experiments in the reading of Section 60(5)(b) UK Patents Act.²³⁶ In another decision, the Court of Appeal held that the subject-matter of the invention would be the patent as a whole²³⁷ and not just the claims of the patents.

3.3.3. Analysis

The introduction of Section 60(5) (b) of the UK Patents Act 1977 verbatim reproduced the legislator’s will that the use of a patented invention for experimental purposes was not patent infringement. The introduction arguably was acknowledging the fact that researching would be in the public interest and should not unduly be hindered by patent rights.²³⁸ This was affirmed by the case law: In *Corevalve* the deputy judge stated that “[i]n general, the purpose of this defence is to encourage scientific research while protecting the legitimate interests of

²³² *Monsanto v. Stauffer Chemical* [1985] RPC 515, 522.

²³³ *ibid* 522.

²³⁴ *ibid* 523.

²³⁵ This was noted by the German Federal Court in the Clinical Trials I decision - BGH, GRUR 1996, 109 (112) - Klinische Versuche I = BGH, RPC 1997, 623 (640-641) - Clinical Trials I.

²³⁶ This was noted by the German Federal High Court in the Clinical Trials I decision - BGH, GRUR 1996, 109 (113) - Klinische Versuche I = BGH, RPC 1997, 623 (640-641) - Clinical Trials I.

²³⁷ *Auchincloss v. Agricultural & Veterinary Supplies Ltd* [1999] RPC 397, 406.

²³⁸ Bently and Sherman posit that the exception for experimental purposes is grounded on several policies, one of them being that the grant of patents should not be inhibiting scientific development -Lionel Bently and Brad Sherman, *Intellectual Property Law* (4th edn, OUP 2014) 635.

the patentee.”²³⁹ This stipulates that researching as such, as well as the other exempted uses within Section 60(5) would be in the public interest.²⁴⁰

The courts however, seemed to meander around the issue whether commercially orientated experiments were also fully included within exception. While this was acknowledged by the Court of Appeal in *Monsanto v Stauffer*, other courts have continued to discard such experiments as falling outside of the scope of the exemption that are have a preponderant commercial orientation. The courts have not applied the built-in limitation of Section 60 (5) (b): The exception provision provides a basis to limit the scope of applicability by its limitation to the subject matter of the patented invention. It appears that the courts wanted to limit the extent of the exception by a narrow interpretation of “experimental purposes”. They did so by applying the rationale of pre-1977 Act case law to interpreting such purposes.

Generally, it appears that the courts have had difficulties in adopting the new scenario with new statutory law. This may be the case because courts in the United Kingdom are deemed to adopt a more literal interpretation of statutory law than other jurisdictions. This is because they wish to adopt Parliament’s will as being the supreme source of legislation. The courts did not really engage with the historical template that was aimed at clearly allowing experiments that had a commercial intention.

The narrow approach that the courts apply may be based on the fact that most notable cases in relation to the experimental use defence related to whether trials conducted for regulatory approval would fall within the provisions. This led to the interpretive dilemma that experiments with this regard do not in first line serve technological advance as they tend to duplicate the findings that the patent owner already provided for. It remains to be seen how courts would decide how commercially orientated experiments would have been perceived where new data and information is being devised.

The narrow scope of interpretation of the research exception with regards to regulatory approval led to the inception of a Bolar exception which derives from EU legislation.²⁴¹

²³⁹ *Corevalve Inc v Edwards Lifesciences AG* [2009] EWHC 6 [72].

²⁴⁰ Paul G. Cole and Stephen F. Jones (eds), *CIPA Guide to the Patent Act 1977* (7th edn, Sweet & Maxwell 2011) [60.13].

²⁴¹ Section 60(5)(i) UK Patents Act 1977:

- (i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or
- (ii) any other act which is required for the purpose of the application of those paragraphs.

Additionally, the UK had introduced new legislation within Article 60(6D)²⁴² which clarifies that certain medicinal product assessments are to be considered as being experimental purposes in the meaning of Article 60(5)(b).²⁴³ This could stipulate that Parliament as the legislator is required to apply public interest considerations which courts then apply rather than courts themselves providing for an interpretation in the public interest.

3.4 The law in Germany

3.4.1. Introduction

The experimental use defence which is now codified in § 11 Nr. 2 of the German Patent Act²⁴⁴ has been introduced into German Patent law by “soft implementation” of the provisions of the CPC.²⁴⁵ Prior to this, the 1968 Act deemed experimental use to be an infringing use under § 6 of the 1968 Patent Act (or its predecessors) as mentioned above.²⁴⁶ The German legislator applied the Resolution on the Adjustment of National Patent Law through an amendment of the German Patent Act.²⁴⁷ The result of this is that the entire provision of § 11 of the German Patent act is based on Art 31 CPC 1975 (Art 17 CPC 1989) with the exception of § 11 Nr. 2 a) and b) which were introduced at a later point.²⁴⁸ In its official reasoning in relation to the draft of the Act on the Community Patent and the

²⁴² “(6D) For the purposes of subsection (5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention.

²⁴³ “These changes will allow companies to use a patented product, when carrying out testing or other activity to provide information to the regulatory authorities who decide whether a drug should be given a marketing authorisation. Companies will also be allowed to use a patented product in testing or other activity carried out to supply information for health technology assessments.” - ‘The Legislative Reform (Patents) Order 2014 - Explanatory document by the Intellectual Property Office, an Executive Agency of the Department for Business, Innovation and Skills’ (UK Intellectual Property Office 2014) 2

<www.legislation.gov.uk/ukxi/2014/1997/pdfs/ukxi0d_20141997_en.pdf> accessed 23 May 2015.

²⁴⁴ Originally the research exception was implemented within § 6 b) of the German Patent Act (Art 17 III GPatG) but was later incorporated within § 11 PatG - Alfred Keukenschrijver (ed), *Busse Patentgesetz* (7th edn, De Gruyter 2013) § 11[1]. It is applicable for all German Patents and European Patents that designate Germany²⁴⁴ as of 01st January 1981 (§ 12 (1) GPatG. Conversely, the old law was still applicable for any such patent granted before that date - Benkard, *Patentgesetz* (10th edn, C.H. Beck 2006) §1 [1]).

²⁴⁵ Martin Fändrich and Wilfried Tilmann, ‘Patentnutzende Bereitstellungshandlungen bei Versuchen’ [2001] GRUR) 901, 903.

²⁴⁶ supra 2.3.

²⁴⁷ Gesetz über das Gemeinschaftspatent und zur Änderung patentrechtlicher Vorschriften vom 25. Juli 1979, BGBl. I, S. 1269. See also - Alfred Keukenschrijver (ed), *Busse Patentgesetz* (7th edn, De Gruyter 2013) Einl [25]

²⁴⁸ See the discussion in 3.3.2.

amendment of patent provisions, the German legislator refers to the reasoning in the Memorandum on the Agreement over the European Patent for the Common Market (Community Patent Convention) in relation to § 6 b that corresponds to Article 31 CPC 1975.²⁴⁹

The German legislator was highly influenced by this Memorandum when it provided for a statutory exception for research purposes. The Memorandum stated that Article 31 CPC 1975 would provide for a limitation of the effects of the patent rights as they are found within national regulations.²⁵⁰ It continues that such exceptions would be rooted within codified law, or are based on international conventions.²⁵¹ In relation to Article 31 (b) CPC 1975, many national patent laws would similarly permit using the Community Patent for experimental purposes.²⁵² The Memorandum specifically mentions that the particular wording of the provisions would clarify that the experiment itself must relate to the subject matter of the patented invention. This should prohibit the extension of the exception to where the invention is used in an experiment that relates to other subject matter.²⁵³

The new provision led to the similar difficulty as to whether the old case law on experimental uses would still be applicable. In an *obiter dictum*, the German Federal High Court has held in its *Ethofumesate* decision from 21st of February 1989²⁵⁴ that the case law on experimental use on the old § 6 PatG 1968 would not just be applicable for cases relating to the old law²⁵⁵ but would also be applicable for interpreting § 11 Nr. 2 PatG.²⁵⁶ It bases its line of argumentation on other commentators²⁵⁷ and lower court's decisions.²⁵⁸

²⁴⁹ Begründung zum Entwurf eines Gesetzes über das Gemeinschaftspatent und zur Änderung patentrechtlicher Vorschriften (Gemeinschaftspatentgesetz) [1979] BIPMZ 276, 280.

²⁵⁰ Denkschrift zum Übereinkommen über das europäische Patent für den Gemeinsamen Markt (Gemeinschaftspatentübereinkommen), (BIPMZ 1979) 325, 333.

²⁵¹ *ibid* 333.

²⁵² *ibid* 333.

²⁵³ Denkschrift zum Übereinkommen über das europäische Patent für den Gemeinsamen Markt (Gemeinschaftspatentübereinkommen) (BfPMZ 1979) 325, 333.

²⁵⁴ The case related to the 1968 Patent Act.

²⁵⁵ See 2.3.3.

²⁵⁶ BGH, GRUR 1990, 997 (1000 – 1001) - Ethofumesat = BGH, IIC 1991, 541 (545-546) - Ethofumesate.

Through this the experiments exceed from the mere gathering of information which extended beyond the scope of § 6 PatG 1968.

²⁵⁷ See for instance - Gottfried Freier, 'Patentverletzung und Versuchsprivileg' [1987] GRUR 1987 664 and Hans-Heinrich Schmieder, 'Deutsches Patentrecht in Erwartung europäischen Gemeinschaftspatents' [1980] NJW 1190, 1193.

The commentators argued that § 11 Nr. 2 PatG would only codify the current practice under § 6 PatG 1968. Therefore, only such private use and such use that would assess the technical viability of the invention - Thomas Hieber, 'Die Zulässigkeit von Versuchen an patentierten Erfindungen nach § 11 Nr. 2 Pat G 1981' [1996] GRUR 439, 441.

Eventually, the German Federal High Court altered its opinion and gave an unequivocal answer to this question. In *Clinical Trials I*²⁵⁹ it held that the principles regarding experimental use as stated in the *Ethofumesate* decision were no longer directly applicable in relation to the new law.²⁶⁰ Here and within its *Clinical Trials II*²⁶¹ decision it also discussed the new law in relation to application and scope of § 11 Nr. 2 PatG. The court provided guidance as to when an unauthorised use is deemed to be privileged under the experimental use exception. Additionally, the German Federal Constitutional Court has had the opportunity to assess the constitutionality of the PatG, in particular its relationship to the fundamental right of property enacted within Article 14 (1) of the German Basic Law.²⁶²

The approach to discard the old law that emphasised so heavily the commercial nature of the user's purpose was the most significant change from the old law. In finding that the old law would not apply the court allowed such experiments *ex ante* that were based on a commercial interest. The finding of the court can be based on the literal-systematic interpretation of § 11 Nr. 2 PatG that makes no reference to commercial intent anymore or a historical interpretation from the *travaux* of Article 31 b CPC 1975. What however, is important is that the court took the evolution of scientific research of present days into account by tacitly acknowledging that experiments are often undertaken with a commercial intent.²⁶³

3.4.2. § 11 Nr 2 PatG

The term “experimental” in the understanding of § 11 Nr. 2 PatG is a novelty within German statutory patent law. It introduces a legal term which can encompass a broad array of uses²⁶⁴

²⁵⁸ So the District Court of Berlin (LG Berlin, GRUR 1985, 375 (376) - Klinischer Versuch) that held that the legislator codified the prevailing view in the literature as to whether experiments would fall under § 6 PatG 1968.

²⁵⁹ BGH, GRUR 1996, 109 - Klinische Versuche I = BGH, RPC 1997, 623 - Clinical Trials I.

²⁶⁰ BGH (GRUR 1996) 109, (113) [Klinische Versuche I] = BGH, RPC 1997, 623 (640) - Clinical Trials I.

²⁶¹ BGH, NJW 1997, 3092 - Klinische Versuche II = BGH, RPC 1998, 423 - Clinical Trials II.

²⁶² BVerfGE, GRUR, 2001, 43 - Klinische Versuche.

²⁶³ “As research in genetic engineering mostly takes place in commercial corporations due to the high costs associated with such research, and given, as well, that in the case of research carried out in universities or institutes commercial interests are also decisive, clinical experiments with a genetically engineered pharmaceutical will always be based on commercial considerations. The intention that is thus associated with an activity begun and carried out for research purposes cannot categorise said activity as an unlawful activity of infringement merely on the basis of the fact that the results of the research will not solely serve research purposes but above all will serve commercial purposes as well.”- BGH, NJW 1997, 3092 (3095) - Klinische Versuche II = BGH, RPC 1998, 423 (437 - 438) - Clinical Trials.

²⁶⁴ Peter Chrocziel, ‘Benutzung zu Versuchszwecken als Einwand gegenüber einem Anspruch wegen Patentverletzung (Q 105)’ [1992] GRUR Int 203, 204.

such as purely scientific research to such which related to an assessment of profitability.²⁶⁵ The Federal Court of Justice held that the provision of § 11 Nr 2 PatG does not relate to specific uses or actions like § 9 PatG that regulate patent infringement. It rather circles around the purpose of the use in question²⁶⁶ which here is to conduct experiments.²⁶⁷ The Federal Court of Justice has defined experiments as “any (planned) procedure for obtaining information, irrespective of the purpose which the information gained is eventually intended to serve”.²⁶⁸ The emphasis of the purpose of the use provides a broad scope of application as the court itself admits.²⁶⁹ Therefore, § 11 Nr. 2 PatG “exempts all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-matter of the invention, including its use.”²⁷⁰ It states:

Since the provision makes no limit, either qualitative or quantitative, on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests.²⁷¹

It based its finding on the template of § 11 Nr. 2 PatG and the Memorandum that accompanied it:

The memorandum explains the specific experimental acts which are to be permitted only by way of example. The expressly stated experimental purposes, namely checking the utilizability and the possibilities of further development, give a clear indication that the exempted 5 experimental acts are not limited to experiments on a narrowly defined subject-matter of the patent but include a range which goes beyond this and covers in any event checking of the utilizability of the subject-matter of the patented invention and checking possibilities of further development of this invention.²⁷²

In *Clinical Trials II*, the court elaborates on the point of the memorandum providing the examples such as “to test its usability and possibility of further development.”²⁷³ Since this notion stipulates “commercially orientated goals”²⁷⁴ would mean that the provision does not only cover purely scientific experiments.

²⁶⁵ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 149.

²⁶⁶ BGH, GRUR 1996, 109 (112) - Klinische Versuche I = BGH, RPC 1997, 623 (638) - Clinical Trials I; Peter Mes, *Patentgesetz* (3rd edn, C.H. Beck 2011) § 11 [6].

²⁶⁷ BGH, GRUR 1996, 109 (112) - Klinische Versuche I = BGH, RPC 1997, 623 (638) - Clinical Trials I.

²⁶⁸ BGH, GRUR 1996, 109 (112) - Klinische Versuche I = BGH, RPC 1997, 623 (638) - Clinical Trials I.

²⁶⁹ BGH, GRUR 1996, 109 (112) - Klinische Versuche I = BGH, RPC 1997, 623 (638) - Clinical Trials I.

²⁷⁰ BGH, GRUR 1996, 109 (113) - Klinische Versuche I = BGH, RPC 1997, 623 (639) - Clinical Trials I.

²⁷¹ BGH, GRUR 1996, 109 (113) - Klinische Versuche I = BGH, RPC 1997, 623 (639) - Clinical Trials I.

²⁷² BGH, GRUR 1996, 109 (114) - Klinische Versuche I = BGH, RPC 1997, 623 (642) - Clinical Trials I.

²⁷³ BGH, NJW 1997, 3092 (3094) - Klinische Versuche II = BGH, RPC 1998, 423 (433) - Clinical Trials II.

²⁷⁴ BGH, NJW 1997, 3092 (3094) - Klinische Versuche II = BGH, RPC 1998, 423 (433) - Clinical Trials II]. This finding of the court contrasts Freier’s statement that the term “ ” used in the Memorandum would not necessarily stipulate commercially orientated use of the invention but rather its general applicability such as to test its functionality - Gottfried Freier, ‘Patentverletzung und Versuchsprivileg’ [1987] GRUR 664, 667-668.

Thus, the analysis of the historical legislative background enabled the court to apply a broad interpretation.²⁷⁵ Similarly to the Court of Appeal in *Monsanto v Stauffer*, the court additionally applied a systematic interpretation of the provision with § 11 Nr. 1 PatG that explicitly refers to private and non-commercial uses. The omission of such a notion within § 11 Nr. 2 PatG implies that the legislator did not want to “differentiate between commercial and non-commercial uses.”²⁷⁶

The courts’ approach with regards to the language of the provision as well as its assessment of the historical and systematic interpretation led to the broad understanding of “experimental purposes”. The fact that it discarded any qualitative or quantitative restrictions as to what would fall under the exception allowed commercial aims of the experiments to become permissible.²⁷⁷ This interpretation provides a broad scope for uses to be subsumed under the term “experimental”. Limits to this approach in relation to trials are that they must “serve to gain information and to serve the purpose of technological progress. For example, trials must not be carried out on too large a scale, or carried out with the intention of persistently disturbing or interfering with the patentees’ marketing of the patent end products.”²⁷⁸

According to Freier, this scope is also narrowed to such use that relates to investigating and removing an uncertainty.²⁷⁹ This would ban such uses where the intention is the user is not aimed at removing such uncertainty. This is the fact where a product is just rebuilt in order to sell it.²⁸⁰ This notion is emphasised by the fact that only such uses are privileged that are conducted for experimental *purposes*. This limits the scope of the exception to such uses where the user has the voluntative element of experimenting.²⁸¹

²⁷⁵ Trevor Cook, ‘A European Perspective as to the extent to which experimental use, and certain other defences to patent infringement apply to differing types of research’ (IPI Report 2006) 20.

²⁷⁶ BGH, NJW 1997, 3092 (3094) - Klinische Versuche II = BGH, RPC 1998, 423 (433) - Clinical Trials II. A notion that was argued by Chrocziel before the decision, Peter Chrocziel, ‘Benutzung zu Versuchszwecken als Einwand gegenüber einem Anspruch wegen Patentverletzung (Q 105)’ [1992] GRUR Int 203, 205.

²⁷⁷ BGH, GRUR 1996, 109 (113) - Klinische Versuche I = BGH, RPC 1997, 623 (639) - Clinical Trials I. This was confirmed by the Federal Court of Justice in *Clinical Trials II* where it states: „The provision does not differentiate between commercial and non-commercial experiments“ - BGH, NJW 1997, 3092 (3094) - Klinische Versuche II = BGH, RPC 1998, 423 (433) - Clinical Trials II.

²⁷⁸ Trevor Cook, ‘A European Perspective as to the extent to which experimental use, and certain other defences to patent infringement apply to differing types of research’ (IPI Report 2006) 40.

²⁷⁹ Gottfried Freier, ‘Patentverletzung und Versuchsprivileg’ [1987] GRUR 664, 666-667.

This finding mirrors the Court of Appeal’s approach in *Monsanto v Stauffer* of what constitutes an experiment – supra 3.3.2.

²⁸⁰ Thomas Hieber, ‘Die Zulässigkeit von Versuchen an patentierten Erfindungen nach § 11 Nr. 2 Pat G 1981’ [1996] GRUR 439, 441.

²⁸¹ Martin Fändrich and Wilfried Tilmann, ‘Patentnutzende Bereitstellungshandlungen bei Versuchen’ [2001] GRUR 901, 902.

Apart from being conducted for experimental purposes, the use of the patented invention must relate to its subject matter. The court found that this subject matter would include the technical teaching of the patented claim, which includes the use of inventive material.”²⁸² This approach disallows to differentiate between the patented product and its application as two separate items and has been endorsed by the literature.²⁸³ Holzapfel concludes that such an interpretation is possible when referring back to the Memorandum that stipulates that permitted experimental use is such that assesses the invention’s feasibility and its aptitude for further technological development.²⁸⁴ This would extent to uses that go beyond a mere assessment of functionality.²⁸⁵

The Federal High Court found that this wide definition of exempted experimental use was limited by the fact that the experiments would need to relate to the subject matter of the patented invention.²⁸⁶ This notion stipulates “some finality between the act for a specific experimental purpose and the subject matter of the invention.”²⁸⁷ This wording does not allow such experiments where they were not conducted *on* but *with* the patented invention.²⁸⁸ In other words, the patented invention must relate to the subject matter of the experiments and it is not possible to go beyond such a literal interpretation.²⁸⁹

So if the invention was used in order to conduct experiments on other subject matter, then this falls outside the scope of the exception and constitute an infringement. Crucial with this regard is the delineation when the experiments go beyond the subject matter of the

²⁸² BGH, GRUR 1996, 109 (113) - Klinische Versuche I = BGH, RPC 1997, 623 (639) - Clinical Trials I - “However § 11 No. 2 of the Patents Act refers - unlike § 9 of the Patents Act - not to the "subject-matter of the patent" but to the "subject-matter of the patented invention". This term can also be understood, in respect of the experimental acts related to it, to mean that the subject-matter of the invention is the claimed technical teaching, which also includes the use of the inventive substance. This is because it is intrinsic to the nature of the inventive technical teaching that it can be used for profit”.

²⁸³ *ibid* 13.

²⁸⁴ *ibid* 13.

²⁸⁵ Thomas Hieber, ‘Die Zulässigkeit von Versuchen an patentierten Erfindungen nach § 11 Nr. 2 Pat G 1981‘ [1996] GRUR 439, 441.

²⁸⁶ BGH, GRUR 1996, 109 (112 - 113) - Klinische Versuche I = BGH, RPC 1997, 623 (638-639) - Clinical Trials I; Peter Mes, *Patentgesetz* (3rd edn, C.H. Beck 2011) § 11 [6]; Ingve Björn Stjerna, ‘Die Voraussetzungen des patentrechtlichen Versuchsprivileg‘ [2004] *Mitteilungen der deutschen Patentanwälte* 343, 345.

²⁸⁷ Johannes W. Bukow in Maximilian Haedicke and Henrik Timmann (ed), *Patent Law - A Hand book on European and German Patent Law* (2014 C.H. Beck Verlag) § 9 [16] = p. 795. Freier states that the uncertainties that the experiments wish to eradicate must relate the subject matter of the invention - Gottfried Freier, ‘Patentverletzung und Versuchsprivileg‘ [1987] GRUR 664, 667.

²⁸⁸ BGH, GRUR 1996, 109 (112 -113) - Klinische Versuche = BGH, RPC 1997, 623 (638-639) - Clinical Trials I.

²⁸⁹ Georg Benkard, *Patentgesetz* (10th edn, C.H. Beck 2006) § 11 [7]; Rudolf Kraßer, *Patentrecht* (6th edn, C.H. Beck 2006) 787; Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 150, 151; Johannes W. Bukow in Maximilian Haedicke and Henrik Timmann (ed), *Patent Law - A Hand book on European and German Patent Law* (C.H. Beck Verlag 2014) § 9 [16].

invention.²⁹⁰ This is the case where it is used as a means to experiment on other subject matter.²⁹¹ Chrocziel highlights the difficulties of how to differentiate between experiments relating to the subject matter of the invention and where they have been used as a means.²⁹² He suggests looking at whether the invention has been used in the intended way.²⁹³ This would mean use of the invention in the way the patent claims stipulate. This is given when the solution disclosed by the patented invention is being applied.²⁹⁴

3.4.3 Analysis

What clearly distinguishes the German approach in applying the research exception is its purposive interpretation of the provision. As a general statement, the BGH held in the *Clinical Trials I* decision that the only common ground of the various exception provisions of § 11 PatG lies in balancing the interests of the patent holder with those of the general public.²⁹⁵ This general notion renders the research exception to an instrument of balancing between these interests. What the statutory exception provisions stipulate is that the exercise of the patent right may go too far while some spaces should remain free of patent rights.²⁹⁶

The decision by the Federal High Court to allow commercially orientated research on the subject matter is a good example of this balancing exercise that the courts undertook. The old differentiation of commercial/non-commercial research did not reflect the reality of research

²⁹⁰ The Federal High Court, for instance held that the subject matter of the invention in relation to a product patent did not just include the product as such but also its application – BGH, GRUR 1996, 109, 113) -Klinische Versuche = BGH, RPC 1997, 623 (639) - Clinical Trials I.

²⁹¹ Georg Benkard, *Patentgesetz* (10th edn, C.H. Beck 2006) § 11 [7]; Rudolf Kraßer, *Patentrecht* (6th edn, C.H. Beck 2006) 787; Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 150-15; Peter Mes, *Patentgesetz* (3rd edn, C.H. Beck 2011) § 11 [5].

²⁹² Chrocziel discusses for instance whether this question can be answer by considering the experimenters' interest (whether he or she wants to use it as a simple means or whether it is an essential part of the experiments) or on the hypothetical question of what would occur if the patented invention would be extracted from the experiments. If used as a means to conduct the experiments then its absence would not jeopardise the whole experiment - Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 151.

²⁹³ *ibid* 152.

²⁹⁴ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 151.

²⁹⁵ BGH, GRUR 1996, 109 (113) Klinische Versuche I = BGH, RPC 1997, 623(639) – Clinical Trials I.

²⁹⁶ Alfred Keukenschrijver (ed), *Busse Patentgesetz* (7th edn, 2013 De Gruyter) § 11 [5]; Johannes W. Bukow in Maximilian Haedicke and Henrik Timmann (ed), *Patent Law - A Handbook on European and German Patent Law* (2014 C.H. Beck Verlag) § 9 [8].

anymore.²⁹⁷ The old law envisaged the scientist researching alone in his laboratory. Research nowadays is however conducted by private entities and is profit-orientated.²⁹⁸ Even research at universities is often conducted with the assistance of third-party funds.²⁹⁹ If legislators wanted to permit any research to be conducted on the subject matter of the invention they are mandated to allow commercially orientated research. Otherwise, the provisions would be ineffective or rather futile. The introduction of § 11 Nr.2 PatG, being held as serving the public interest, therefore also serves third party interests and emphasises how these concepts influence one another.

The court decisions in *Clinical Trials I and II* demonstrate that the *ratio legis* of § 11 Nr. 2 PatG is clearly based on allowing technological advance as it permits the use of the patented invention which would otherwise constitute an infringement. Krasser states that the research exception is justified because of the information and incentive function of patents.³⁰⁰ It provides the user with the necessary freedom to test patented inventions for their viability, to assess the details of its disclosed solutions for advantages and disadvantages and use the derived information to find improved, different or continuative applications and solutions.³⁰¹

The exclusive right is curtailed in order to prevent impairing the development of new technologies. Experimental uses are deemed to be directly socially useful activities.³⁰² In comparison to other exception provisions within the German Patent Act, the rationale for providing an experimental use exception is identical to the one for granting an exclusive right over inventions. They serve technological progress and contribute to a better supply of needs.³⁰³ They can serve to provide new products or can help to invalidate patents which may serve freedom of competition.³⁰⁴ This mandates legislators to balance the exercise of the right of patent holder with that of third parties.

²⁹⁷ This was criticised by Beier - Friedrich-Karl Beier, 'Zukunftsprobleme des Patentrechts' [1972] GRUR 214, 222 (within fn 64).

²⁹⁸ Martin Fändrich and Wilfried Tilmann, 'Patentnutzende Bereitstellungshandlungen bei Versuchen' [2001] GRUR 901, 901.

²⁹⁹ Thomas Hieber, 'Die Zulässigkeit von Versuchen an patentierten Erfindungen nach § 11 Nr. 2 Pat G 1981' [1996] GRUR 439, 445.

³⁰⁰ Rudolf Kraßer, *Patentgesetz* (6th edn, C.H. Beck 2009) 787.

³⁰¹ *ibid* 787.

³⁰² Similarly di Cataldo - Vincenzo di Cataldo, 'The experimental use of the patented invention: a free use of an infringing use?' in Emanuela Arezzo and Gustavo Ghidini (eds), *Biotechnology And Software Patent Law – A Comparative Review of New Developments* (Edward Elgar) 102.

³⁰³ Henrik Holzapfel, 'Die patentrechtliche Zulässigkeit der Benutzung von Forschungswerkzeugen' [2006] GRUR 10, 12.

³⁰⁴ *ibid* 12.

Since the legislator provided patent rights to incentivise research and development for technological advance, he is only mandated to do so to the extent that this is needed to reward the inventor and to incentivise new inventions.³⁰⁵ This has been achieved with § 11 Nr. 2 PatG as it only allows such experiments which are related to the subject matter of the invention. An infringement would however be found where the invention is being used as a tool because this would directly affect the commercialisation of the patented invention by its owner. Any further reaching use of the invention requires the patent holder's consent and allows him or her to monetise from the invention. Eventually, this purposive German approach strikes a balance between the interests of the patent holder and that of third parties interested in conducting research in relation to the patented invention: The experimental use regularly does only curtail to a limited extent while further going research is not unreasonably hampered.

3.4.4 The fundamental rights discourse and its influence on public interest considerations within German patent law

What the German courts additionally discussed with regards to exceptions to IP rights in general³⁰⁶ and in relation to patent rights was the impact that fundamental rights would have on the assessment. Hence, it is important to analyse how the fundamental rights discourse informs the patent rights-exception discourse in general and to see how this relates to considerations of public interest.

3.4.4.1. The impact of fundamental rights on ordinary law and its interpretation

In contrast to the United Kingdom, Germany has provided for a codified catalogue of fundamental rights within its Basic Law³⁰⁷ since 1949.³⁰⁸ The importance of the Fundamental

³⁰⁵ The Court is applying an economic analysis of patent rights and its function. See also Dreier who states that “the optimum [according to economic wisdom] is to be found not in maximum protection, but in a form of reduced exclusivity somewhere between no protection and high level protection (assuming, of course that both no protection and too much protection may stifle creativity and innovation and that granting some form of intellectual property protection has a positive effect on creativity and innovation).” - Thomas Dreier, ‘How much ‘property’ is there in IP?’ in Helena R. Howe and Jonathan Griffiths (eds), *Concepts of Property in Intellectual Property Law* (Cambridge University Press 2013) 131.

³⁰⁶ In relation to the general discussion on IP law before constitutional courts - Thomas Dreier and Marco Ganzhorn, ‘Intellectual property decisions of national Constitutional Courts in Europe’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) pp 219.

³⁰⁷ The fact that the German Basic Law is not specifically referred to as the Constitution of the Federal Republic of Germany is based on the historical context of its inception. When it was drafted only the part of the German people residing in the Western parts of Germany were involved in its drafting and Western Germany itself was not fully sovereign being under the administration of the Western Allied Powers after the Second World War. It

Rights in comparison to other provisions of the Basic Law is demonstrated by the fact that they are not subject to any amendments.³⁰⁹ These fundamental rights were not merely conceptualised to serve as programmatic guidelines but to display the core values that the Federal Republic of Germany wishes to adhere to. Their codification makes them appear as positive rules, but they can be perceived as a second and superior level of norms that constantly need to be considered by all state power.³¹⁰ They are hierarchically the highest norms within the German legal system.³¹¹ This hierarchical positioning results in them binding “the legislature, the executive and the judiciary as directly applicable law.”³¹²

The importance of fundamental rights has increased since the adoption of the Basic Law. Initially, they were perceived to serve as a safety net against state power.³¹³ But their role has altered. They expanded from their traditional function as protecting the *status negativus*.³¹⁴ This evolution can be described as being twofold: First, fundamental rights provide a set of programmatic rules within the German jurisdiction.³¹⁵ The German Federal Constitutional Court has held that the German Basic Law proposes that fundamental rights display a set of constitutional values that must apply to the law and inform all branches of state power.³¹⁶

Second, they protect an individual where the ordinary law does not or not sufficiently protect its fundamental rights position. If a person³¹⁷ finds that his or her fundamental rights have

was therefore considered to be a provisional text until Germany would be reunified. It has lost the provisional status after the Unification of the German Federal Republic with the German Democratic Republic in 1990 but the title still remains unchanged - Hans Jarass in Hans Jarass and Bodo Pieroth, *Grundgesetz* (13th edn, C.H. Beck Verlag 2014) Einleitung [1].

³⁰⁸ The Fundamental Rights within the German Basic Law are found within its first chapter under Articles 1-19.

³⁰⁹ Article 79 (3) Basic Law states: “Amendments to this Basic Law affecting the division of the Federation into Länder, their participation on principle in the legislative process, or the principles laid down in Articles 1 and 20 shall be inadmissible.” (Emphasis added). Any other amendment of the Basic Law requires a 2/3 majority in favour by the German Parliament, the Bundestag - Article 79 (1) and (2) of the Basic Law.

³¹⁰ Johann Braun, *Rechtsphilosophie des 20. Jahrhundert – Die Rückkehr der Gerechtigkeit* (C.H. Beck 2001) 9. Braun argues that fundamental rights are full of political and idealistic rationales which leads to a perceived that while some adheres a positivist perception of the law when one then recourse towards natural law principles as set out in fundamental rights - *ibid* page 9.

Similarly, the emphasis of guaranteeing human dignity within Article 1 I of the German Basic Law can for instance be regarded as pre-positivistic fundament, or “a kind of natural law anchor” - Martin Schulte, *Eine soziologische Theorie des Rechts* (Duncker & Humblot 2011) 36.

³¹¹ Frank Fechner, *Geistiges Eigentum und Verfassung* (Mohr Siebeck 1999) 188.

³¹² Article 1 (3) Basic Law.

³¹³ BVerfGE 7, 198 (204-205) – Lüth.

³¹⁴ This term links back to the work of Georg Jellinek - Georg Jellinek, *System der subjektiven öffentlichen Rechte* (Mohr & Siebeck 1892) pp. 89.

³¹⁵ Frank Fechner, *Geistiges Eigentum und Verfassung* (Mohr Siebeck 1999) 189.

³¹⁶ BVerfGE 7, 198 (205) - Lüth.

³¹⁷ This can be a natural person and where applicable to domestic legal persons “to the extent that the nature of such rights permits” - Article 19 (3) Basic Law.

been violated, he or she may seek relief by the Constitutional Court when other means of legal recourse have generally been exhausted.³¹⁸ The Court can then declare a piece of legislation void when it finds it to violate fundamental rights.³¹⁹ Therefore, fundamental rights do not just set the policy framework to provide guidance for the legislator, but can force him to take action to eliminate an unconstitutional condition.³²⁰

The combination of these additional functions with their superior position entails practical consequences for the three branches of the state (i.e. legislature, judiciary and administration/government): The legislator has to generally adhere to the constitutional order and to fundamental rights particularly when exercising its prerogative to legislate. Failure to provide for constitutional legislation can result in the Federal Constitutional Court finding this piece of legislation to be void and hence requiring amendment.³²¹ But not just the legislature, also the executive power is bound by these parameters. Additionally, the judiciary is mandated to constantly consider fundamental rights as well as the constitutional order in their judgements when interpreting the ordinary law.

Another important consequence of this evolution of fundamental rights is their horizontal effect: While they primarily bind and instruct state power, the German Constitutional Court has acknowledged that fundamental rights indirectly have an effect on third parties relationships within private law, i.e. they influence the relationship between private subjects.³²² Within a private dispute, the courts are bound to consider fundamental rights when assessing the interests of the parties.³²³ The Constitutional Court has held that this can be particularly achieved by applying fundamental rights considerations through the general

³¹⁸ § 90 (1)2 BVerfGG.

³¹⁹ § 90 (3) BVerfGG.

³²⁰ Frank Fechner, *Geistiges Eigentum und Verfassung* (Mohr Siebeck 1999) 190.

³²¹ This feature makes the German legal tradition stand in stark contrast to the United Kingdom where „acts of Parliament are not as such subject to control by the newly created UK Supreme Court.“ - Thomas Dreier and Marco Ganzhorn, ‘Intellectual property decisions of national Constitutional Courts in Europe’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 221-224.

³²² The horizontal effect of fundamental rights is referred to as „Drittwirkung“.

³²³ In the *Lüth* Decision the Constitutional Court held that newly as well as already enacted legislation would have to be in line with constitutional parameters. In relation to the already enacted law this is accomplished by interpreting it in light of the constitution. While a case between individuals remains to be a private law matter its interpretation is guided by the Constitution - BVerfGE 7, 198 (205-206) - Lüth.

clauses within the ordinary law.³²⁴ When interpreting the ordinary law courts are therefore bound to consider the constitutional values and therefore fundamental rights.³²⁵

As seen, fundamental rights informs and influences all ordinary law in Germany greatly. The legislator is directly bound to provide for law which is constitutional. This means that they need to consider the fundamental rights positions of the persons concerned. The courts are held to consider fundamental rights positions as well. This has important implications for patent rights and exceptions thereof which the courts have acknowledged. This is because the public interest surrounding an exception provision can be influenced on a fundamental right position informing its interpretation.

3.4.4.2. Article 14 – The Guarantee of property

Intellectual property is only specifically mentioned within Article 71 (1) Nr. 9 of the German Basic Law. The provision grants the Federal State the exclusive legislative power in relation to this subject matter. The German Basic Law provides for an array of fundamental rights that needs to be observed by all branches of the State relating to the subject matter of intellectual property. The constitutional guarantee of property (Article 14), the freedom of the arts and science (Article 5), occupational freedom (Article 12) as well as the general personal freedom with Article 2, influence and inform intellectual property rights, its legislation and adjudication in Germany.³²⁶ This means that the legislator, the courts and administration are bound to consider any fundamental right position of patent holders that may be affected in their actions.

The fundamental right that primarily applies in relation to the protection of intellectual property and is foremost applied by the German Constitutional Court³²⁷ is the guarantee of

³²⁴ Canaris states that this cannot just be limited to general clauses as even concrete provisions could serve to promote fundamental rights – Claus-Wilhelm Canaris, ‘Grundrechte und Privatrecht’ [1984] Archiv für civilistische Praxis 201, 223.

³²⁵ BVerfGE 18, 85 (92) - Spezifisches Verfassungsrecht.

³²⁶ Theodor Maunz, ‘Das geistige Eigentum in verfassungsrechtlicher Sicht’ [1973] GRUR 107, 107.

³²⁷ *ibid* 107.

Under the identical circumstances the right to property is *lex specialis* in relation to the fundamental right of occupational freedom as enacted in Article 12 of the German Basic Law - Theodor Maunz, ‘Das geistige Eigentum in verfassungsrechtlicher Sicht’ [1973] GRUR 107, 107. This is the case in particular where the economic aspects of the patent right are concerned - Frank Fechner, *Geistiges Eigentum und Verfassung* (Mohr Siebeck 1999) 192. The general fundamental right of personal freedoms as legislated within Article 2 is only applicable when the scopes of other, more specific fundamental rights do not apply anymore -Theodor Maunz, ‘Das geistige Eigentum in verfassungsrechtlicher Sicht’ [1973] GRUR 107, 107.

This focus on the property right in IP decisions appears to be prevalent in other constitutional courts in Europe - Thomas Dreier and Marco Ganzhorn, ‘Intellectual property decisions of national Constitutional Courts in

property in Article 14 of the German Basic Law:³²⁸ While other fundamental rights such as the general freedom as legislated within Article 2 (1) or the protection of human dignity as provided Article 1 (1) can be applicable in a fundamental rights discourse, especially when considering the personal interest of the inventors, the focus of this work will be on the economic interests surrounding the patent right.

The fundamental right to property is an economic right which protects against interferences by the state through legislative and executive measures as well as acts of the judiciary. The guarantee of personal property is considered to provide a conduit for personal freedom within the commercial sphere by providing for and protecting the material basis of personal self-determination.³²⁹ It allows the owner to decide upon production, circulation and use of the goods within a free market economy. This ultimately secures the distribution of failure or success of private initiative and achievements.³³⁰

Importantly, the fundamental right to property is a so-called normatively informed right.³³¹ This means that the right to property constitutes itself as a creation of the law. Conversely to other fundamental rights that can be derived from pre-legal, natural law, like for instance matrimony, personal freedom or freedom of expression, property allots goods normatively to persons by the behest of the legislator.³³² In other words, property is created by the law or rather it is the legislator who provides for its protection.³³³ “No property without the law”.³³⁴ The notion appears to provide the legislator with the means to alter the rules of property or

Europe’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 234.

³²⁸ The provision is based on historical preceding norms such as 164 of the Frankfurt Constitution of the German Empire of 1849 and Article 153 of the Weimar Constitution of 1919.

³²⁹ Hans Hofmann in Bruno Schmidt-Bleibtreu, Hans Hofmann and Axel Hopfauf (eds), *Grundgesetz* (12th edn, Carl Heymanns Verlag 2011) Art. 14 [1]; Peter Badura, ‘Zur Lehre von der verfassungsrechtlichen Institutsgarantie des Eigentums, betrachtet am Beispiel des “geistigem Eigentums”’ in Peter Lerche, Hans Zacher and Peter Badura (eds), *Festschrift für Theodor Maunz* (C.H. Beck 1981) 11.

³³⁰ Peter Badura, ‘Zur Lehre von der verfassungsrechtlichen Institutsgarantie des Eigentums, betrachtet am Beispiel des “geistigem Eigentums”’ in Peter Lerche, Hans Zacher and Peter Badura (eds), *Festschrift für Theodor Maunz* (C.H. Beck 1981) 11.

³³¹ “Normgeprägtes Grundrecht”.

³³² Bodo Pieroth, Bernhard Schlink, Thorsten Kingreen, Ralf Poscher, *Grundrechte Staatsrecht II* (29th edn, C.F. Müller 2013) [972]; Joachim Wieland in Horst Dreier (ed), *Grundgesetz Kommentar* (Bd I, 3rd edn, Mohr Siebeck, 2013) Art 14 [27]. Fechner states that the is a particularity of Article 14 (1) of the German Basic Law in relation to all other fundamental rights - Frank Fechner, *Geistiges Eigentum und Verfassung* (Mohr Siebeck 1999) 199.

³³³ Frank Fechner, *Geistiges Eigentum und Verfassung* (Mohr Siebeck 1999) 199.

³³⁴ Otto Depenheuer in Hermann von Mangoldt, Friedrich Klein and Christian Starck, *Kommentar zum Grundgesetz: GG* (6th edn, Vahlen 2010) Art. 14 [30].

even to abolish them. This however is not permissible as Art 14 (1) 1 of the Basic Law states that “[p]roperty and the right of inheritance shall be guaranteed.”³³⁵

This guarantee of property as a fundamental right has two functions: First, it protects the legal institution of property.³³⁶ This means that private property as a legal concept is constitutionally guaranteed.³³⁷ Such interpretation can be based on the systematic positioning of this notion in the first sentence of subsection 1 of Article 14. The legislator cannot arbitrarily delineate what constitutes property and what not as this would make the constitutional guarantee futile. Additionally, this mandates all state power to acknowledge the core of the property right which ought to remain unhampered.³³⁸ The core of the property right constitutes of the general allocation and private use of the object of the property right to its owner and also entails the general right to transfer the object of the property right.³³⁹

Secondly, the constitutional guarantee also protects and guarantees the individually held property right against any statutory act. This guarantee however, only provides constitutional protection for property in the scope that the legislator has initially legislated in general.³⁴⁰ The individual guarantee can only be invoked where property protection already exists. It does not serve to claim for the creation of new property rights. This also means that property rights have to be measured according to the institutional guarantee of property where the legislator has provided for their protection.³⁴¹

While the institutional guarantee provides that a meaningful property regime is provided and ensured, it means that the state is only required to maintain a basic set of norms for it to fulfil the prerequisites of Article 14. When this consideration is met, the legislator may regulate its content and limitations in accordance with Article 14 (1)2 of the German Basic Law.³⁴² Furthermore, the legislature is held to define its scope and limitation³⁴³ as a democratic

³³⁵ This creates a paradox according to Peukert since the state on the one side creates property protection but then is limited restricts interfering with it on the other - Alexander Peukert, ‘The fundamental right to (intellectual) property and the discretion of the legislature’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 139.

³³⁶ The so-called *Institutionsgarantie*.

³³⁷ Joachim Wieland in Horst Dreier (ed), *Grundgesetz Kommentar* (Bd I, 3rd edn, Mohr Siebeck, 2013) Art 14 [143].

³³⁸ Hans Hofmann in Bruno Schmidt-Bleibtreu, Hans Hofmann and Axel Hopfauf (eds), *Grundgesetz* (12th edn, Carl Heymanns Verlag 2011) Art. 14 [4].

³³⁹ BVerfGE 50, 290 (339) – Mitbestimmung.

³⁴⁰ Frank Fechner, *Geistiges Eigentum und Verfassung* (Mohr Siebeck 1999) 200.

³⁴¹ *ibid* 200.

³⁴² BVerfGE 24, 367 (389) - Hamburgisches Deichordnungsgesetz.

³⁴³ Bodo Pieroth, Bernhard Schlink, Thorsten Kingreen, Ralf Poscher, *Grundrechte Staatsrecht II* (29th edn, C.F. Müller 2013) [972].

duty.³⁴⁴ This leads to the difficulty of assessing what the right to property protects, and where its impenetrable core lies.

While the German Basic Law acknowledges and guarantees the existence and exercise of personal property, it also prescribes that property has a social function. This tension between liberal natural law approaches of personal property with its social function was already incorporated within the Weimar Constitution.³⁴⁵ The German Basic Law has maintained this tension in its Article 14:³⁴⁶ While it specifically acknowledges and guarantees property it allows to provide legislation regarding its content and limit in Article 14 (1) 2. Furthermore, it *expressis verbis* mandates that “[p]roperty entails obligations”³⁴⁷ and has to fulfil a social function.³⁴⁸ The legislator is mandated to provide for a socially acceptable use of the object of property.³⁴⁹ Ultimately, the constitutional guarantee of property provides the legislator with a wide scope to legislate IP rights as long as a minimum standard of protection is provided.

3.4.4.3. Patents and the fundamental right to property

The term property within the German Basic Law covers property in its private law diction but is not limited to it. The Constitutional Court has held that property has to be given an autonomous meaning.³⁵⁰ This has enabled it to encompass intellectual property rights within the constitutional guarantee.³⁵¹ The German Federal Constitutional Court for instance, held that the work created by an author would constitute property in the understanding of Article

³⁴⁴ Joachim Wieland in Horst Dreier (ed), *Grundgesetz Kommentar* (Bd I, 3rd edn, Mohr Siebeck, 2013) Art 14 [28].

³⁴⁵ Article 153 of the Weimar Constitution.

³⁴⁶ Hans Hofmann in Bruno Schmidt-Bleibtreu, Hans Hofmann and Axel Hopfauf (eds), *Grundgesetz* (12th edn, Carl Heymanns Verlag 2011) Art. 14 [2].

³⁴⁷ Article 14 (2) 1 Basic law.

³⁴⁸ Article 14 (2) 2 Basic Law. The provision can be regarded as an extension and elaboration of the principle of the social state that constitutes the Federal Republic of Germany according to Article 20 (1) of the German Basic Law (“The Federal Republic of Germany is a democratic and social federal state.”).

³⁴⁹ Joachim Wieland in Horst Dreier (ed), *Grundgesetz Kommentar* (Bd I, 3rd edn, Mohr Siebeck, 2013) Art 14 [31].

³⁵⁰ BVerfGE 58, 300 (335) - Naßauskiesung. Dreier states that this is based that property as a constitutional right has a different objective to the notion in statutory law: „In Civil Law countries, ..., the fundamental right as circumscribed in a constitutional charter guarantees ‚property‘ as an institution against its abolition, undue restriction or taking by the state. ‚Property‘ as defined by way of a simple legal norm serves the function both of granting the property right and of defining its limits vis- à-vis private parties.“ - Thomas Dreier, ‘How much ‘property‘ is there in IP?’ in Helena R. Howe and Jonathan Griffiths (eds), *Concepts of Property in Intellectual Property Law* (Cambridge University Press 2013) 123.

³⁵¹ This notion conflicts with Germany’s Roman law heritage that stipulates that property can only be held in tangible objects - Thomas Dreier, ‘How much ‘property‘ is there in IP?’ in Helena R. Howe and Jonathan Griffiths (eds), *Concepts of Property in Intellectual Property Law* (Cambridge University Press 2013) 116.

14 (1) of the Basic Law.³⁵² The Court mentioned that this principle would also apply in relation to technical author's right which has not yet manifested itself as a patent right.³⁵³ Finally, the Constitutional court has held in its *Clinical Trials* decision that the patent right constitutes property in accordance with the German Fundamental Law.³⁵⁴

Anyone can be the carrier of the fundamental right to property. It does not discriminate against foreign individuals as some other fundamental rights do. Importantly, it is a fundamental right that is also available to legal persons according to Art 19 (3) German Basic Law. The constitutional guarantee of patent rights safeguards the commercial aspects of the patent right. This entails its propriety aspects and the ability to commercialise the right as far as Art. 14 I GG guarantees private property as a legal institute. The right holder's ability is then largely defined through private use and the ability to do with it as one pleases as the Constitutional Court states.³⁵⁵ These abstract delineations have been transposed this into the patent scenario: The Constitutional Court regarded the constitutionally protected core of the patent right in being provided by the principle allocation of the commercial assets of the creative output to the patent holder through the mechanism of private law as well as the right holder's ability to freely dispose over them.³⁵⁶

The Constitutional Court held that the legislator has fulfilled the institutional guarantee for patent holders mandated by Article 14 of the Basic Law by providing for the provisions on direct and indirect patent infringement, §§ 9 and 10 PatG without elaborating more on this. It followed the German Federal High Court in its finding that the inventor deserves a reward for providing the public with a useful invention.³⁵⁷ The German Federal High Court however, does not verbatim state that patent rights would fall under the protection of Article 14 of the German Basic Law; a notion the Constitutional Court also observes.³⁵⁸

The High Court subtly refers to the constitutional considerations³⁵⁹ within its teleological interpretation of the provisions of §§ 9 and 11 of the German Patent Act. It argues that both

³⁵² BVerfGE 31, 229 (239-240) - Schulbuchprivileg; BVerfGE 31, 275 (283) - Bearbeiter-Urheberrechte; 49, 382.

³⁵³ BVerfG GRUR, 2001, 43- Klinische Versuche.

³⁵⁴ *ibid* 44.

³⁵⁵ BVerfGE 24, 367 (389) - Hamburgisches Deichordnungsgesetz; BVerfGE 31, 229 (240-241) – Schulbuchprivileg.

³⁵⁶ BVerfG GRUR, 2001, 43 (44) - Klinische Versuche.

³⁵⁷ *ibid* 44 referring to BGH GRUR 1996, 109 (114) - Klinische Versuche.

³⁵⁸ *ibid* 44

³⁵⁹ It does so by mentioning that the principles of the freedom of research and the social obligation of property would mandate that “unlimited protection by the patent is unjustified where further technological development

provisions would simultaneously serve the incentive function and the reward function of patent rights.³⁶⁰ It adds that both functions are the *raison d' être* of granting patent rights.³⁶¹

3.4.4.4. Limitation of the fundamental right to property

The right to property as set out in the German Constitution is not an absolute right. This means that the legislator can place property under conditions or limit its contents. Similarly to the situation within Article 1 of the Protocol on the ECHR³⁶², the German Basic Law provides that the right to property can be interfered with through deprivation; Article 14 (3). Article 14(1) 2 of the German Law³⁶³ prescribes additionally that its “content and limits shall be defined by the laws”.³⁶⁴ By this, the legislator can regulate the rights and obligations of property owners.³⁶⁵ This can be done through any legal norm.³⁶⁶

The Constitutional Court has delineated to what extent the legislator can limit the exercise of the patent right in its *Clinical Trials* decision.³⁶⁷ Following its jurisprudence in relation to other forms of “property”, it held that the legislator must leave the core of the property right untouched in order to meet the institutional guarantee of property.³⁶⁸ This does not leave all

is impeded”. While not expressly referring to the respective articles within the Basic Law the express use of these terms demonstrates that the courts applied fundamental rights notions in its findings - BGH, GRUR 1996, 109 (114) - Klinische Versuche I = BGH RPC 1997, 623 (642) [Clinical Trials].

³⁶⁰ “The reason for conferring the exclusive right of a “patent” is regarded essentially as being, on the one hand, recognition for a particular contribution in the industrial sector and, on the other hand, providing remuneration - which is also to be understood as encouragement of further contributions - for the inventor having enriched industrial progress and general technical knowledge” – BGH, GRUR 1996, 109 (114) - Klinische Versuche I = BGH, RPC 1997, 623 (642) - Clinical Trials I.

³⁶¹ BGH GRUR 1996, 109 (114) - Klinische Versuche I = BGH, RPC 1997, 623 (642) - Clinical Trials.

³⁶² Infra 4.4.1.

³⁶³ The provision is comparable to Article 1 (2) of the Protocol to the ECHR - Doris König, ‘Der Schutz des Eigentums im europäischen Recht‘ in Otto Depenheuer (ed), *Eigentum – Ordnungsidee, Zustand, Entwicklungen* (Springer 2005) 114.

³⁶⁴ The German Federal Constitutional Court does not differentiate between the two terms of regulating content and limits of property in its case law. It generally refers to ‘regulations regarding content and limits’ (German: “Inhalts- und Schrankenbestimmungen”) when referring to the provision of Article 14 (1) 1 of the Basic Law. Thormann differentiates the two terms as regulations regarding the content and that of limit. The former being an abstract-general that effects the future while the latter term then refers to a concrete-individual regulation of existing property - Martin Thormann, *Abstufungen in der Sozialbindung des Eigentums* (Boorberg 1996) 155. A translation of these two terms into exclusions and exceptions can therefore not seamlessly apply. Since the German Federal Constitutional Court applies both terms conjunctively with regards to the experimental use exception of § 11 Nr. 2 PatG - BVerfG GRUR, 2001, 43- Klinische Versuche. The question what term would apply for exceptions to patentee’s right appears to be academic.

³⁶⁵ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchs- und Forschungszwecken* (Carl Heymanns 1986) 208.

³⁶⁶ This can also be done by secondary law based on a primary law - Joachim Wieland in Horst Dreier (ed), *Grundgesetz Kommentar* (Bd I, 3rd edn, Mohr Siebeck, 2013) Art 14 [103]; Hans D. Jarass in Hans Jarass and Bodo Pieroth, *Grundgesetz* (13th edn, C.H. Beck Verlag 2014) § 14 [35].

³⁶⁷ BVerfG GRUR 2001, 43 - Klinische Versuche.

³⁶⁸ supra 3.4.4.2.

possible ways of exploitation exclusive for the patent holder. The constitutional standards only require “a very basic minimum of IP protection.”³⁶⁹ The institutional guarantee only sets a foundation of norms that have to be present so that the right can be labelled as property as acknowledged by §§ 9 and 10 PatG.³⁷⁰

Importantly, the legislator is also held to provide for an appropriate framework within the structure of patent law ensuring appropriate use³⁷¹ and adequate remuneration in accordance with the nature and social function of the right by Article 14 I (2) of the German Basic Law. Thus, the Court mandates the legislator to provide for a just balance between the sphere of the individual and the public interest. This is directly linked to the social function of property: Article 14 (2) of the German Basic Law demands that the legislator takes the social dimension of the existence and use of property into equation when fulfilling its constitutional duty to provide for the content and scope of property.³⁷² Hence, property simultaneously has to serve the public good.³⁷³

The social function of property is being informed by the constitutional order that the Basic Law provides according to the German Federal Constitutional Court. It held that the legislator “has to take public welfare into consideration when regulating property and the rights and obligations of the proprietor.”³⁷⁴ In relation to providing for interferences with the fundamental right of property the programmatic rule of the social state within Article 20 (1) German Basic Law (and its extension within Article 14 (2)) allows the legislator to enforce aspects of the common social welfare. Here, Article 14 (2) is perceived as a concretisation of the principle of the welfare state principle, one of the fundamental principles constituting the Federal Republic of Germany that Article 20 (1) stipulates. And the legislator has to apply this principle as a directly applicable rule as Article 1 (3) German Basic Law states.

Of importance is the fact that the boundaries for regulating property differ depending on the subject matter of property. Additionally, these boundaries are not perpetually fixed but

³⁶⁹ Alexander Peukert, ‘The fundamental right to (intellectual) property and the discretion of the legislature’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 144.

³⁷⁰ BVerfG, GRUR 2001, 43 (44) - Klinische Versuche.

³⁷¹ *ibid* 44.

³⁷² Hans Hofmann in Bruno Schmidt-Bleibtreu, Hans Hofmann and Axel Hopfauf (eds), *Grundgesetz* (12th edn, Carl Heymanns Verlag 2011) Art. 14 [36].

³⁷³ This mandate for the legislator is referred to as “Sozialbindung des Eigentums” and would translate to the social function or obligation of property.

³⁷⁴ BVerfGE 25, 112 (117) - Niedersächsisches Deichgesetz; BVerfGE 37, 132 (140 – 141) - Vergleichsmiete I; BVerfGE 68, 361 (367) - Eigenbedarf I.

provide flexibility.³⁷⁵ The legislator can therefore have a widened scope for regulation in order to adopt changes in the economy or society.³⁷⁶ In relation to intellectual property, the constitutional framework leaves substantial scope for legislators to “manoeuvre”. Fechner states with this regard that “[t]he constitutional considerations can only display the boundaries of legislative activity. The details cannot be derived from constitutional considerations. Therefore, the limitations to copyright represent a rule for accommodating the interests of the public with those of the creator, without being the only constitutionally possible decision of the legislator.”³⁷⁷

Additionally, the legislator has a wider ambit to legislate for the scope and limitations of property where the object of property stands within a social context and fulfils a social function according to the German Constitutional court.³⁷⁸ The more the protected object of property has social relevance, the more this allows the legislator to define its exact scope and provide for limitations in order to emphasise its social function.³⁷⁹ The court has also elaborated when such a heightened social relevance of property is given. It held that this is provided when the object of the property right does not just fall within the interest sphere of the right holder, but also touches upon the interests of others that are dependent of its use.³⁸⁰

As such, the German Basic law obliges the legislator in Art 14 II GG to provide for an appropriate framework to guarantee the use of the right deriving from the nature and social importance and the appropriate exploitation. Personal property right can subdue more

³⁷⁵ Hans Hofmann in Bruno Schmidt-Bleibtreu, Hans Hofmann and Axel Hopfauf (eds), *Grundgesetz* (12th edn, Carl Heymanns Verlag 2011) Art. 14 [38].

³⁷⁶ *ibid* [38]; Hans Jarass in Hans Jarass and Bodo Pieroth, *Grundgesetz* (13th edn, C.H. Beck Verlag 2014) [45].

³⁷⁷ Frank Fechner, *Geistiges Eigentum und Verfassung* (Mohr Siebeck 1999) 241. Similarly - Alexander Peukert, ‘The fundamental right to (intellectual) property and the discretion of the legislature’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 144.

³⁷⁸ Martin Thormann, *Abstufungen in der Sozialbindung des Eigentums* (Boorberg 1996) 155 referring to BVerfGE 42, 263 (294) - Contergan; BVerfGE 50, 290 (340) - Mitbestimmung; BVerfGE 53, 257 (292) - Versorgungsausgleich I; BVerfGE 70, 191 (201) - Fischereibezirke; BVerfGE 84, 382 (38).

Hans Hofmann in Bruno Schmidt-Bleibtreu, Hans Hofmann and Axel Hopfauf (eds), *Grundgesetz* (12th edn, Carl Heymanns Verlag 2011) Art. 14 [38]; Joachim Wieland in Horst Dreier (ed), *Grundgesetz Kommentar* (Bd I, 3rd edn, Mohr Siebeck, 2013) Art 14 [106]; Hans D. Jarass in Hans Jarass and Bodo Pieroth, *Grundgesetz* (13th edn, C.H. Beck Verlag 2014) Art. 14 [42].

³⁷⁹ Peter Badura, ‘Zur Lehre von der verfassungsrechtlichen Institutsgarantie des Eigentums, betrachtet am Beispiel des “geistigem Eigentums”’ in Peter Lerche, Hans Zacher and Peter Badura (eds), *Festschrift für Theodor Maunz* (C.H. Beck 1981) 12.

³⁸⁰ Martin Thormann, *Abstufungen in der Sozialbindung des Eigentums* (Boorberg 1996) 155 referring to BVerfGE 50, 290 (pp 340) - Mitbestimmung. Thormann acknowledges that this test remains blurry. The question on whether the use of the property right by its owner would have any effect outside his sphere or whether the property right is indispensable for third parties should apply should be answered in favour of the wider, former approach according to Thormann - *ibid* 156. Limitations of the property right can become necessary for all sorts of reasons and are not restricted to situations where third parties are granted use of the object of property - *ibid* 156.

restrictions the more the object of the property rights is embedded “within a social context and a social function.”³⁸¹ The German Federal Constitutional Court for instance has held that copyright, which also falls within the definition of property of Article 14 has a heightened social relevance.³⁸² This is because once it is published it does not remain restricted to its owner.³⁸³ Based on an analogy from the field of copyright law, this social function of the patented invention becomes clear when the disclosure of the invention during the registration process can be regarded as “a step into the public.”³⁸⁴ Thormann generally holds that this understanding would apply to all types of IP.³⁸⁵

The accommodation of public interest which the legislator is constitutionally mandated to adhere to also stipulates that the interests of third parties requiring the use of the property for their livelihood and to secure their liberties are considered.³⁸⁶ This statement is particularly important for limitations and exceptions of intellectual property, which are often based on the need of third parties to have access to the protected item. Such third party interests can derive from the freedom of expression, the freedom of information or the freedom of arts and sciences according to Geiger.³⁸⁷ The interests of the user relying on the experimental use exception are to freely use the patented invention to the extent necessary for conducting the research without any restrictions as hinted in *Clinical Trials I*.³⁸⁸ Additionally, the Constitutional court has similarly held that research and technological advance are only possible through experiments that build upon the latest research findings assuring that these interests would prevail over the interest of the patent holder.³⁸⁹

³⁸¹ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 219; Peter Badura, ‘Zur Lehre von der verfassungsrechtlichen Institutsgarantie des Eigentums, betrachtet am Beispiel des “geistigem Eigentums”’ in Peter Lerche, Hans Zacher and Peter Badura (eds), *Festschrift für Theodor Maunz* (C.H. Beck 1981)1, 12.

³⁸² BVerfG 31, 229 - Schulbuchprivileg = "School Book" [1972] IIC 394

³⁸³ BVerfG GRUR 2001, 151 – Germania 3.

³⁸⁴ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 220.

³⁸⁵ Martin Thormann, *Abstufungen in der Sozialbindung des Eigentums* (Boorberg 1996) 162.

³⁸⁶ BVerfGE 68, 361 (368) - Eigenbedarf I; Joachim Wieland in Horst Dreier (ed), *Grundgesetz Kommentar* (Bd I, 3rd edn, Mohr Siebeck, 2013) Art. 14 [106].

³⁸⁷ Christophe Geiger, ‘Fundamental Rights as Common Principles of European (and International) Intellectual Property Law’ in Ansgar Ohly (ed), *Common Principles of European Intellectual Property Law* (Mohr Siebeck 2012) 230.

³⁸⁸ Chrocziel relies on a survey conducted whereby 60, 9% of respondents have said that research should be able on patented inventions without restrictions. It was also said that there respondents find that it would be unacceptable to intellectual property rights. 32% of respondents however stated that these findings are wrong - Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 213 referring to the findings of a survey he conducted (at page 94).

³⁸⁹ BVerfG GRUR 2001, 43 (44) - Klinische Versuche.

The legislator must follow the principles of necessity of the regulation and is bound to take the constitutional order into consideration when regulating property,³⁹⁰ especially the principle of proportionality.³⁹¹ This means that the German legislator has to undertake a balancing exercise between the different interests. On the one hand, he has to maintain the guarantee of property while on the other hand acknowledge the social function of property that Article 14 (2) 2 mandates. Importantly, the German Constitutional Court has held that these differing interests need to be taken into account and given weight equally and that the legislator must bring the protectable interests of all concerned parties into a fair balance and to a proportionate relation to one another.³⁹² Finally, public interest needs to be taken into account at the balancing exercise. The public interests lie in a functioning patent system while also in the advance of technology and science which impacts on the economic development.³⁹³

Translated into the scenario within patent law, the German Federal Constitutional Court has held that the legislator is obliged to bring the interests of the patent holder with that of public interest to a fair balance.³⁹⁴ Article 14 of the German Basic Law specifically provides for two ways of how the legislator can interfere with property. He can provide for a limitation of the protected use or exploitation (*Schrankenbestimmung*) to the withdrawal of the protected position (*Entzug*). The differentiation is important as a regulation of limitations could be achieved without providing remuneration this would need to be done in relation to a withdrawal of the right as Article 14 (3) states. Intellectual property law is familiar with such a system of remunerated and unremunerated uses without the right holders consent. The uses allowed within § 11 PatG do all not require remuneration of the patent holder. § 24 PatG, which regulates the grant of a compulsory licence where this would be in the ‘public interest’ or where the licensee would want to work a dependent invention, provides that the patent holder may be remunerated.

In order for the use to be unremunerated, it would need to be based on a heightened public interest. Only “such considerations of public interest would legitimise the extensive excision of the right of exploitation which, while considering the principle of proportionality, prevail

³⁹⁰ BVerfGE 34, 139 (146) – *Fahrbahndecke*.

³⁹¹ BVerfGE 52, 1 (29-30) – *Kleingarten*; BVerfGE 70, 191 (200) – *Fischereibezirke*.

³⁹² BVerfGE 68, 361 (368) – *Eigenbedarf I*

³⁹³ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 214.

³⁹⁴ BVerfG GRUR 2001, 43 (44) – *Klinische Versuche*.

against the constitutionally protected right”³⁹⁵ of the inventor.³⁹⁶ Badura consequently requires an “especially essential and paramount reasons for the public good”³⁹⁷ for a regulation that provides for an unremunerated use of a copyright protected work .

The research exception can therefore be regarded as such a proportionate matter. First, because of the purpose it aims to achieve, i.e. technological advance. The Constitutional Court held that research and development within the sciences is only possible through experiments, these would prevail over the patent holder’s interest of exclusivity.³⁹⁸ This means that experimenting is necessary to achieve this purpose. Second, the exception is also proportionate because it only allows experiments on the patented invention, not with it.³⁹⁹

Other exceptions, such as those exempting certain uses on vessels, aircraft and land vehicles⁴⁰⁰ or the exception based on the Chicago Convention⁴⁰¹ can also be considered to be proportionate in the fundamental rights context. The exceptions provide for legal clarity for third parties. Conversely, the uses that these exceptions cover are likely to have minimal effect on the patent holder’s interest. On the other hand, the transaction costs for enforce the patent rights would be disproportionately high.

Where the exception provision would then disproportionately impair the patent holder’s position, legislators can provide for remunerated exceptions. This is for instance the case where the third party use would directly affect the primary commercialisation of the patented invention by using it in its intended way. The cases where compulsory licensing within § 24 PatG is available are such cases where remuneration is required aside from being within the public interest.⁴⁰²

³⁹⁵ BVerfGE 49, 382 [62] - Kirchenmusik.

³⁹⁶ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 221.

³⁹⁷ Peter Badura, ‘Zur Lehre von der verfassungsrechtlichen Institutsgarantie des Eigentums, betrachtet am Beispiel des “geistigem Eigentums”’ in Peter Lerche, Hans Zacher and Peter Badura (eds), *Festschrift für Theodor Maunz* (C.H. Beck 1981)12.

³⁹⁸ BVerfG GRUR 2001, 43 (44) - Klinische Versuche.

³⁹⁹ Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) 222.

⁴⁰⁰ The Hague revision of the Paris Convention in 1925 introduced Article 5ter Convention. The United Kingdom and Germany already had such provisions in their law before they were prescribed by the Convention -Dieter Stauder, ‘Die Freiheit des internationalen Verkehrs im Patentrecht - - Schiffsschraube, Gaffelklaue und Sonnenpaddel’ [1993] GRUR 306.

⁴⁰¹ Convention on International Civil Aviation (also known as Chicago Convention).

⁴⁰² § 24 PatG for instance allows the grant of a compulsory license where a third party attempts using its invention but this use would infringe a previous patented invention.

3.4.4.5. Collision of fundamental rights and the public interest

The German Federal High Court has held in its *Clinical Trials I* decision that the provision of § 11 Nr.2 PatG serves at providing a balance between the interest of the patent holder and that of the public.⁴⁰³ The interest of patent holders is codified within the provisions of §§ 9 and 10 PatG that regulate the exclusive rights. Through these exclusive rights it should be ensured that patent holders maintain the right to determine when and how the protected substance is being used.⁴⁰⁴ The patent holder receives remuneration when someone wishes to utilise the invention.

The Court however, has held that patent rights are not unlimited. The public interest in technological advance warrants a limitation of the “extensive protection by the patent”.⁴⁰⁵ Importantly, the court referred to the principle of freedom of research – a fundamental right according to Article 5 (3) of the Basic Law in its judgement. It held that freedom of research was *inter alia* influencing the balance between the interests of the patent holder with those of the public achieved by the research exception.⁴⁰⁶

This is an important notion as it abstractly links the public interest of limiting the right for technological advance with the constitutionally guaranteed freedom of third parties wishing to use the invention for research purposes. This third party interest is encapsulated within the freedom of research and wishes to establish that scientific research is not unduly hampered by any state act. This ultimately links back to the finding that public interest considerations in relation to exceptions are generally based on some form of third party interest.⁴⁰⁷

The public interest in technological advance was being served by experimenting as the court held. However there must be someone conducting these experiments. What this ultimately means is that the interests of the public in technological advance and of those experimenting overlap when experiments serve technological advance. In this scenario, the public interest in limiting the patent right can be based on the freedom of research. This means that the property right of the patent holder is limited by the freedom of research in the public interest.

⁴⁰³ BGH,GRUR 1996, 109 (114-115) - Klinische Versuche I = BGH, RPC 1997, 623 (643) - Clinical Trials I.

⁴⁰⁴ BGH,GRUR 1996, 109 (114) - Klinische Versuche I = BGH, RPC 1997, 638 (643) - Clinical Trials I].

⁴⁰⁵ BGH, GRUR 1996, 109 (115) - Klinische Versuche I = BGH, RPC 1997, 623 (643) Clinical Trials I.

⁴⁰⁶ BGH, GRUR 1996, 109 (115) - Klinische Versuche I = BGH, RPC 1997, 623 (643) Clinical Trials I.

⁴⁰⁷ supra 2.4.

The subsumption of an exception provision under a fundamental right has considerable effect on its interpretation: First, the *singularia* rule whereby exceptions ought to be interpreted narrowly⁴⁰⁸ would not apply where the exception provision is based on a constitutionally protected position.⁴⁰⁹ Secondly, and importantly, is that the conflict of between two colliding fundamental rights needs to be accommodated in a proportionate way. The fact that the third party use is covered by a fundamental right mandates the legislator to acknowledge this constitutionally protected position. This then means that the legislator has more “wiggle room” to provide for exceptions within the public interest when such interest can be transposed to be covered by a fundamental right.

3.4.4.6. Conclusion

The fundamental rights discourse has significant effect on the interpretation of an exception provision.⁴¹⁰ First, this is because legislators can provide for such exceptions where they are in the public interest. The deference from the property right cannot be conducted arbitrarily and cannot be disproportionate. But it is important to summarise here that the constitutional parameters provide the German legislator with a considerably wide scope when legislating intellectual property laws.⁴¹¹ Additionally, the legislator has a wide margin of appreciation

⁴⁰⁸ It has been held with regards to copyright law that exceptions based on the social function of the constitutionally guaranteed property right must generally be interpreted narrowly as it would otherwise limit the exclusive right attributed to the author – BGH, GRUR 2001, 52 - Reichweite der Erschöpfung ; BGH, GRUR 2002, 606 - Unzulässige Herstellung von Postkarten einer zeitlich befristeten Ausstellung .Keukenschrijver applies this reasoning to the situation in patent law - Alfred Keukenschrijver (ed), *Busse Patentgesetz* (7th edn, De Gruyter 2013) § 11[5].

⁴⁰⁹ With reference to the decision of the German Federal High Court - Alfred Keukenschrijver (ed), *Busse Patentgesetz* (7th edn, De Gruyter 2013) § 11[5]. Hoeren states that “[e]xemptions in the public interest are not “exceptions” to the general rule that works are copyrighted. They are limitations in favor of fundamental rights such as freedom of the press, public access or the necessities of research. “ - Thomas Hoeren, ‘Access Right as a postmodern symbol of Copyright Deconstruction?’ in APDI - Associação Portuguesa de Direito Intelectual, *Direito da Sociedade da Informação - Volume VI* (2006) 489.

⁴¹⁰ The German fundamental rights discourse may play a significant role in relation to the patent with unitary effect. Chapter III of the Regulation of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection provides for how European Patents with unitary effect should be treated as objects of property. The provision regulates a legal fiction whereby the European patent with unitary effect shall be treated as a national patent of a contracting state. Under which national patent regime the unitary patent falls under is depends on the “residence or principal place of business on the date of filing of the application for the patent” of the proprietor (Art. 10 I (a)). If this does not apply then the place of business at the filing date is relevant (Art. 10 I (b)). Article 10 II regulates which national patent regime is applicable in the case where the patent register names joint proprietors. Lastly, where none of the above is applicable then the national patent regime of the seat of the European Patent Organisation shall apply. Therefore German law would constitute the property regime in this case as the seat of the European Patent Organisation is in Munich (Art. 6 I EPC).

⁴¹¹ This is what Dreier and Ganzhorn posit in relation to copyright protection - Thomas Dreier and Marco Ganzhorn, ‘Intellectual property decisions of national Constitutional Courts in Europe’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 230. This situation however is applicable in patent law.

identifying what the particular public interest is when interfering with the right of property through exceptions to patent rights.

Secondly, the assessment changes where the purpose of the exception can be based on a fundamental right and overlaps with the public interest in limiting the patent right. Then legislators and courts are obliged to take this position into consideration and aim to bring the conflicting interest into a proportionate balance. Importantly, where courts base an exception provision on a fundamental right then this would underline the provision's additional legislative purpose: Exceptions basically serve to "realise certain fundamental freedoms."⁴¹² Such fundamental rights based interpretation could provide a clearer guideline for courts to interpret the exception provision. This is because the acknowledgement and application of the third party's fundamental right position encapsulates the third party interest. It therefore may serve as a concretisation of what constitutes of public interest.

Eventually, the elevation of the "conflict" of patent owners and users wishing to use the invention onto a fundamental rights discourse additionally serves the public interest. Since both fundamental rights need to be protected by legislators and courts the conflict between these two fundamental rights positions needs to be accommodated. This is done in a way to provide both fundamental rights position as much scope as possible, i.e. to bring them into a proportionate balance. Such a constitutionally mandated proportionate balance between fundamental rights positions between right holders and users is then in the public interest.

3.5 Comparison of both approaches and limits of the research exception

3.5.1 Scope

The soft harmonisation achieved by Article 27 b CPC 1975 provided the UK and Germany with a common statutory basis towards the research exception. Additionally, the interpretation of the provisions in both jurisdictions shows a similar approach towards

⁴¹² Alexander Peukert, 'The fundamental right to (intellectual) property and the discretion of the legislature' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 145.

allowing experimental uses.⁴¹³ Importantly, researching on the patented invention is not discarded by an underlying commercial interest on behalf of the experimenter. Both approaches allow such uses now but the German approach appears to be more lenient.⁴¹⁴ According to von Maibom and Pitz the restrictive approach in Germany changed in the 1990ies and may be based on the German particularity of bifurcation.⁴¹⁵ The alleged infringer can normally not rely on attacking the patent of the claimant on the grounds of patentability in an infringement proceeding.⁴¹⁶ This was particularly the case in relation to biotechnological inventions which contained wide claims.⁴¹⁷ Together with the narrow scope of privileged experiments under the old law research and development was almost impossible which lead the courts to liberalise the approach through compulsory licensing or a widening of the research exception.⁴¹⁸

Generally, the approaches in Germany and the UK have widened the scope of application for exempting experiments from patent infringement since the adoption of statutory exception provisions.⁴¹⁹ It can even be said that, in comparison to the situation in Germany before the inception of § 11 Nr. 2 PatG, the interpretation provided by the German Federal High Court in the Clinical Trials cases provides for a significant limitation of the patent right, in particular in relation to product patents while widening the scope for experimental uses.⁴²⁰ This can be based on the fact that commercial orientated research is now generally permitted though the reach of this differs between both jurisdictions. German courts do not seem to differentiate on what the dominant objectives of the experiments are. Their UK counterparts however hold that where the “preponderant purpose” of the use in question by the alleged “experimenter” was not to gain information as to possible future applications it would not fall within the scope of the exception. In other words, while the German approach does not differentiate on whether the experiments are conducted with a commercial orientation and

⁴¹³ Henrik Holzapfel and Joshua Sarnoff, ‘A Cross-Atlantic Dialog on Experimental Use and Research Tools’ (2008) IDEA 122, 154.

⁴¹⁴ Supra.

⁴¹⁵ Wolfgang von Meibom and Johann Pitz, ‘Klinische Versuche – eine transatlantische Betrachtung vor dem Hintergrund der Entscheidung des BGH “Klinische Versuche II”’ [1998] Mitteilungen der deutschen Patentanwälte 244, 246.

⁴¹⁶ *ibid* 246.

⁴¹⁷ *ibid* 246.

⁴¹⁸ *ibid* 246.

⁴¹⁹ This is notable for the situation in Germany. William Cornish has argued that the widening of the scope of the experimental use exception may have been the result for the broadening the scope of patentable subject-matter, for instance to cover “claims to pharmaceutical substances as such, and claims to compositions for second and subsequent medical uses.” - William Cornish, ‘Experimental use of patented inventions in European Community states’ [1998] IIC 735, 737.

⁴²⁰ Susanne Scheil, ‘Klinische Versuche’ [1996] Mitteilungen der deutschen Patentanwälte 345, 346-347.

would allow such experiments as long as they can still be regarded as experiments⁴²¹, UK courts would disallow such experiments which are predominantly commercially orientated.⁴²²

3.5.2 Limitation

Since both jurisdictions provide for a differing scope of the exception, the way the exception is limited in scope differs as well. As seen, English courts applied a narrower interpretation of what would be use for experimental purposes.⁴²³ In Germany, such purposes were defined broadly and the scope is limited through the use of the second limb of § 11 Nr. 2 PatG where it was assessed whether the use was in relation to the subject matter of the invention.

The leading cases both in Germany (*Clinical Trials I and II*) and the United Kingdom (*Monsanto v Stauffer*) on the research exception involved notably such experiments that were conducted to receive regulatory approval. This led to the difficulty in finding whether such trials can be regarded as being conducted for “experimental purposes”. Experiments can be interpreted as the discovery of something unknown or the testing of a hypothesis while trials relate to assessing the qualities or performance of something.⁴²⁴ Hence, it appears that trials cannot *ex ante* be discarded from falling under experimental purpose.

In the United Kingdom the Court of Appeal in *Monsanto v Stauffer*, has held that trials that are conducted in order to receive regulatory approval do not fall within the scope of Section 60(5)(b) UK Patents Act 1977.⁴²⁵ The finding of the court can be based on a quite literal interpretation of the term “experimental”. The court has specifically stated that experiments in the meaning of Sec. 60(5)(b) UK Patents Act 1977 must relate to such retrieving new

⁴²¹ The German Federal High Court in *Clinical Trials II* discarded the decision of the Higher Regional court of Düsseldorf that did not allow the experiments under § 11 Nr. 2 PatG as they “served commercial interests rather than scientific purposes; the defendants only carried them out in order to obtain data” - Trevor Cook, ‘The Significance of the “Clinical Trials II” Decision for the Development of the Experimental Use Defence in Europe and Elsewhere’ in Christian Harmsen, Oliver Jan Jüngst and Felix Rödiger (eds), *Festschrift für Wolfgang von Meibom* (Carl Heymanns Verlag 2010) 24. The Düsseldorf court hence provided a similar reasoning as the courts in the UK with their focus on the preponderant purpose of the experiments - supra 6.2.2.

⁴²² With this regard - Ashley Roughton, Phillip Johnson and Trevor Cook, *The Modern Law of Patents* (3rd edn, Lexis Nexis 2014) [7.119].

⁴²³ This has also been said within the to the Explanatory Notes to the Legislative Reform (Patents) Order 2014 – ‘The Legislative Reform (Patents) Order 2014 - Explanatory document by the Intellectual Property Office, an Executive Agency of the Department for Business, Innovation and Skills’ (UK Intellectual Property Office 2014) 2 < www.legislation.gov.uk/ukxi/2014/1997/pdfs/ukxi0d_20141997_en.pdf> accessed 23 May 2015.

⁴²⁴ Andries van der Merwe, ‘Experimental use and submission of data for regulatory approval’ [2000] IIC 380, 384.

⁴²⁵ *Monsanto v. Stauffer Chemical* [1985] RPC 515, 542.

information although a further commercialisation would not discard the use from falling under the research exception.⁴²⁶

In comparison, the German approach stipulates that such use would not constitute an experiment that seeks out new findings but merely reproduce previous research.⁴²⁷ It is however now permissible in Germany to conduct such clinical trials for regulatory approval and even to assess further medical uses of the patented invention and for them to be exempted from patent infringement according to the research exception within § 11 Nr. 2 PatG.⁴²⁸ The experiments to receive regulatory approval generally are undertaken to confirm the properties which the patent holder originally has provided for.⁴²⁹

These different approaches are remarkable with the German law providing a particularly wide scope. Notable is that with regards to trials, the public interest in technological advance could not rightly serve as an interpretive guideline as could be seen in the UKs approach. These do not contribute “to innovation and progress in technology”.⁴³⁰ The German approach however has a more permissive approach. In *Clinical Trials II* the court emphasised that the trials could not be discarded because the indication or consistency of the agent was already known. What made the trials permissible was the fact that they related to exploring uncertainties and dosages which the court held to be unknown properties. This conversely raises the question whether the court would have allowed the trials where none of these uncertainties existed. Importantly, the court held that to overcome the uncertainties to overcome would serve “to alleviate and cure human diseases.”⁴³¹ The court therefore, however very much influenced by the facts of the case, appears to have taken additional public interest considerations within its assessment of the scope of the research exception. It could be argued that the court considered public health considerations in that decision.⁴³²

⁴²⁶ The IPO Report outlined that the research “exception only extends to experiments which generate genuinely new information; it does not extend to experiments which are designed to verify existing knowledge. As a result, trials to obtain regulatory approval are not acts done for experimental purposes and so are not within the exception.” - UK Intellectual Property Office, ‘The Patent Research Exception: A Consultation’ (UK Intellectual Property Office 2008) 3.

⁴²⁷ supra 3.4.2.

⁴²⁸ Alfred Keukenschrijver (ed), *Busse Patentgesetz* (7th edn, De Gruyter 2013) § 11 [12].

⁴²⁹ Ingve Björn Stjerna, ‘Die Voraussetzungen des patentrechtlichen Versuchsprivileg’ [2004] *Mitteilungen der deutschen Patentanwälte* 343, 347.

⁴³⁰ Andries van der Merwe, ‘Experimental use and submission of data for regulatory approval’ [2000] *IIC* 380, 385; BGH, NJW 1997, 3092 (3095) - *Klinische Versuche II* = BGH, RPC 1998, 423 (436) - *Clinical Trials II*.

⁴³¹ BGH, NJW 1997, 3092 (3095) - *Klinische Versuche II* = BGH, RPC 1998, 423 (436) - *Clinical Trials II*.

⁴³² The German Federal High Court has held in *Clinical Trials II* that “in clinical experiments conducted on humans, the curing and alleviation of diseases stands in the forefront, even if these experiments are introduced and carried out with the commercial goal of obtaining the necessary legal pharmaceutical permission with the

To overcome this interpretative dilemma of subsuming clinical trials for regulatory approval under the research exceptions and hence providing more legal certainty, the European legislator provided for a regulatory approval exception.⁴³³ Recital 3 of the Directive clearly stipulates that its *ratio legis* was to harmonise national laws with respect to regulatory approval in order to realise “a high level of human health protection”.⁴³⁴ This clearly demonstrates that the heightened public interest in public health urged the legislator to adopt such a measure which would be outside the ambit of the wording of the research exception.

Both jurisdictions clearly see a limitation of the exception provision due to the fact that the experiments must relate to the subject matter of the invention. This leads to the question as to what extent the use of so-called research tools may be exempted from patent infringement. Research tools are products or processes that are being used to gather information about other objects.⁴³⁵ The patented invention is not being used as the object of the experiments but is rather used as means to conduct research on another object.⁴³⁶ § 11 Nr. 2 PatG however requires that the experiments are conducted in relation to the subject matter of the invention. Based on the findings of the German Federal it appears unlikely that the use of research tools would to a large extent not be covered by § 11 Nr. 2 PatG. A similar approach is perceivable under UK law. Where such research tools are used for screening purposes then the application of such a use would be considered as the proposed use which would fall within the ambit of the exclusive right. If such a use would fall under the research exception then the economic value of the patent would be rendered irrelevant.

help of the data obtained in the experiments.” - BGH, NJW 1997, 3092 (3095) - Klinische Versuche II = BGH, RPC 1998, 423 (436) - Clinical Trials II. This comment could be interpreted that the Court looked at the specific nature of the experiments and its beneficial aspects towards human health. By this, the court did not just regard the issue of technological advance as the public interest underlying the research exception but also wider aspects of public health.

⁴³³ See Section 60 (5) (i) UK Patents Act 1977 and §11 Nr. 2b PatG that implemented implements art.10(6) of Directive 2001/83/EC [2001] OJ EC L311/67 on the Community code for medicinal products for human use, substituted by art.1(8) of Directive 2004/27/EC of the European Parliament and of the Council [2004] OJ EC L136/34, and art.13(6) of Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products [2001] OJ EC L311/1, substituted by art.1(6) of Directive 2004/28/EC [2004] OJ EC L136/58.

⁴³⁴ Directive 2004/27/EC.

⁴³⁵ Henrik Holzapfel, ‘Die patentrechtliche Zulässigkeit der Benutzung von Forschungswerkzeugen’ [2006] GRUR 10, 11.

⁴³⁶ Vincenzo di Cataldo, ‘The experimental use of the patented invention: a free use of an infringing use?’ in Emanuela Arezzo and Gustavo Ghidini (eds), *Biotechnology And Software Patent Law – A Comparative Review of New Developments* (Edward Elgar) 98.

Hence, the use of research tools is not covered by the experimental use exception.⁴³⁷ In order to use the patented invention for such a purpose the user would have to receive the consent of the patent holder in order not to infringe. Other jurisdictions have addressed this issue by providing a compulsory licence for research tools which would provide remuneration to the patent holder.⁴³⁸ Belgium however, has amended the research exception in their patent act in 2005.⁴³⁹ The amended provision states that “the rights of a patent holder do not extend to acts carried out for scientific purposes on or with the subject matter of the invention.”⁴⁴⁰ This would probably not be possible under UK and German law.⁴⁴¹

3.5.3 Public interest considerations

What is noticeable when comparing the case law with regards to the research exception in both jurisdictions is the significant difference as to how public interest considerations were applied. While the German case law takes public consideration considerations greatly into account, this is hardly the case in the United Kingdom. German courts have applied a thorough teleological discussion that analyses the purpose of the regulation in question in both *Clinical Trials* decisions. Such a teleological or purposive interpretation of exception provisions highlights the legislative purpose for limiting the patent right. This purpose is in the public interest as the courts have held.⁴⁴²

When law is regarded as fulfilling a certain regulatory purpose then a teleological interpretation provides courts with the ability to give emphasis to the underlying purpose of a statutory provision. In many events, the purpose of the law has been identified by the

⁴³⁷ Henrik Holzapfel, ‘Die patentrechtliche Zulässigkeit der Benutzung von Forschungswerkzeugen’ [2006] GRUR 10, 16; Georg Benkard (ed), *Patentgesetz* (10th ed C.H. Beck 2006) § 11 [7]; also O’Connor who states that this would adversely affect the patent holder’s economic interests.“ - Sean O’Connor ‘Enabling research or unfair competition? De jure and de facto research use exceptions in major technology countries’ in Toshiko Takenaka (ed), *Patent Law and Theory – A Handbook of Contemporary Research* (Edward Elgar 2008) 531.

⁴³⁸ So for instance Section 40 b of the Swiss Patent Act in relation to biotechnological inventions.

⁴³⁹ Article 28 § 1 (b) Belgium Patent Act.

⁴⁴⁰ Geertrui Van Overwalle and Esther van Zimmeren, ‘Reshaping Belgian Patent Law: The Revision of the Research exemption and the Introduction of a Compulsory License for Public Health’ (IIP Forum (Japan), February 2006) 2 <http://www.iip.or.jp/e/e_publication/pdf/vol64_overwalle_and_zimmeren.pdf> accessed 23.05.2015; Geertrui Van Overwalle, ‘The Implementation of the Biotechnology Directive in Belgium and its After-Effects. The Introduction of a New Research Exemption and a Compulsory Licence for Public Health’ [2006] IIC 905–908.

⁴⁴¹ It is also doubtful whether such a broad exception would be compatible with Article 30 TRIPs – infra 5.4.

⁴⁴² The courts have held that the purpose of the research exception relates to technological advance (supra 3.4.3). In *Clinical Trials II* the German Federal High Court hinted that also public health issues surround the provision (supra 3.3.2).

legislator as being in the public interest.⁴⁴³ A teleological or purposive interpretation of an exception provision then seeks to underline the public interest in limiting the patent right. Such an interpretation is actually warranted since the exception provisions within § 11 PatG present themselves are formulated in a way where they do not exempt *certain uses* from liability but *certain purposes*, as the BGH finds.⁴⁴⁴

What also assisted the breadth of public interest considerations that have been applied is the fact that the German courts have resorted to the fundamental rights discourse in order to align their decisions with the constitutionally mandated fundamental rights.⁴⁴⁵ The German approach specifically bases its public policy considerations on constitutional parameters.⁴⁴⁶ This forces the courts to acknowledge the interests of the potential users of the exception provision particularly where such interest itself can be based on a fundamental right.⁴⁴⁷ This then legitimises the curtailment of another right⁴⁴⁸, here the property right of the patent holder. Because of their particular purpose, those third party interests can be in the public interest.⁴⁴⁹

The approach taken by UK courts stands in stark contrast to the situation before the introduction of a statutory provision analysed within chapter 2. If one reconsiders the approach taken in *Frearson v Loe* where the court has specifically mentioned that “[p]atent rights were never granted to prevent persons of ingenuity exercising their talents” and by this applying a purposive interpretation of patent law then the current situation appears to be having a lesser degree of public interest considerations applied in the United Kingdom. The apparent reluctance of the courts to fully appreciate the new provision may be attributed to the fact that common law courts would tend to recur to old law in form of precedents.⁴⁵⁰ This arguably would make adapting a new approach through statutory legislation difficult. Conversely, German inflexible law with regards to patent infringement made adaptation to

⁴⁴³ Häberle states that the public interest is guised as the purpose of the act - Peter Häberle, *Öffentliches Interesse als juristisches Problem* (Athenäum Verlag 1970) 57.

⁴⁴⁴ BGH (GRUR 1996) 109, (112) [Klinische Versuche I] = BGH, RPC 1997, 623 (638) - Clinical Trials I.

⁴⁴⁵ Guido Westkamp, ‘The ‘Three-Step Test’ and Copyright Limitations in Europe: European Copyright Law between Approximation and National Decision Making’ [2008] *Journal of the Copyright Society of the USA* 1, 52.

⁴⁴⁶ The reference to “freedom of research and the social obligation of property” as mentioned refer to norms of the German Constitution. (Article 5 and 14 (1) of the Basic Law).

⁴⁴⁷ *supra* 3.4.4.6.

⁴⁴⁸ Robert Uerpmann, *Das öffentliche Interesse: seine Bedeutung als Tatbestandsmerkmal und als dogmatischer Begriff* (Mohr Siebeck 1999) 69.

⁴⁴⁹ *supra* 3.4.4.5.

⁴⁵⁰ The court in *Monsanto v Stauffer*, for instance, readily recurred to old precedents – *supra* fn 228.

new scenarios difficult. But when these provisions change courts are willing to adopt the new provisions more likely and not recur to old law.

The reluctance of British courts to apply wider public interest considerations can also be correlated to the fact that they generally do not seek to apply a teleological interpretation of legislative provisions. This emphasis of a literal interpretation of statutory law can be explained due to the supremacy of Parliament. This means that courts are to apply the law, not to make it where the Parliament has already done so. It appears that in the United Kingdom, it is the legislator who is called upon to provide for public interest legislation as courts will not generally provide for an interpretation which emphasises the public interest underlying the provision. This explains the recent amendment of the UK Patents Act with Section 60(6D). What remains to be seen is whether a wider application of human rights principles through the Human Rights Act 1998 would change this approach.⁴⁵¹

3.6 Conclusion

The analysis in chapter 3 has shown that public interest considerations are currently primarily being applied by the legislator in the United Kingdom and Germany. The example of the research exception has documented that the legislators have seen a necessity to introduce a statutory tool to allow experiments on the patented invention. The purpose that the exception provision aims to serve is scientific and technological advance - purposes which have been found to be in the public interest as acknowledged by the courts.⁴⁵²

Legislative intervention through a statutory tool was necessary both in the Germany and the United Kingdom as the case law before the introduction of the provisions did generally not allow conducted with an underlying commercial purpose.⁴⁵³ The change of approach was warranted due to the changing nature of research. Thus, the public interest in technological advance urged legislators to widen the scope for experimental purposes to cover such uses that are commercially orientated. Through this, the means, i.e. patent law, had to be updated to achieve the end, the public interest goal in technological advance. This affirms the

⁴⁵¹ *infra* 4.7.

⁴⁵² BGH, GRUR 1996, 109 (115) - Klinische Versuche I = BGH, RPC 1997, 623 (643) - Clinical Trials I and *Corevalve Inc v Edwards Lifesciences AG* [2009] EWHC 6 [72].

⁴⁵³ *supra* 2.4.

assumption that the law needs to be responsive to the developments outside of its sphere in order to foster the public interest.⁴⁵⁴

Another important finding is that the exception provisions in both jurisdictions are the result of a balance of interest between the interests of the patent holder and those of third parties. In the end, an exception wishes to allow uses by third parties which would otherwise constitute an infringement. Importantly, the purpose of the use must serve the public interest to excuse it from liability. The balance of interest can be seen with regards to the research exception that the courts have argued that scientific progress should be enabled by third parties the interests of the patent holder would also need to be considered.⁴⁵⁵ This follows an economic understanding of patent law by which protection should only be provided as far as it incentivises R&D necessary to overcome market failure.⁴⁵⁶ Hence, the acknowledgement of the patent holders' interests needs to be considered in order not to significantly decrease the incentive function.

With regards to experimental purposes, this consideration was achieved by only allowing such experiments that would relate to the subject matter of the invention. While allowing general research on the patented invention,⁴⁵⁷ this would disallow such uses that would use the patented invention on other items. Such application of its technical teaching should remain under the control of the patent holder. Otherwise, this would affect the patent holder's interests significantly and would arguably decrease the incentive function. The limitation of the research uses on the patent invention was already discussed in the Memorandum on the Community Patent.⁴⁵⁸

But it would be understated if one would assume that public interest considerations in relation to the research exception were just based on paradigms of economic efficiency.⁴⁵⁹ Courts in

⁴⁵⁴ supra 2.4.

⁴⁵⁵ *Corevalve Inc v Edwards Lifesciences AG* [2009] EWHC 6 [72].

⁴⁵⁶ Lionel Bently et al, 'Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights' (WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I, World Intellectual Property Organisation 2010) 56.

⁴⁵⁷ Chrocziel has elaborated that most experimental uses on the patented invention would even not conflict with the interests of the patent holder - Peter Chrocziel, *Die Benutzung patentierter Erfindungen zu Versuchszwecken* (Carl Heymanns Verlag 1986) pp. 174.

⁴⁵⁸ Denkschrift zum Übereinkommen über das europäische Patent für den gemeinsamen Markt (Gemeinschaftspatentübereinkommen) [1979] BIfPMZ 325, 333.

⁴⁵⁹ Arguably, economic efficiency can be considered to be in the public interest - Burton A. Weisbrod, 'Conceptual Perspective on Public Interest: An Economic Analysis' in Burton A. Weisbrod, Joel F. Handler and Neil K. Komesar (eds), *Public Interest Law – An Economic and Institutional Analysis* (University of California Press 1978) 4. A purely utilitarian approach, which is closely related to the economic approach, does not seem feasible as sole arbiter of the public interest. Rawls states that no one would choose a social contract that entails

Germany asserted third party interest to use the invention for experimental purposes when they are founded on fundamental rights.⁴⁶⁰ They have provided a proportionate balancing between the rights of the patent holders and those of third parties to accentuate the scope of the research exception. And arguably, this balancing of interest ultimately serves the public interest.

The courts do not take centre stage in devising public interest considerations with regards to exceptions to patent rights as such. Devising exception provisions is a matter of policy making. The separation of powers both in Germany and the United Kingdom would forbid such policy making of the courts. Courts can interpret the law but generally cannot make it.⁴⁶¹ Their importance is however, paramount when applying the law. Through a purposive interpretation of an exception provision, they can accentuate the public interest considerations intended by the legislator.⁴⁶² Such purposive interpretation generally entails consideration of third party interest, especially when these interests can be based on fundamental rights as seen in Germany.⁴⁶³

In summarising all findings, the example of the research exception has shown that exceptions to patent rights generally serve the public interest. The fact that statutory tools have been devised highlights that they reflect contemporary commercial realities. This then means that the law needs to be responsive to be in the public interest. Importantly, legislators have considered all involved interests and balanced the interest of the patent holder with the public interest in curtailing the right. The fact that the exception now allows commercially orientated research means that legislators have also taken third party interest of potential experimenters into account.

utilitarian considerations due to the risk of potentially being disadvantaged under such as system - John Rawls, *A Theory of Justice* (Harvard University Press 1999) 25.

⁴⁶⁰ supra 3.4.4.5.

⁴⁶¹ Similarly - Alexander Peukert, 'The fundamental right to (intellectual) property and the discretion of the legislature' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 142.

⁴⁶² supra 3.3.3.

⁴⁶³ supra 3.4.4.5.

Part 2: International law and its impact on public interest considerations in exceptions to patent rights

Part 1 demonstrated that the nation state and its legislator take centre stage in deciding and applying public interest considerations in exceptions to patent rights: It ultimately decides what interests constitute public interest. In relation to exception to patent rights this is done by applying them into the case groups of purposes which exempt the otherwise infringing use from infringement. Moreover, in Germany, the legislator is bound to follow fundamental rights considerations as they are deemed to be in the public interest.

International law, however, plays an important role in the assessment of such considerations nowadays. This is due to the fact that the present framework of intellectual property rights presents itself as a transnational or global one that emerged from a solely national ambit. These international frameworks of intellectual property “rules” play a crucial role for national or regional legislators. They often pose binding rules that national legislators need to consider when assessing public policy considerations within their patent legislation. This can lead to the dilemma that adherence to such transnational law may limit the possibilities to provide for domestic public interest considerations.⁴⁶⁴

⁴⁶⁴ Dinwoodie and Dreyfuss state that the freedom to create exceptions is crucial and should be part in an *acquis* of intellectual property law - Graeme B. Dinwoodie and Rochelle C. Dreyfuss, 'An international *acquis*: Integrating regimes and restoring balances' in in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 143. This “*acquis* would create a legal framework to structure future international lawmaking...” - *ibid*123.

Chapter 4: The European Human Rights Framework

4.1 Introduction

Human rights frameworks external to intellectual property law, such as provided by the European Charter on Fundamental Rights or the European Convention on Human Rights (ECHR), might need to be taken into consideration within national IP legislation of EU Member States.⁴⁶⁵ This particularly is the case when one perceives these rights to have *Drittwirkung*, i.e. horizontal effect so that these fundamental or human rights directly influence the interpretation of ordinary law.⁴⁶⁶ Additionally, the assessment of these frameworks and their potential relevance for public interest considerations in patent exceptions is heightened by the fact that both frameworks are hierarchically above national law.

The human rights discourse in relation to exceptions to intellectual property is normally perceived as interferences with the right to property.⁴⁶⁷ This perspective arguably may favour intellectual property rights holders.⁴⁶⁸ Subsuming patent rights as human rights may serve as an additional layer of protection by using it as a rhetorical weapon⁴⁶⁹: A commentator stated with this regard that protecting IPRs as human rights would then only permit limiting the right when there is an exceptionally overwhelming instance of public interest present.⁴⁷⁰ Such

⁴⁶⁵ This is because “international human rights law restricts the power of states” – Rhona Smith, ‘Interaction between international human rights law and the European legal framework’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 54.

⁴⁶⁶ Christophe Geiger, ‘Fundamental Rights as Common Principles of European (and International) Intellectual Property Law’ in Ansgar Ohly (ed), *Common Principles of European Intellectual Property Law* (Mohr Siebeck 2012) 225-226.

⁴⁶⁷ The subsumption of intellectual property rights under the umbrella of human rights protection has been criticised. See for instance - Rochelle C. Dreyfuss, ‘Patents and human rights; where is the paradox’ in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) pp 72.

⁴⁶⁸ See: Wendy J. Gordon, ‘Current patent law cannot claim the backing of human rights’ in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) 157. Moreover, Dreyfuss states that acknowledging patents as human rights would lead to them only being outweighed by other human rights; Rochelle C. Dreyfuss, ‘Patents and human rights; where is the paradox’ in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) 74.

⁴⁶⁹ Lawrence Helfer, ‘Mapping the interface between human rights and intellectual property’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 9.

⁴⁷⁰ Andrea Ottolia, *The Public Interest and Intellectual Property Models* (G. Giappichelli Editore 2010) 134; Rochelle C. Dreyfuss, ‘Patents and human rights; where is the paradox’ in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) 74. Ottolia also states that this notion would

approaches would stipulate that domestic public interest considerations in relation to exceptions to patent rights would appear to be more difficult to adopt.⁴⁷¹

This concern may be alleviated. Human rights frameworks specifically mention that the right to property can be interfered with by the state in the public or general interest.⁴⁷² Additionally, the “patent right/exceptions”- discourse can be perceived from the viewpoint that the human right of the patent holder receives is not superior to the fundamental rights of users wishing to apply the exception. The particular use of a patented object may itself be guaranteed by a fundamental right, even where the use is not authorised by the patent holder. The rationale of exceptions can, for instance, be based on fundamental rights such as freedom of expression or the freedom of science. Such conflicting fundamental rights are equally relevant and therefore need to be balanced with the human right to property. This balancing exercise then urges to be considered in relation to exceptions to patentee’s rights.

Moreover, the existence and enforcement of intellectual property rights itself can be regarded as an interference with other fundamental rights. This reverses the above mentioned traditional property-interference, i.e. patent-exception conundrum. The ECtHR, for instance, has recently discussed such a constellation where the enforcement of copyright may be regarded as an interference with freedom of expression.⁴⁷³ This has potentially wide reaching ramifications for providing public interests considerations in relation to exception to patent rights.

Therefore, it has been argued that human rights frameworks could serve as an external measure that governs a balanced application and interpretation of intellectual property rights.⁴⁷⁴ The perceived legislative bias towards strong intellectual property rights favouring

make fine-tuning the IP system different, probably more difficult than this is possible in a utilitarian IP system like that of the United States.

⁴⁷¹ With regards to the situation in copyrights Griffiths finds that “[c]opyright interests have tended to be regarded as property rights with a settled and universally applicable value. Courts have frequently questioned the value of the defendant’s claim, but have tended not explicitly to evaluate the significance of the competing claim of the claimant.” - Jonathan Griffiths, ‘Copyright law after Ashdown - time to deal fairly with the public’ [2002] IPQ 240, 259.

⁴⁷² See for instance Article 1 of the Protocol 1 of the ECHR or Article 17(1) of The EU Charter on Fundamental Rights. Fundamental rights protection of property in Germany follows a similar scheme within Article 14 of the Basic Law. For this see generally 3.4.4.

⁴⁷³ *Case of Ashby Donald and others v France* App no 36769/08 (ECtHR, 10 January 2013).

⁴⁷⁴ Geertrui van Overwalle, ‘Human rights’ limitation in patent law’ in Willem Grosheide (ed), *Intellectual Property and Human Rights – A Paradox* (Edward Elgar 2010) 237.

right holders could be reconciled by applying human rights considerations.⁴⁷⁵ Geiger, for instance, states that the shift of powers in favour of private entities due to the countries' emphasis on economic well-being has made it necessary for judges to apply fundamental rights as "external rules...in order to correct the overprotective tendencies of intellectual property legislation and to re-establish a proper balance of interests."⁴⁷⁶ Arguably, such an approach would provide sufficient leeway for providing public interest considerations within exception provisions.

The following chapter will analyse the notion of public interest deviation for property rights in regional jurisdictions in Europe. By this, it will showcase the influence that legislative measures by the European Union (including the EU Charter of Fundamental Rights, which is legally binding following the Lisbon Treaty⁴⁷⁷) and the ECHR, which is governed by the Council of Europe, have and may have in future on national patent legislation. Importantly, it will analyse how conflicting human rights are accommodated within these frameworks and how this relates to patent rights and exceptions thereof.

4.2 The framework of fundamental/human rights in Europe

In 1948, the newly established United Nations set out the Universal Declaration of Human Rights (UDHR). The Human Rights it entailed were elaborated upon within the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social, and Cultural Rights (ICESCR). Within Europe, a regional framework was established under the auspices of the Council of Europe with the European Convention on Human Rights. The EC itself, which was founded by the Roman Treaties in 1957, did not establish such a framework until the inception of the Lisbon Treaty with the EU Charter on

⁴⁷⁵ Simon Walker, 'A Human Rights Approach to the WTO's TRIPS Agreement' in Frederick M. Abbott, Christine Breining-Kaufmann and Thomas Cottier (eds), *International Trade and Human Rights: Foundations and Conceptual Issues* (The University of Michigan Press 2006) 173.

⁴⁷⁶ Christophe Geiger, 'Fundamental Rights as Common Principles of European (and International) Intellectual Property Law' in Ansgar Ohly (ed), *Common Principles of European Intellectual Property Law* (Mohr Siebeck 2012) 226; similarly - Xavier Seuba, 'Human Rights and Intellectual Property Rights' in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, Kluwer Law International 2008) 418.

⁴⁷⁷ See Article 6 (1) TEU. The EU Charter shall have the same legal value as the Treaties.

Fundamental Rights.⁴⁷⁸ But many EU member states included catalogues of fundamental rights within their constitutional laws.

Notable is the difference in terminology between “fundamental” rights on the one hand and “human” rights on the other. While there often may be an overlap between human and fundamental rights, the effects of both vary considerably. A clear distinction can be made by the effects of such rights on a national legal order. From the perspective of a nation state, the term “Human Rights” stipulates that these rights are suprapositive in the sense that they exist without or outside a legal order.⁴⁷⁹ Fundamental rights or liberties, on the other side, relate to positive rights within the constitutional order of a nation state. They are constitutionally guaranteed and protected as primary rights, hence the term “fundamental rights”.⁴⁸⁰

Fundamental rights, as positive rights can therefore normally be enforced by the right holder in a given jurisdiction.⁴⁸¹ As they are often incorporated within the constitution of that particular jurisdiction, they also rank hierarchically on top of legislation⁴⁸² as seen in Germany. This means that all national legislation within that jurisdiction refers to these rights as fundamental rights.⁴⁸³ Conversely, human rights frameworks operate within public international law aside other frameworks.⁴⁸⁴ Here they set a framework of values commonly shared by the contracting member states.⁴⁸⁵ The divergences between “human” and “fundamental” rights then lie in the different degree of integration in a jurisdiction.⁴⁸⁶ This raises the question as to the possible effects on public interest considerations to patent holder’s rights that each set of frameworks may have.

The different level of integration within the European legal framework explains the ECHR’s reference to the term “Human” Rights. It is a regional convention guaranteeing these rights without the hierarchically set legal order of a jurisdiction.⁴⁸⁷ Conversely, the European Union

⁴⁷⁸ This may result from the fact that the EU’s predecessor, the European Communities, have initially had their focus on economic integration and development.

⁴⁷⁹ Katharina Gebauer, *Parallele Grund- und Menschenrechtssysteme in Europa? – Ein Vergleich der Europäischen Menschenrechtskonvention und des Straßburger Gerichtshof mit dem Grundrechtsschutz in der Europäischen Gemeinschaft und dem Luxemburger Gerichtshof* (Duncker & Humblot 2007) 26.

⁴⁸⁰ *ibid* 26.

⁴⁸¹ *ibid* 29.

⁴⁸² Katharina Gebauer, *Parallele Grund- und Menschenrechtssysteme in Europa? – Ein Vergleich der Europäischen Menschenrechtskonvention und des Straßburger Gerichtshof mit dem Grundrechtsschutz in der Europäischen Gemeinschaft und dem Luxemburger Gerichtshof* (Duncker & Humblot 2007) 29.

⁴⁸³ *ibid* 29.

⁴⁸⁴ *ibid* 29.

⁴⁸⁵ *ibid* 29.

⁴⁸⁶ *ibid* 41.

⁴⁸⁷ *ibid* 27. It however has to be noted that the ECHR has constitutional level within Austria.

has an established legal order and has additionally received legal personality by the Treaty of Lisbon.⁴⁸⁸ This explains the reference within the EU Charter to “Fundamental” Rights. The Union has placed them firmly on the top level of hierarchy of EU norms.⁴⁸⁹ Nation states, like Germany, also refer to them as fundamental rights (i.e. *Grundrechte*) within their constitutional law.

As mentioned, the regional legislative fundamental/human rights framework in Europe is twofold: On the one hand, there is the ECHR, an instrument of the Council of Europe, which has been adopted by 47 States in Europe. On the other hand, there is the recently enacted EU Charter on Fundamental Rights. These two sets of frameworks may impact public interest considerations differently, which warrants to be assessed. Two important things in relation to these two sets of frameworks need to be noted here: First, the EU Charter follows the text of the ECHR very closely. It adds new rights such as data protection rights⁴⁹⁰ and the freedom of science⁴⁹¹. The other important issue in light of the fact that there are two treaties and two courts is that the CJEU has followed the jurisprudence of the ECtHR very closely in determining fundamental rights concerns, including those of the public interest.⁴⁹² In this way, the CJEU tries to ensure that divergence between the opinions of the courts are kept to a minimum. With respect to the 'public interest', divergence from the abovementioned right to property is likely to be a comparable position between the two courts.

4.2.1 European Convention on Human Rights

The Convention was signed by 12 Member States of the Council of Europe on the 4th of November 1950 and entered into force the 3rd of September 1953. After the Second World War, the Member States of the Council of European sought to establish a common human rights framework.⁴⁹³ The Convention is governed by the Council of Europe, an entity distinct

⁴⁸⁸ Article 1 (3) TEU.

⁴⁸⁹ The charter has been given the same hierarchical place as the treaties according to Article 6(1)TEU. This means that the Charter is placed on the top of norms of the Union as both the TEU and the TFEU build the Union according to Article 1 TEU.

⁴⁹⁰ Article 8 EU Charter of Fundamental Rights.

⁴⁹¹ Article 13 EU Charter of Fundamental Rights.

⁴⁹² The then European Court of Justice has applied principles of the ECHR and national constitutional law. It began referring to fundamental rights considerations in 1969 in its *Stauder* decision (Case 29/69 *Stauder* [1969] ECR 419).

⁴⁹³ This development runs parallel to the Universal Declaration of Human Rights by the United Nations.

from the EU. However, all current EU Member States are members of the Council of Europe and are therefore signatory states of the ECHR.⁴⁹⁴

The ECHR was signed by the United Kingdom and Germany on the 4th of November 1950. The United Kingdom ratified it with effect from the 8th of March 1951; the first signatory having done so.⁴⁹⁵ The Convention entered into force in the Federal Republic of Germany signed on 03 September 1953.⁴⁹⁶ The European Union as such has not acceded to the ECHR yet as this was only possible after the Treaty of Lisbon entered into force. Now Article 6 (2) of the TEU sets out that the European Union “shall accede to the European Convention for the Protection of Human Rights and Fundamental Freedoms.” The process of the European Union acceding to the ECHR is still on-going.⁴⁹⁷

The ECtHR has held that the Convention does not stipulate a prescribed manner of how the principles of the ECHR apply within national law.⁴⁹⁸ This explains why the Convention affects national laws of Council of Europe States differently. Only Austria has provided the ECHR with constitutional rank within its jurisdiction.⁴⁹⁹ In Germany, it has become a piece of federal legislation.⁵⁰⁰ Other jurisdictions rank it between constitutional and ordinary

⁴⁹⁴ See <<http://www.coe.int/en/web/about-us/who-we-are>> accessed 23 May 2015.

⁴⁹⁵ Michael H.W. Koch, *Zur Einführung eines Grundrechtskataloges im Vereinigten Königreich von Großbritannien und Nordirland* (Dunker & Humblot 1991) 66-67.

⁴⁹⁶ Bekanntmachung über das Inkrafttreten der Konvention zum Schutze der menschenrechte und Grundfreiheiten vom 15 Dezember 1953 (BGBl. II S. 14); Bekanntmachung der Neufassung der Konvention vom 4. November 1950 zum Schutze der Menschenrechte und Grundfreiheiten vom 17. Mai 2002 (BGBl. II S. 1054).

⁴⁹⁷ Negotiators of the 47 Council of Europe States and the European Commission have recently submitted a draft Agreement on the Accession of the European Union to the European Convention on Human Rights. An opinion of the CJEU has been sought to clarify the consistency of this draft agreement with the EU Treaties.

<http://www.coe.int/t/dghl/standardsetting/hrpolicy/accesion/default_EN.asp> accessed: 23 May 2015.

The CJEU has now held that the draft agreement on the accession of the European Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms is not compatible with EU law – Press Release No 180/14 of the CJEU from 18 December 2014 <<http://curia.europa.eu/jcms/upload/docs/application/pdf/2014-12/cp140180en.pdf>> accessed 23 May 2015.

⁴⁹⁸ *Swedish Engine Drives Union v Sweden* App no 5614/72 (ECtHR 6 February 1976) [50].

⁴⁹⁹ Article II Nr. 7 BVG (Bundesverfassungsgesetz) vom 4.3.1964 BGBl Nr 59.

⁵⁰⁰ Bekanntmachung der Neufassung der Konvention vom 4. November 1950 zum Schutze der Menschenrechte und Grundfreiheiten vom 17. Mai 2002 (BGBl. II S. 1054).

law.⁵⁰¹ The United Kingdom has provided yet another way to incorporate the ECHR within national law with the Human Rights Act 1998 (HRA 1998).⁵⁰²

In Germany, legislation is bound to be interpreted in a way to conform to ECHR principles. This is due to the principle of public international law-friendly interpretation. Only where the German legislator has clearly expressed the will not to follow ECHR principles are authorities and courts bound not to apply an ECHR conforming interpretation.⁵⁰³ The German Federal Constitutional Court even interprets the German Basic Law⁵⁰⁴, including its fundamental rights, in conformity with the ECHR.⁵⁰⁵ It often analyses parallel fundamental rights within the ECHR when interpreting national fundamental rights.⁵⁰⁶ Therefore, the ECHR has an effect that clearly extends beyond its role as an ordinary law. This constitutional relevance⁵⁰⁷ means that it serves as an important guideline which is applied when analysing the scope of protection of fundamental rights⁵⁰⁸, as well as limitations thereof.⁵⁰⁹

The ECHR has significant effect for the United Kingdom as a country that does not possess a written constitution⁵¹⁰ with a catalogue of fundamental rights.⁵¹¹ This is due to the

⁵⁰¹ Katharina Gebauer, *Parallele Grund- und Menschenrechtssysteme in Europa? – Ein Vergleich der Europäischen Menschenrechtskonvention und des Straßburger Gerichtshof mit dem Grundrechtsschutz in der Europäischen Gemeinschaft und dem Luxemburger Gerichtshof* (Duncker & Humblot 2007) 54.

⁵⁰² Michael H.W. Koch, *Zur Einführung eines Grundrechtskataloges im Vereinigten Königreich von Großbritannien und Nordirland* (Dunker & Humblot 1991) 67.

⁵⁰³ This is based on a decision of the German Federal Constitutional Court that stated that it cannot be assumed that the legislator would want to act against its international obligations unless clearly stated. (BVerfGG: - Anne Peters and Tilmann Altwicker, *Europäische Menschenrechtskonvention* (2nd edn, C.H. Beck 2012) § 1 [12].

⁵⁰⁴ supra 3.4.4.

⁵⁰⁵ BVerfGE 128, 326 (368-369) - EGMR Sicherungsverwahrung.

⁵⁰⁶ BVerfG, 1 BvR 2084/05, 13 December 2006 [36].

⁵⁰⁷ Anne Peters and Tilmann Altwicker, *Europäische Menschenrechtskonvention* (2nd edn, C.H. Beck 2012) § 1 [13].

⁵⁰⁸ BVerfG, 2 BvR 2307/06, 4 February 2010 [21].

⁵⁰⁹ BVerfGE 120, 180, (199 – 200) –Caroline von Monaco III.

⁵¹⁰ See for instance - 'Legislation on Human Rights: A Discussion Document' (Home Office, 1976), [2.01-2.05].

It however cannot be said that the United Kingdom does neither possess constitutional law nor that it has not protected positions that would fall under fundamental rights protection. In England, the common law and its relationship to statutory law was able to provide for applications that were conducted by fundamental rights in other countries, meaning that a written constitutional document was not required. Dicey states that "... the constitution is the result of the ordinary law of the land"; Albert V. Dicey, *An Introduction to the Study of the Law of the constitution* (10th ed. 1969) 203.

⁵¹¹ In explaining the lack of such written rights Kavanagh refers to a statement by Jeremy Bentham that abstract statement of rights are 'non-sense upon stilts' - Aileen Kavanagh, *Constitutional Review under the UK Human Rights Act* (Cambridge University Press 2009) 3. Teubner mentions that in relation to state organisation and fundamental right protection the can be compared to that of continental constitutions - Gunther Teubner, 'Globale Zivilverfassungen: Alternative zur staatszentrierten Verfassungstheorie' [2003] ZaöRV 1, 16.

introduction of the HRA 1998⁵¹² that wishes to “bring back human rights home”.⁵¹³ The Act came into force in 02.10.2000 and serves as a conduit to incorporate the rights from the ECHR: Section 3(1) mandates primary legislation to have an as far reaching as possible ECHR-compatible interpretation.⁵¹⁴ It also allows claimants to bring cases before a national court stating that an action is incompatible with Convention rights. Since the United Kingdom was already a signatory of the ECHR, British citizens were able to bring cases against the United Kingdom before the ECtHR prior to the inception of the HRA 1998.⁵¹⁵ But the HRA 1998 now allows ECHR rights to be directly enforceable before British courts.⁵¹⁶

The inception of a catalogue of human rights through the HRA 1988 does not hamper the fundamental constitutional pillar of the United Kingdom, that being the sovereignty of parliament.⁵¹⁷ The ECHR does not take a hierarchically superior position in the UK through the HRA 1998.⁵¹⁸ This can, for instance, be seen in the fact that a court cannot suspend UK legislation it deems to be inconsistent with the ECHR, but rather declare it as incompatible with the Convention.⁵¹⁹ Albeit this limitation, it has been said that “[t]he provisions of the Human Rights Act can affect both the interpretation and application of legislation and the development of the common law, and can reach into most areas regulated or affected by law.”⁵²⁰ It clearly mandates public authorities to take account of the principles deriving from the ECHR. This ultimately means that British primary legislation now has to conform to the principles of the ECHR according to Sec. 3 of the HRA 1998. Through this effect, the HRA

⁵¹² Teubner mentions that in relation to state organisation and fundamental right protection the can be compared to that of continental constitutions - Gunther Teubner, ‘Globale Zivilverfassungen: Alternativen zur staatszentrierten Verfassungstheorie’ [2003] ZaöRV 1, 16.

⁵¹³ The White Paper in relation to the Human Rights Bill was named “Rights Brought Home: The Human Bill” - Home Department, *Rights Brought Home: The Human Rights Bill* (Cm 3782, 1997).

⁵¹⁴ Sebastian M. Heselhaus and Carsten Nowak, *Handbuch der Europäischen Grundrechte* (C.H. Beck Verlag 2006) § 32 [20]; John F. McEldowney, *Public Law* (3rd edn, Sweet & Maxwell 2002) [16-007].

⁵¹⁵ One reason for incorporating the ECHR rights within British law is the fact that the enforcement route of these rights were costly - Home Department, *Rights Brought Home: The Human Rights Bill* (Cm 3782, 1997) cl.1.14.

⁵¹⁶ Chris Ryan, ‘Human rights and intellectual property’ [2001] EIPR 521, 521.

⁵¹⁷ See - Home Department, *Rights Brought Home: The Human Rights Bill* (Cm 3782, 1997) cl. 2.13.

⁵¹⁸ Katharina Gebauer, *Parallele Grund- und Menschenrechtssysteme in Europa? – Ein Vergleich der Europäischen Menschenrechtskonvention und des Straßburger Gerichtshof mit dem Grundrechtsschutz in der Europäischen Gemeinschaft und dem Luxemburger Gerichtshof* (Duncker & Humblot 2007) 55.

⁵¹⁹ Section 4 HRA 1998. The fact that an incompatible law would still remain valid and applicable can be regarded as a “Pyrrhic victory” of the victim - Michael J. Allen and Brian Thompson, *Cases and Materials on Constitutional and Administrative Law* (10th edn, OUP 2011) 469.

A fast track procedure can be applied by fast track procedure (Sec. 10 HRA 1998 and Schedule 2). Where no action is taken the victim would need to resort to enforcement through the ECHR mechanism.

⁵²⁰ S.J. Bailey, J.P.L. Ching and N.W. Taylor, *Smith, Bailey and Gunn on the Modern English Legal System* (5th edn, Sweet and Maxwell 2007) 8-001.

1998 signifies a change of paradigms for the interpretation of British legislation and the British legal system as a whole.⁵²¹

The Convention itself is governed by the European Court of Human Rights (ECtHR) which has its seat in Strasbourg. The Court can only be called upon once “all domestic remedies have been exhausted.”⁵²² The defendant before the ECHR is not the authority that is responsible for the alleged violation of fundamental rights deriving from the ECHR but the Member State itself.⁵²³ If the Court declares that a breach of the fundamental rights has been committed by the Defendant Member State, Article 46(1) ECHR holds it to abide to the judgement. The Council of Europe later assesses whether Member States are abiding to the Court’s judgements.⁵²⁴

The effects of the decisions of the ECtHR differ from Member State to Member State. In Germany, the German Federal Constitutional Court has held that all national institutions are bound to follow the decisions of the ECtHR.⁵²⁵ This obliges them to eliminate a status which is contrary to the Convention while having to establish such status that complies with the Convention.⁵²⁶ Importantly, this does not render national acts not conforming to the Convention invalid.⁵²⁷ In relation to the United Kingdom, the Human Rights Act 1988 stipulates that decisions by the ECtHR as well as certain opinions and decisions of the previous Commission on Human Rights need to be taken into account by the national judge.⁵²⁸ This does not mean that the court is bound by these decisions.⁵²⁹ It only means that the ECtHR’s case law needs to be considered by national courts.

The question ultimately arises how the principles deriving from the ECHR and its interpretation by the ECtHR may influence national public interest considerations with regards to exceptions to patent rights. Initially, the provisions of the Convention were conceived as having only vertical effect i.e. in relationship between the Member State and its

⁵²¹ However, often the Convention conforming interpretation would come to the same result as common law - *ibid* 8-028.

⁵²² Article 35 (1) ECHR.

⁵²³ See Articles 33 and 34 ECHR.

⁵²⁴ This is done by the Committee of Ministers of the Council of Europe. See: <http://www.coe.int/t/dghl/monitoring/execution/Presentation/Pres_Exec_en.asp> accessed: 23 May 2015.

⁵²⁵ BVerfG NJW 2004, 3407, 3408.

See also - Bodo Pieroth, Bernhard Schlink, Thorsten Kingreen, Ralf Poscher, *Grundrechte Staatsrecht II* (29th edn, C.F. Müller 2013) [56-59].

⁵²⁶ BVerfG NJW 2004, 3407, 3408.

⁵²⁷ Hans D. Jarass, *EU-Grundrechte* (C.H.Beck Verlag 2005) § 1[16].

⁵²⁸ Article 2(1) a) and b) HRA 1998.

⁵²⁹ *R (on the application of Alconbury Developments Ltd) v Secretary of State for the Environment, Transport and the Regions* [2001] UKHL 23.

citizen. A development, however, has taken place where its provisions have horizontal effect and therefore can be applied in relation between individuals.⁵³⁰ This would mean that these rights do not just exist between the state and the individual in a vertical relationship. They additionally outline the freedom spheres between individuals, like such between patent holders and users of the invention.

The question of whether ECHR rights would have a horizontal effect arose in relation to the HRA 1998.⁵³¹ A point affirming such effect is the fact that the courts, as public authorities within the meaning of Article 6 Human Rights Act 1988, are obliged to consider the principles of the ECHR in private disputes.⁵³² Hunt states that the HRA 1988 stipulates that ECHR Rights have some degree of horizontal effect in cases between private litigants.⁵³³ He additionally states that the model that the UK chose goes further than the Canadian or German approaches of indirect horizontal effect.⁵³⁴ Birnhack favours a horizontal effect of the HRA 1998 in relation to copyright law.⁵³⁵ The exclusive right over a work is provided by the state and the right holders can control the use of the work and through this the public discourse.⁵³⁶ This control over information that Birnhack stipulates within copyright law is similar to the situation in patent law which makes his finding that the HRA 1998 has horizontal effect open to analogy.

What remains uncertain is the degree that the Convention influences British law. Conformity with the Convention could stipulate that common law is applied in a way compliant with it. On the other hand, it could lead to new law being generated.⁵³⁷ Murray states that the duty to establish compatibility with the Convention would require the courts “[i]n some cases...undoubtedly [to] actively [] modify or develop the common law in order to achieve

⁵³⁰ Christophe Geiger, ‘Fundamental Rights as Common Principles of European (and International) Intellectual Property Law’ in Ansgar Ohly (ed), *Common Principles of European Intellectual Property Law* (Mohr Siebeck 2012) 225.

It was held that German Fundamental Rights have a limited or indirect horizontal effect – See: 3.4.4.1.

⁵³¹ There is considerable debate on whether and to what extent a horizontal effect derives from the HRA 1998. See generally on the debate - Jane Wright, ‘A damp squib? The impact of section 6 HRA on the common law: horizontal effect and beyond’ [2014] Public Law pp 289.

Youngs states that that “[t]he extreme views that the Convention is not horizontally effective at all and that it is fully horizontally effective are wrong: the truth is somewhere in between.” - Raymond Youngs, *English, French & German Comparative Law* (3rd edn, Routledge 2014) 128.

⁵³² S.J. Bailey, J.P.L. Ching and N.W. Taylor, *Smith, Bailey and Gunn on the Modern English Legal System* (5th edn, Sweet and Maxwell 2007) [8-014].

⁵³³ Murray Hunt, ‘The "horizontal effect" of the Human Rights Act’ [1998] Public Law 423, 441.

⁵³⁴ Murray Hunt, ‘The "horizontal effect" of the Human Rights Act’ [1998] Public Law 423, 441.

⁵³⁵ Michael Birnhack, ‘Acknowledging the conflict between copyright law and freedom of expression under the Human Rights Act’ [2003] Entertainment Law Review 24, 30.

⁵³⁶ *ibid* 30.

⁵³⁷ See *Douglas v Hello* in relation to right of privacy - *Douglas v Hello Ltd* (2001) H.R.L.R 512.

such compatibility”.⁵³⁸ Where this line can be drawn, i.e. the line between legitimate development of the common law and illegitimate law making violating Supremacy of Parliament, however, remains to be seen.⁵³⁹

4.2.2 EU Charter of Fundamental Rights

Aside from its pending accession to the ECHR, the European Union recently adopted the Charter on Fundamental Rights in the European Union. The reason why such a catalogue of positive fundamental rights was only adopted relatively late in its integration process can be attributed to the Union’s primary historical goal. The then European Economic Community’s aim, as its previous denominator suggests,⁵⁴⁰ was to create a common market within its Member States. This explains the importance of the 4 General Freedoms which the Treaty of Rome foresaw.⁵⁴¹ Economic integration was paramount within the Communities. A framework for fundamental rights did therefore not appear to be a top priority.⁵⁴² But the increasing integration of EU Member States did not solely involve economic considerations. It extended more and more to other societal fields which urged for more political integration. This development can be regarded to have triggered a possible “shift from expanding fundamental market freedoms to strengthening fundamental rights.”⁵⁴³

The adoption of the EU Treaty with the ratification of the Treaty of Maastricht provided for a firmer acknowledgment of fundamental rights within the framework of the Communities. The Treaty stipulated that the European Union would “respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of the Union's

⁵³⁸ Murray Hunt, ‘The "horizontal effect" of the Human Rights Act’ [1998] Public Law 423, 441.

⁵³⁹ *ibid* 441.

⁵⁴⁰ The European Economic Community was renamed by the Maastricht Treaty into European Community. (Art G A. 1 of the Maastricht Treaty).

⁵⁴¹ These are the free movement of goods, capital, services, and people.

⁵⁴² Lord Goldsmith, ‘A Charter of Rights, Freedoms and Principles’ [2001] Common Market Law Review 1201, 1202.

⁵⁴³ Jürgen Kühling, ‘Fundamental Rights’ in Armin von Bogdandy and Jürgen Bast (eds), *Principles of European Constitutional Law*(2nd edn, Hart Publishing, C.H. Beck 2008) 482.

law.”⁵⁴⁴ This allowed the ECJ to resort to the common traditions of EC Member States and the ECHR for applying fundamental rights principles.

But it was considered insufficient to refer to such rights outside the legal order of the European Union.⁵⁴⁵ The European Parliament elaborated a written text in its “Declaration on fundamental rights and freedoms.”⁵⁴⁶ Apart from fundamental freedoms similarly to those in the ECHR, the text also contained social fundamental rights.⁵⁴⁷ The adoption of such a text was seen as a necessary safeguard since the acts of the European Communities/Union had more and more impact over the lives of European citizens.⁵⁴⁸

The Convention on the Future of Europe headed by former French president Valéry Giscard d’Estaing received the mandate by the European Council to draft a constitution for the EU which would contain the protection of fundamental rights. The proposed Constitution of the European Union however failed to be ratified.⁵⁴⁹ The text of the Part II of the Constitution however still became law as the EU Charter through the Treaty of Lisbon which was signed on the 13th of December 2007. The Treaty came into force on the 1st of December, 2008 and amended the Treaty on the European Union and the Treaty of the Functioning of the European Union. The adoption of the Charter firmly roots fundamental rights within the European *acquis* as part of its primary legislation.⁵⁵⁰

From a technical point, Art 6 (1) of the TEU states that the Union “recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union of 7 December 2000, as adapted in Strasbourg, on 12 December 2007, which shall have the same legal value as the Treaties”. Indeed, the EU Charter has increasingly been used by the CJEU in deciding cases involving IP rights, because the right to property, including IP is protected under Article 17 of the Charter.⁵⁵¹

⁵⁴⁴ Article F Nr.2 of the Maastricht Treaty. Reworded within Article 6(2) of the TEU.

⁵⁴⁵ Hans D. Jarass, *EU-Grundrechte* (C.H.Beck Verlag 2005) § 1[19]. The discussion hereby was spearheaded by the German Federal Constitutional Court that as long as the Solange Decision! - BVerfGE 37, 271, 280 - Solange I.

⁵⁴⁶ European Parliament, ‘Declaration on fundamental rights and freedoms’ [1989] OJ C 120/51-57.

⁵⁴⁷ Hans D. Jarass, *EU-Grundrechte* (C.H.Beck Verlag 2005) § 1[19].

⁵⁴⁸ *ibid* § 1[20].

⁵⁴⁹ The Constitution failed to be adopted in referenda in France and the Netherlands.

⁵⁵⁰ Christophe Geiger, ‘Fundamental Rights as Common Principles of European (and International) Intellectual Property Law’ in Ansgar Ohly (ed), *Common Principles of European Intellectual Property Law* (Mohr Siebeck 2012) 223.

⁵⁵¹ - *infra* 4.5.

Because of the direct effect⁵⁵² and supremacy of EU law,⁵⁵³ the EU Charter is, within the boundaries of EU law, legally binding on member state courts as well. The question then arises to what extent the Charter could influence national legislation and public interest considerations with regards to exceptions to patent rights. The Charter itself answers this as it provides its scope of application. The Charter is applicable and directly binding for the Union and its agencies.⁵⁵⁴ The Member states are only obliged to follow the Charter when “implementing Union law.”⁵⁵⁵ The question however remains when exactly Member States are implementing Union law. The CJEU has held recently in the *Fransson* decision that this would be the case where EU law is applicable.⁵⁵⁶ This makes the Charter applicable where national law derives from EU law which ultimately provides the CJEU with “a broad jurisdiction to scrutinize the conformity of Member State norms with EU fundamental rights.”⁵⁵⁷

In relation to the United Kingdom, Protocol 30 applies which may limit the application of the EU Charter.⁵⁵⁸ The Protocol was inserted to provide some procedural safeguards.⁵⁵⁹ In an

⁵⁵² Case 26/62 *NV Algemene Transporten Expeditie Onderneming van Gend en Loos v Nederlandse Administratis der Belastingen* [1963] ECR 1.

⁵⁵³ Case 6/64 *Flaminio Costa v ENEL* [1964] ECR 585.

⁵⁵⁴ According to Article 51 (1) the Charter solely binds the EU and its organs. The rationale of the Charter was to provide for a fundamental rights framework for the Union and its organs. It was therefore a matter of discussion to separate the framework of the Charter with the national frameworks of fundamental rights as it was feared that the jurisdiction of the ECJ would expand.

⁵⁵⁵ Art 51 Nr. 1 EU Charter on Fundamental Rights.

⁵⁵⁶ “Since the fundamental rights guaranteed by the Charter must therefore be complied with where national legislation falls within the scope of European Union law, situations cannot exist which are covered in that way by European Union law without those fundamental rights being applicable. The applicability of European Union law entails applicability of the fundamental rights guaranteed by the Charter.” - *C-617/10 Åklagaren v Hans Åkerberg Fransson* (CJEU 26 February 2013) [21].

The Advocate General provided a more cautious approach and stated that “[t]he mere fact that such an exercise of public authority has its ultimate origin in Union law is not of itself sufficient for a finding that there is a situation involving the implementation of Union law.” - *Case C-617/10 Åklagaren v Hans Åkerberg Fransson* (CJEU 26 February 2013), Opinion of the Advocate General Cruz Villalón delivered on 12 June 2012 [40].

This means that where national law derives from EU law the Charter would be applicable which provides the CJEU with “a broad jurisdiction to scrutinize the conformity of Member State norms with EU fundamental rights.

⁵⁵⁷ Tuomas Mylly, ‘The constitutionalization of the European legal order: Impact of human rights on intellectual property in the EU’ framework’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 106.

⁵⁵⁸ Poland is also a signatory to the Protocol.

⁵⁵⁹ Article 1

1. The Charter does not extend the ability of the Court of Justice of the European Union, or any court or tribunal of Poland or of the United Kingdom, to find that the laws, regulations or administrative provisions, practices or action of Poland or of the United Kingdom are inconsistent with the fundamental rights, freedoms and principles that it reaffirms.
2. In particular, and for the avoidance of doubt, nothing in Title IV of the Charter creates justiciable rights applicable to Poland or the United Kingdom except in so far as Poland or the United Kingdom has provided for such rights in its national law.

obiter dictum in *R (on the application of AB) v Secretary of State for the Home Department*,⁵⁶⁰ the judge however has held that the Charter would be part of the domestic law. Additionally, it has been said that the protocol simply constitutes an affirmation of Article 52 of the Charter and does not constitute an opt-out from its application.⁵⁶¹

To what extent the Charter would be applicable within national EU Member State jurisdictions is important since it could potentially introduce new rights that need to be considered. According to Article 52 (3) of the Charter, its rights should provide the same amount of protection as the ECHR; it would however allow for more extensive protection.⁵⁶² This leads to the question whether such additional rights would need to be addressed by national law.⁵⁶³ The question of applicability of the Charter is also relevant because of its heightened effect on UK domestic law: In comparison to ECHR rights which only need to be applied and considered by public authorities through the HRA 1998, Charter rights can lead to the non-applicability of an Act of Parliament due to the primacy of EU Law.⁵⁶⁴

The uncertain scope of applicability of the Charter that has arisen after *Fransson* case could lead to conclude that its effect on national patent legislation may *ex ante* be limited. It remains certain however that where patent law is based on European Union Directives the

Article 2

To the extent that a provision of the Charter refers to national laws and practices, it shall only apply to Poland or the United Kingdom to the extent that the rights or principles that it contains are recognised in the law or practices of Poland or of the United Kingdom.

⁵⁶⁰ *AB, R (on the application of) v Secretary of State for the Home Department* [2013] EWHC 3453 (Admin) (07 November 2013).

⁵⁶¹ “In brief, the Charter Protocol is not an opt-out but a guarantee. An explicit confirmation that in relation to the UK and UK law, the limitations and constraints on what it is and what it will do will be strictly observed.” Was it necessary? No, it was not necessary, so long as the Charter was interpreted in the right way. I understand people want additional protections—bootstraps—to make sure there are safeguards. That is the flavour” - House of Commons- European Scrutiny Committee, *The application of the EU Charter of Fundamental Rights in the UK: a state of confusion* (Forty-third Report of Session 2013–14) 21.

⁵⁶² Lord Goldsmith said: That last sentence was obviously deliberate, which is to say that the Charter established a floor, not a ceiling - *ibid* 17.

⁵⁶³ This was mentioned in the report of the European Scrutiny Committee in relation to the “provision on protection in the event of unjustified dismissal under Article 30 of the Charter. The Charter Explanations say that this Article draws in part on the revised European Social Charter—a 1996 Council of Europe treaty that the UK has not ratified.” - *ibid* 18.

⁵⁶⁴ “In this respect our expert witnesses agreed that if a legal challenge were possible under both the Human Rights Act and the Charter, the benefit of a challenge under the Charter would be that it would oblige the court to disapply an Act of Parliament that was inconsistent with a Charter right, in accordance with the principle of the primacy of EU law. Under the Human Rights Act (HRA) a court can only make a “declaration of incompatibility” if an Act of Parliament is inconsistent with a European Convention on Human Rights (ECHR) right. This does not affect the validity of the Act in question until and unless Parliament amends it” - House of Commons- European Scrutiny Committee, *The application of the EU Charter of Fundamental Rights in the UK: a state of confusion* (Forty-third Report of Session 2013–14) 50.

Charter becomes applicable, and hence relevant. This is particularly the case in relation to biotechnological inventions where the law is heavily influenced by the Biotech Directive.⁵⁶⁵

The Charter may still have an indirect influence on national patent legislation. The Patent with Unitary Effect which is currently being established may provide for such a conduit. While the contracting members to the unitary patent package have tried their utmost to eliminate the CJEU's influence on substantive patent law by integrating the respective provisions within the Agreement⁵⁶⁶, it still stipulates in its Article 21 (4) (a) that Union law, i.e. including the Charter, is a source of law for the unitary patent courts.

As seen, exceptions to patent rights are heavily influenced by EU/EC law in one way or the other, either through Directives or the soft harmonisation by the resolution to approximate national law as adopted within the CPC 1975 Agreement. The patent with unitary effect and its rules could be regarded as a succeeding set of laws in relation to the Community Patent Convention. This could lead national courts to adopt a similar interpretation as the unitary patent courts with regards to mirroring provisions within their patent law. And this interpretation of the unitary patent courts might have been assisted by applying fundamental rights deriving of the Charter.

Whether this might occur remains uncertain. But it is possible that national courts would follow the interpretation of the Unitary Patent Courts. Aside from this, it has been argued that the provisions on infringement and exceptions to infringement of a patent with unitary effect may not escape the jurisdiction of the CJEU.⁵⁶⁷ This would mean that these decisions would

⁵⁶⁵ In a decision in relation to copyright, the CJEU “invited the parties referred to in Article 23 of the Statute of the Court of Justice of the European Union to make submissions at the hearing as to the effect that certain rights under the Charter could have on the interpretation of the exception concerned.” - Case C-201/13 [2014] *Deckmyn* (CJEU 03 September 2014) Opinion of the Advocate General Cruz Villalón delivered on 22 May 2014 [3].

The Court actively urged the national courts to assess what EU Charter Rights could be affected within the case in suit. Peifer regards this as problematic since national courts were not provided with any guidance on how to assess the Charter rights within their national law with the final decision in C-201/13 [2014] *Deckmyn* – Karl-Nikolaus Peifer, ‘Die neuen Freiheiten und die unsicheren Grenzen der Parodie’ (jurisPR-WettbR 2/2015) < <https://www.juris.de/jportal/portal/page/homerl.psml?nid=jpr-NLWR000000515&cmsuri=%2Fjuris%2Fde%2Fnachrichten%2Fzeigenachricht.jsp> > accessed 23 May 2015.

⁵⁶⁶ Agreement on a Unified Patent Court (2013/C 175/01).

⁵⁶⁷ So for instance Professor Hanns Ullrich - Hanns Ullrich, ‘ECJ and UPCT: A comment’ Managing Intellectual Property Patent Forum: From Structure to Strategy, Hotel Vier Jahreszeiten, Munich 19 September 2013, Lecture.

very likely include fundamental rights considerations since the court has increasingly applied these.⁵⁶⁸

4.3 Intellectual Property as a fundamental/human right

4.3.1 Introduction

After having established that both the ECHR and the EU Charter may influence national legislation, the question follows how public interest considerations in relation to exceptions to patent rights may be affected by these frameworks. Both the Charter on Fundamental Rights of the European Union and the European Convention for the Protection of Human Rights and Fundamental Freedoms have provisions relating to the protection of property.⁵⁶⁹ Whether intellectual property is protected under the fundamental rights framework of the EU Charter is straightforward. Article 17(2) of the Charter states *expressis verbis* that “[i]ntellectual property shall be protected”. Such a provision is missing within the ECHR which meant that the ECtHR had to address this issue. Interestingly, the question whether IP could be subsumed under Article 1 of the Protocol to the ECHR has been only recently been an issue for the ECtHR. Larry Helfer states that this could be related to the fact that cases before the ECtHR regarding intellectual property have only become more common in the early 90ies of the last century.⁵⁷⁰ Before this, claimants did not file for any violation of their intellectual property before the Court.⁵⁷¹

⁵⁶⁸Case C-275/06 *Productores de Música de España (Promusicae) v Telefónica de España SAU* (ECJ 29 January 2008); Case C-70/10 *Scarlet Extended SA v SABAM* (CJEU 24 November 2011).

⁵⁶⁹Article 1 Protocol of the European Convention on Human Rights; Article 17 EU Charter on Fundamental Rights.

⁵⁷⁰Lawrence Helfer, ‘The New Innovation Frontier? Intellectual Property and the European Court of Human Rights’ in Paul Torremans (ed), *Intellectual Property and Human Rights - Enhanced Edition of Copyright and Human Rights* (Kluwer Law International 2008) 27; also Seuba who generally states that “it was during the nineties when international human rights law became aware of the influence of intellectual property rights on the satisfaction of basic vital needs.” - Xavier Seuba, ‘Human Rights and Intellectual Property Rights’ in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, Kluwer Law International 2008) 388.

⁵⁷¹Lawrence Helfer, ‘The New Innovation Frontier? Intellectual Property and the European Court of Human Rights’ in Paul Torremans (ed), *Intellectual Property and Human Rights - Enhanced Edition of Copyright and Human Rights* (Kluwer Law International 2008) 27.

4.3.2 European Convention on Human Rights

A fundamental right to property was not included in the original text of the Convention. This is largely due to the fact that there were differing positions among the Member States of the European Council of what this guarantee should entail.⁵⁷² It was already included in the 1st Protocol on the Convention in 1952. Its Article 1 provides that “(e)very natural or legal person is entitled to the peaceful enjoyment of his possessions.” It continues to state that “(n)o one shall be deprived of his possessions”. This term does not refer to property as such. But both terms, i.e. possessions and property, can be held to be synonymous for the purposes of the Convention.⁵⁷³ This is because the Convention does not want to base the notion of possessions on domestic classification of Member states but rather wishes to establish an autonomous meaning⁵⁷⁴ which can encompass a wide array of economic assets and interests.⁵⁷⁵

The European Commission of Human Rights has been consistently arguing that intellectual property would fall within the scope of Article 1 of the Protocol.⁵⁷⁶ In *Smith Kline and French Laboratories Ltd v The Netherlands* the Commission found that patents would fall under the scope of the term “possession”.⁵⁷⁷ It based its decision by referring to the Dutch Patent Act that terms the holder of the patent right as “proprietor”.⁵⁷⁸ Additionally, its finding

⁵⁷² Christoph Grabenwarter and Katerina Pabel, *Europäische Menschenrechtskonvention* (5th edn, C.H. Beck 2012) § 25 [1]. König states that this was due to the close link of property with the economic and social order based on ideological differences - Doris König, ‘Der Schutz des Eigentums im europäischen Recht’ in Otto Depenheuer (ed), *Eigentum – Ordnungsidee, Zustand, Entwicklungen* (Springer 2005)113. See also - David Harris, Michael O’Boyle and Colin Warbrick, *Law of the European Convention on Human Rights* (2nd edn, OUP 2009) 655.

⁵⁷³ *Case of Gasus Dosier- und Fördertechnik GmbH v. The Netherlands* App no 153745/89 (ECtHR, 23 February 1995) [46]; Mark W. Janis, Richard S. Kay and Anthony W. Bradley (eds), *European Human Rights Law* (3rd edn, OUP 2008) 525.

⁵⁷⁴ Doris König, ‘Der Schutz des Eigentums im europäischen Recht’ in Otto Depenheuer (ed), *Eigentum – Ordnungsidee, Zustand, Entwicklungen* (Springer 2005) 114; Anne Peters and Tilmann Altwicker, *Europäische Menschenrechtskonvention* (2nd edn, C.H. Beck 2012) § 32 [6].

⁵⁷⁵ Mark W. Janis, Richard S. Kay and Anthony W. Bradley (eds), *European Human Rights Law* (3rd edn, OUP 2008) 525.

⁵⁷⁶ The ECtHR itself has not had the opportunity to directly discuss this until 2005 - Lawrence Helfer, ‘The New Innovation Frontier? Intellectual Property and the European Court of Human Rights’ in Paul Torremans (ed), *Intellectual Property and Human Rights - Enhanced Edition of Copyright and Human Rights* (Kluwer Law International 2008) 37.

⁵⁷⁷ *In Smith Kline and French Laboratoires Ltd v The Netherlands* App no 12633/87 (Commission Decision, 04 October 1990).

⁵⁷⁸ *ibid* 70.

was based on the fact that a patent is deemed to be personal and assignable property under the provisions of the Dutch Patent Act.⁵⁷⁹

The case law of the European Court of Human Rights on Article 1 of the Protocol has now established that the exploitation right of an intellectual property right falls under the provision. In the *Anheuser Busch v Portugal* decision, the court made the important statement that intellectual property rights *as such* would be considered as possessions for the purposes of Article 1 of the Protocol.⁵⁸⁰ This contrasts the appealed decision where the Second section of the Court held that only existing rights would fall within the scope of Article 1 of the Protocol.⁵⁸¹ The Grand Chamber of the ECtHR has held that even applications for trade mark registrations can be considered as possessions.⁵⁸² This is based on the fact that ‘the bundle of financial rights and interests that arise upon an application for the registration of a trade mark’ would amount to be a possession. The Court also elaborated at what instance a legitimate interest can materialise to become an asset falling within the scope of article 1 of the Protocol.⁵⁸³

What the Court stipulates is that it is the nature of IP rights as a bundle of financial rights and interests entailing a substantial financial value which renders it to being a human right. It therefore emphasises the economic value of intellectual property as its underlying rationale as serving as a human right. The protection that the human right to property ultimately provides is the peaceful enjoyment of the possessions. This entails many uses such as owning and disposing of the right.⁵⁸⁴ This enjoyment is protected against interferences by the state.⁵⁸⁵ In comparison to national fundamental right protection, the scope of protection that the ECHR provides is limited. In contrast, Article 1 of the Protocol does not provide for a normative

⁵⁷⁹ *In Smith Kline and French Laboratoires Ltd v The Netherlands* App no 12633/87 (Commission Decision, 04 October 1990) 70.

⁵⁸⁰ *Anheuser Busch v Portugal* App no 73049/01 (ECtHR (Grand Chamber), 11 January 2007) [72].

⁵⁸¹ *ibid* [48].

⁵⁸² *ibid* [75-78].

⁵⁸³ “[W]here a proprietary interest is in the nature of a claim, the person in whom it is vested may be regarded as having a “legitimate expectation” if there is *a sufficient basis for the interest in national law*, for example where there is settled case-law of the domestic courts confirming it” - *Case of Kopecký v Slovakia* App no 44912/98 (ECtHR(Grand Chamber), 28 September 2004) [52] (Emphasis added). However, no legitimate expectation can be said to arise where there is a dispute as to the correct interpretation and application of domestic law and the applicant's submissions are subsequently rejected by the national courts - *ibid* [50].

⁵⁸⁴ David Harris, Michael O’Boyle and Colin Warbrick, *Law of the European Convention on Human Rights* (2nd edn, OUP 2009) 662.

⁵⁸⁵ *ibid* 662.

background rooted within that jurisdiction⁵⁸⁶ and does not provide for an institutional guarantee like under German constitutional law.⁵⁸⁷

4.3.3 EU Charter of Fundamental Rights

The development of the fundamental right protection of property in the EU was initially stalled by the fact that the EC Treaty left the property models of Member States largely untouched. Article 30 EC Treaty allowed Member States to deviate from the free movement of goods in order to protect commercial property. Additionally, Article 295 of the EC Treaty (now Article 345 TFEU) stated that the Treaties do not “prejudice the rules in Member States governing the system of property ownership.” The acknowledgment of property as a fundamental right was gradually adopted by the case law of the ECJ. Its first decision acknowledging that EC law would grant protection to property was the *Nold* decision in 1974.⁵⁸⁸ In its reasoning, the ECJ applied the common constitutional traditions of Member States⁵⁸⁹ and international conventions that Member States have acceded to as guidelines.⁵⁹⁰ This led the court to specifically refer to Article 1 of the Protocol to the ECHR in its following decisions.⁵⁹¹ Through this, the ECJ acknowledged that the acts and legislation of the Communities would impact on property rights which made it necessary that the EEC would adhere to its protection.

⁵⁸⁶ Christoph Grabenwarter and Katerina Pabel, *Europäische Menschenrechtskonvention* (5th edn, C.H. Beck, 2012) § 25 [2].

⁵⁸⁷ See 3.4.4.2.

⁵⁸⁸ Case 4/73 *Nold* [1974] ECR 491 [14]. In *Stauder* the ECJ has acknowledged that “Fundamental rights [are] enshrined in the general principles of Community law and protected by the Court.” - Case 29/69 *Stauder* [1969] ECR 419.

⁵⁸⁹ Case 4/73 *Nold* [1974] ECR 491[14].

⁵⁹⁰ The court acknowledged the importance of the ECHR’s protection for the protection of fundamental rights in the then European Communities - Joachim Wieland in Horst Dreier (ed), *Grundgesetz Kommentar - Bd I* (3rd edn, Mohr Siebeck 2013) Art 14 [20].

⁵⁹¹ Case 4/79 *Hauer* (ECJ 13 December 1979) [17].

Joachim Wieland in Horst Dreier (ed), *Grundgesetz Kommentar - Bd I* (3rd edn, Mohr Siebeck 2013) Art 14 [20]. The *Hauer* Decision of the ECJ specifically cites the provision of Article 1 of the Protocol. Additionally, the ECJ has held in the *Kadi* decision (Joined Cases C-402/05 P and C-415/05 P *Yassin Abdullah Kadi and Al Barakaat International Foundation v Council of the European Union and Commission of the European Communities* (ECJ Grand Chamber 03 September 2008)) that “According to settled case-law, the right to property is one of the general principles of Community law.” - *ibid* [355]. And that “In order to assess the extent of the fundamental right to respect for property, a general principle of Community law, account is to be taken of, in particular, Article 1 of the First Additional Protocol to the ECHR, which enshrines that right.” *ibid* [356].

The EU Charter's purpose is to signpost the fundamental rights framework that the EU wished to adapt and adhere to. This has led to the introduction of a provision that specifically acknowledged the fundamental right to property within Article 17 of the Charter. The notion of property is similar to the protection available under the ECHR⁵⁹² due to the fact that the EU applied the principles of the ECHR in drafting the provision within the Charter.⁵⁹³ Hence, the scope of protection for property that the Charter provides resembles to a great extent to that available under the Convention. This is based on the fact that the EU had already adopted the principles of the Convention by applying Article 6 of the EU Treaty.⁵⁹⁴

In relation to intellectual property, Article 17 provides in subsection two that "intellectual property shall be protected".⁵⁹⁵ Conversely to Subsection 1 of the provision which protects "possessions" in general, there is no limitation to the right of property by which the right may be interfered with. Subsection (1), on the other hand, specifically regulates under which circumstances the deprivation of property is permissible. The use of the property is also regulated and is allowed where it is "regulated by law in so far necessary for the general interest".

The similarity between Article 17 (1) and Article 1 of the 1st Protocol of the Convention can be attributed to the fact that the protection of property should follow the Convention's template. Article 17 (2) of the EU Charter then stands awkwardly in the text as it has no direct reference in the ECHR. This, albeit the case law of the ECtHR acknowledged that the subject matter of intellectual property would already fall within the scope of Article 1 of the 1st Protocol. Here it becomes important to introduce the provision of Article 53 (3) of the EU Charter as it plays an important role in interpreting the relationship of the fundamental rights as set out in the EU Charter and those in the ECHR. It reads as follows:

"In so far as this Charter contains rights which correspond to rights guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms, the meaning and scope of those rights shall be the same as those laid down by the said Convention. This provision shall not prevent Union law providing more extensive protection."

The rule seeks to provide consistency with the rules of the ECHR where the rights in both texts correspond to one another. The notion in Article 17 (2) could then be regarded as

⁵⁹² Norbert Bernsdorff in Jürgen Meyer (ed), *Charta der Grundrecht der Europäischen Union* (3rd edn, Nomos 2011) Artikel 17 [1].

⁵⁹³ The Charta explanations displayed Article 1 of the Protocol of the ECHR verbatim - Explanations relating to the Charter of Fundamental Rights [2007] OJ Official Journal of the European Union 303/23.

⁵⁹⁴ And its preceding provisions.

⁵⁹⁵ Before the provision came into existence the CJEU (or ECJ) did consider intellectual property as being protected under the fundamental right to property - C-200/96 *Metronome Music* (ECJ 28 April 1998) [22-23].

providing a more extensive protection for intellectual property. Since Subsection (2) only acknowledges IP as a fundamental right, the sentence does not provide the restrictions that subsection (1) of Article 17 provides.

The English reading of this provision is blurry when compared to the French and German version as Griffiths and McDonagh point out.⁵⁹⁶ The French version of Article 17 (2) states: “*La propriété intellectuelle est protégée*”, whereas the German version states: ‘*Geistiges Eigentum wird geschützt*’. This would translate to English in the fact that intellectual property *is* protected. Indeed, it could furthermore be interpreted that the intellectual property in all its aspects would receive fundamental right protection.⁵⁹⁷ Considerations of public interest that would curtail the right of the patent holder would then be difficult to apply with such a wide and unlimited scope of IP protection.

It has however, been held that the special reference to intellectual property in the EU Charter does not provide for any deviation from the rules that Article 1 of the Protocol to the ECHR has set out.⁵⁹⁸ The Declarations concerning Provisions of the Constitution specially mention that “(t)he guarantees laid down in paragraph 1 [of Article 17 of the EU Charter; added by author] shall apply as appropriate to intellectual property”.⁵⁹⁹ This extends not just to the guarantees of Subsection 1 but also to the limitations that can be provided according to subsection 1.⁶⁰⁰ This is supplemented by the CJEU’s finding that intellectual property is not protected absolutely.⁶⁰¹ In *Luksan v Petrus*,⁶⁰² the CJEU has referred to Article 17(1) Charter directly in relation to the protection of IP before it addressed Article 17(2) – “an explicit illustration on the part of the Court that IP clause of the Charter benefits from the more

⁵⁹⁶ Jonathan Griffiths and Luke McDonagh, ‘Fundamental Rights and European IP Law – the case of Art 17(2) of the EU Charter’ in Christophe Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (Edward Elgar, 2013) 80.

⁵⁹⁷ This would amount at a “maximalist” approach as Geiger and Izyumenko point out - Christophe Geiger and Elena Izyumenko, ‘Copyright on the Human Rights’ Trial: Redefining the Boundaries of Exclusivity Through Freedom of Expression’ [2014] IIC 316, 332.

⁵⁹⁸ Norbert Bernsdorff in Jürgen Meyer (ed), *Charta der Grundrecht der Europäischen Union* (3rd edn, Nomos 2011) Artikel 17 [15].

Ottolito states that a finding which would give intellectual property more protection than real property would appear “illogical” - Andrea Ottolito, *The Public Interest and Intellectual Property Models* (G. Giappichelli Editore 2010) 137.

⁵⁹⁹ OJ [2004] C 310/437.

⁶⁰⁰ Rudolf Streinz in Rudolf Streinz (ed), *EUV/AEUV - Vertrag über die Europäische Union und die Arbeitsweise der Europäischen Union* (2nd edn, C.H. Beck 2012) 2814.

⁶⁰¹ Case C-70/10 *Scarlet Extended SA v SABAM* (CJEU 24 November 2011).

⁶⁰² Case C-277/10 *Martin Luksan v Petrus van der Let* (ECJ 09 February 2012). See also – Case C-314/12 *UPC Telekabel* (CJEU 27 March 2014) [61].

general wording of Article 17(1).⁶⁰³ Finally, the CJEU also *expressis verbis* stated that IP protection would not be absolute.⁶⁰⁴

The special reference in relation to intellectual property was inserted in order to declare that intellectual property as such is considered to be property “because of its growing importance and Community secondary legislation.”⁶⁰⁵ Apart from this, it is considered as “one aspect of the right of property“.⁶⁰⁶ The Declarations continue to explain that Article 17 (2) of the Charter does not just covers “literary and artistic property but also inter alia patent and trademark rights and associated rights.”⁶⁰⁷ The provision does not just encompass the existence of property/possessions as such but specifically also refers to its use and disposal.

4.3.4 Sub-Conclusion

The development to include intellectual property and particularly patent rights within the scope of human rights is noticeable. Patent rights were not verbatim included as being protected as human rights in neither the UN declaration nor the ECHR. Courts in Europe however have acknowledged that patent rights would be protected under the human right of property.⁶⁰⁸ This evolution probably peaked with intellectual property verbatim being protected as a human right in Article 17 (2) of the EU Charter, and hence its positivisation. The human rights framework on international level however only stipulates that the material and immaterial interests of creators need to be protected but as Geiger rightly notes, this does not necessarily require protection through property rights.⁶⁰⁹

⁶⁰³ Christophe Geiger and Elena Izyumenko, ‘Copyright on the Human Rights’ Trial: Redefining the Boundaries of Exclusivity Through Freedom of Expression’ [2014] IIC 316, 334.

⁶⁰⁴ Case C-70/10 *Scarlet Extended SA v SABAM* (CJEU 24 November 2011) [430]; Case C-360/10 *SABAM v. Netlog* (CJEU 16 February 2012) [41]; Case C-314/12 *UPC Telekabel* (CJEU 27 March 2014) [61].

⁶⁰⁵ OJ.[2004] C 310/437.

⁶⁰⁶ *ibid* 437.

⁶⁰⁷ *ibid* 437.

⁶⁰⁸ Brinkhof provides a good point why patent rights were not considered in the drafting of the UDHR which was “driven by the desire to prevent a repeat of the unimaginable horror of the two world wars.” - Jan Brinkhof, ‘On patents and human rights’ in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) 150.

⁶⁰⁹ Christophe Geiger, ‘The Constitutional Dimension of Intellectual Property’ in Paul Torremans (ed), *Intellectual Property and Human Rights - Enhanced Edition of Copyright and Human Rights* (Kluwer Law International 2008) 112 (in footnote 51).

It is surprising that the European Commission of Human Rights acknowledged patents as being possession in the understanding of Article 1 of the Protocol because the Dutch Patent Act referred to patents as property. If one perceives human rights as positivised natural law, it can appear awkward that a human rights framework refers to positive ordinary law to explain why patents are considered to be possessions. This does not fit well within a classical thinking of human rights.⁶¹⁰ Furthermore, the Commission somewhat contradicts the case law of the Court which had been holding that the term “possessions” has an autonomous meaning when it bases its assessment of whether patents are such possessions only on the legal order of the Netherlands.⁶¹¹

The elevation of intellectual property as human/fundamental rights has been criticised.⁶¹² One point raised is that IP is considered to have a social utility⁶¹³ rather than deriving from a natural right.⁶¹⁴ The intrinsic problem with heightening patent rights onto the level of fundamental/human rights protection for providing exceptions to such rights then becomes obvious. In particular, it has two important ramifications for the purposes of this study: On the one hand, the status as a human right can be used as a rhetorical weapon against any curtailment of the right. This could make it more difficult for legislators or courts to limit the IP right for the purposes of public interest.⁶¹⁵ The other problem is a practical one with regards to legislative drafting of exceptions to patent rights. Their qualification as human rights means that legislators cannot arbitrarily curtail the right. Fortunately, the right to property is not provided without limitation. This means that legislators are allowed to interfere with the right to property – in patent terms: provide exceptions to patent rights.

⁶¹⁰ A classical understanding of human rights holds that they serve to protect human activities, i.e. individual freedom. This scope of protection precedes state activity. Protecting possessions as human rights then do not fit this paradigm well since it is the legislator that provides and defines the subject matter of the fundamental rights to property - Alexander Peukert, ‘The fundamental right to (intellectual) property and the discretion of the legislature’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 135 – 136.

⁶¹¹ Similarly - Henning Grosse Ruse-Khan, ‘Overlaps and conflict norms in human rights law: Approaches of European courts to address intersections with intellectual property’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 82.

⁶¹² Rochelle C. Dreyfuss, ‘Patents and human rights; where is the paradox’ in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) 73.

⁶¹³ Burk D L and Lemley M A, ‘Policy Levers in Patent Law’ [2003] *Virginia Law Review* 1575, 1580.

⁶¹⁴ In relation to copyright law - Michael Birnhack, ‘Acknowledging the conflict between copyright law and freedom of expression under the Human Rights Act’ [2003] *Entertainment Law Review* 24, 30.

⁶¹⁵ Birnhack states that intuitively one could come to the conclusion that property rights cannot be trumped by the public interest - Michael Birnhack, ‘Acknowledging the conflict between copyright law and freedom of expression under the Human Rights Act’ [2003] *Entertainment Law Review* 24, 30.

4.4 Interfering with the right to property - Public Interest Considerations

4.4.1 Introduction

As seen, both the Convention as well as the Charter, acknowledge the fundamental right to property. This guarantee has been held to extend to patent rights. Importantly, both pieces of legislation acknowledge that property may be interfered with, which means that while the owner should enjoy their property without constant interference by the state, property is not granted without limitations.⁶¹⁶ Legislators are able to interfere with property when this is in the public or general interest.⁶¹⁷ This stipulates that property and its guarantee serves the purpose to promote “the collective good of the society.”⁶¹⁸ When one translates this to intellectual property considerations, exceptions to patent rights can be regarded as interferences with the fundamental right of property of patent rights.⁶¹⁹ Since such interferences need to be in the general or public interest, exceptions would need to be based on such an interest.

The way that legislators may interfere with property can be twofold according to both pieces of legislation. Legislators may deprive the owner of its property which means expropriation.⁶²⁰ Such deprivation is only permissible according to the Convention where it is “in the public interest and subject to the conditions provided for by law and by the general principles of international law.” The Charter follows a similar wording by requiring that the

⁶¹⁶ “[I]n the case of *Sporrong and Lönnroth*, the Court analysed Article 1 (P1-1) as comprising “three distinct rules”: the first rule, set out in the first sentence of the first paragraph, is of a general nature and enunciates the principle of the peaceful enjoyment of property; the second rule, contained in the second sentence of the first paragraph, covers deprivation of possessions and subjects it to certain conditions; the third rule, stated in the second paragraph, recognises that the Contracting States are entitled, amongst other things, to control the use of property in accordance with the general interest...” - *Case of James and Others v United Kingdom* App no 8793/79 (ECtHR, 21 February 1986) [37].

In relation to the EU Charter Article 17 (1) provides that the right to property may be interfered with in certain circumstances. The provision provides rules of how such interference may be justified within a sliding scale that depends on the impact on the right, from a deprivation of the right to the mere use of property - Jonathan Griffiths and Luke McDonagh, ‘Fundamental Rights and European IP Law – the case of Art 17(2) of the EU Charter’ in Christophe Geiger (ed), *Constructing European Intellectual Property: Achievements and New Perspectives* (Edward Elgar 2013) 81.

⁶¹⁷ Art 1 of Protocol 1 ECHR; Article 17(1) EU Charter.

⁶¹⁸ Ali Riza Çoban, *Protection of Property Rights within the European Convention on Human Rights* (Ashgate 2004) 137.

⁶¹⁹ *In Smith Kline and French Laboratoires Ltd v The Netherlands* App no 12633/87 (Commission Decision, 04 October 1990).

⁶²⁰ Article 1 (1) 2nd sentence of Protocol 1 of the ECHR and Article 17(1)(2) EU Charter.

deprivation is in the public interest. It adds that deprivation can only occur where it is “subject to fair compensation being paid in good time for [the owner’s] loss.”⁶²¹

Apart from being able to deprive owners of their possessions, legislators are permitted to regulate the use of property.⁶²² The control of use has a lesser impact on the right to possessions than its deprivation. Based on the lesser degree of impact on the right, the conditions to regulate property are less strict and are available without compensating the owner. Similarly to the situation with the ECHR and the case law of the courts of EU Member States, the regulation of use of property may also be based to protect the rights or freedom of others within the EU Charter.⁶²³ This is now specifically provided within Article 52 (1) 2 of the EU Charter.⁶²⁴ The wording of the provision (“the need to protect the rights and freedoms of others”) is broad which means that all rights of others can be taken into the equation.⁶²⁵ The applicability of this rule in relation to the more specific rules on limiting the right to property in Article 17 is however disputed.⁶²⁶

The question then arises whether exceptions to patent rights have to be qualified as depriving property or whether they constitute a mere regulation thereof. This constitutes an important query: A different threshold with regards to what public or general interest considerations need to be established depending on which category of interference exceptions to patent rights can be subsumed. Arguably, the threshold for regulation of possessions is lower than that for deprivation.

⁶²¹ This is a notable distinction from the corresponding provision in Article 1 of the Protocol that does not have such a specific regulation of when a deprivation may occur. It appears however that the ECtHR has a tendency to acknowledge that deprivation needed to be compensated - Sebastian Heselhaus in Sebastian M. Heselhaus and Carsten Nowak, *Handbuch der Europäischen Grundrechte* (C.H. Beck Verlag 2006) §32 [73].

⁶²² Article 1 (2) of Protocol 1 of the ECHR and Article 17(1)(3) EU Charter.

⁶²³ Sebastian M. Heselhaus and Carsten Nowak, *Handbuch der Europäischen Grundrechte* (C.H. Beck Verlag 2006) §32 [81].

⁶²⁴ ”Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.”

⁶²⁵ Sebastian M. Heselhaus and Carsten Nowak, *Handbuch der Europäischen Grundrechte* (C.H. Beck Verlag 2006) § 32 [81]. The author mentions in the footnote that the ECJ has not yet been called to adjudicate a collision of fundamental rights. It however has been called to adjudicate collisions with the fundamental freedoms of the Union.

⁶²⁶ The use of this general rule of limiting fundamental rights is not barred because of Article 52 (3) EU Charter because it provides a higher level of protection than the ECHR - Sebastian M. Heselhaus and Carsten Nowak, *Handbuch der Europäischen Grundrechte* (C.H. Beck Verlag 2006) § 32 [79].

4.4.2 Deprivation

According to the case law of the ECtHR, deprivation of property is given where a formal deprivation of property has taken place. This is generally provided with a transfer of ownership.⁶²⁷ Deprivation therefore includes measures such as expropriations, nationalizations, confiscations and other comprehensive dispositions.⁶²⁸ The Court acknowledged that the ECHR aims to guarantee rights in a “practical and effective”⁶²⁹ way. This expands its protection to *de facto* deprivations of property. Such a *de facto* deprivation occurs where the effects of an intervention are as economically taxing as a formal deprivation.⁶³⁰ The Court has held that a situation would not be considered as such *de facto* deprivation where the property right loses only some of its substance but does not disappear as such. In such circumstances, the owner is still able to use their possessions in a meaningful way. This would not amount to depriving property but the control of its use which would fall under second paragraph of Article 1 of the Protocol.

Article 17 (1) of the EU Charter provides that a deprivation in the public interest can take place when an adequate compensation is paid. Bearing in mind that the Charter follows the principles of the ECHR, the approach here resembles that of the ECHR. Conversely to the EU Charter on Fundamental Rights that specifically states in Article 17 (1) that a deprivation can only take place where this is “subject to fair compensation being paid in good time for their loss”, the ECHR does not specifically provide that a deprivation of possessions needs to be remunerated.⁶³¹ The case law of the ECtHR however has formulated that such compensation should be paid where a deprivation takes place.⁶³² The court has furthermore held that not just in relation to interferences in regards to deprivation of possession but there

⁶²⁷ Hans-Werner Rengeling and Peter Szczekalla, *Grundrechte in der Europäischen Union – Charta der Grundrechts und Allgemeine Rechtsgrundsätze* (Carl Heymanns Verlag 2004) § 20 [820].

⁶²⁸ Lawrence Helfer, ‘The New Innovation Frontier? Intellectual Property and the European Court of Human Rights’ in Paul Torremans (ed), *Intellectual Property and Human Rights - Enhanced Edition of Copyright and Human Rights* (Kluwer Law International) 34.

⁶²⁹ *Case of Airey v. Ireland* App no 6289/73 (ECtHR, 09 October 1979) [24].

⁶³⁰ *Case of Sporrang and Lönnroth v. Sweden*, App no 7151/75, 7152/75 (ECtHR, 23 September 1982) [63].

See: Hans-Werner Rengeling and Peter Szczekalla, *Grundrechte in der Europäischen Union – Charta der Grundrechts und Allgemeine Rechtsgrundsätze* (Carl Heymanns Verlag 2004) § 20 [820]; Norbert Bernsdorff in Jürgen Meyer (ed), *Charta der Grundrecht der Europäischen Union* (3rd edn, Nomos 2011) Artikel 17 [20].

⁶³¹ This is a notable distinction from the corresponding provision in Article 1 of the Protocol that does not have such a specific regulation of when a deprivation may occur.

⁶³² *Case of James and Others v United Kingdom* App no 8793/79 (ECtHR, 21 February 1986) [54].

is an expectation that such compensation is also paid in relation to other forms of interferences.⁶³³

In relation to exceptions to patentee's rights, the question arises whether they would amount to a *de facto* deprivation or a regulation of use of the patent. What is clear is that an exception does not amount to a formal deprivation of the property in a patent: No transfer of the patent right is conducted that would amount to the formal deprivation of the right when applying an exception. The patent holder still remains the proprietor of the right. So exceptions could either be regarded as a *de facto* deprivation or a regulation of use. The distinction between both interferences is important since deprivation will entail compensating the right holder while regulation of use may not. There however, is not a straight forward answer to this question as it is highly fact specific and will apply to the specific right holder (or moreover the technology covered by the right) and the extent of use that the exception permits.⁶³⁴

In comparison to tangible property, the assessment of whether the possession of an intellectual property right has been deprived from its owner is influenced by the specific nature of the subject matter encompassed by the intellectual property right. This is due to their intrinsic nature as a public good: An owner cannot be deprived of the information that underlies the patented invention as he will always be able to use it. The question therefore needs to be approached by looking at whether the patent right is being deprived by the interference. In other words, when does the curtailment of a patent right by an exception render it to be a deprivation of the property right?

This assessment needs to be conducted while bearing in mind that a patent conveys a bundle of rights to their proprietors. The question may also be related to what use the exception permits. Often an exception provision is provided for a specific purpose such as an experimental purpose or for private uses. These conditions under which an exception may apply do not generally permit the use of the patented invention. Only under these particular circumstances may an unauthorised use by a third party be exempted from patent infringement. This conditioning inhibits that patent owners are totally deprived from their

⁶³³ Mark W. Janis, Richard S. Kay and Anthony W. Bradley (eds), *European Human Rights Law* (3rd edn, OUP 2008) 554.

⁶³⁴ Additionally, the European Commission on Human Rights has held in *In Smith Kline and French Laboratoires Ltd v The Netherlands* that the compulsory license in suit was a control of the use of property - *In Smith Kline and French Laboratoires Ltd v The Netherlands* App no 12633/87 (Commission Decision, 04 October 1990). This means that even where compensation is paid to the patent holder for an unauthorised use through the licence fee this does not amount for a compulsory licence to be considered as a *de-facto* deprivation of the property for the purposes of Article 1 of the 1st Protocol to the ECHR.

rights. This may also depend on how broad the permitted use is being drafted. All these considerations stipulate that exception generally do not constitute a *de facto* deprivation of the patent right but regulate the right.

Another point in favour of regarding exceptions to patent rights as regulations of property is the finding of the German Federal Constitutional Court. It held that the research exception as codified in § 11 Nr. 2 of the German Patent Act are regulating property.⁶³⁵ The German Basic Law provides for similar provisions regarding the deprivation of property; the German Federal Constitutional Court however did not consider the exception provision of § 11 Nr. 2 PatG as a deprivation. It rather made the statement of it being a regulation of the property right at the very beginning of its reasoning. Since the protection of property as a fundamental/human rights follows a similar pattern with regard on how interferences are treated, it can be argued that exceptions such as § 11 Nr. 2 PatG are regulations of property in the understanding of the ECHR. This is relevant since § 11 Nr. 2 PatG is modelled on Article 31 CPC 1975 which has been transposed into the patent legislations of other European jurisdiction, *inter alia*, in the United Kingdom with Sec. 60(5)(b) UK Patents Act 1977.⁶³⁶

4.4.3. Regulating the use of property

The second category of interferences that the Charter and the Convention provide for is the regulation of possessions. Within Article 17 (1) 3 of the Charter permits the regulation of use of property when this is necessary for the general interest.⁶³⁷ This provision mirrors that of Article 1 (2) of the Protocol. Importantly and conversely to the deprivation of property, the use thereof may be regulated without having to compensate the owner for the interference. The regulation must in both cases be in accordance with the law, follow a legitimate aim and must be proportionate. Since exceptions cannot be regarded as deprivation, they can only be seen as regulating possessions. Hence, the criteria surrounding the regulation of possessions need to be applied when assessing conformity of an exception provision with the Charter/Convention.

⁶³⁵ BVerfG GRUR, 2001, 43- Klinische Versuche: “§11 Nr. 2 PatG ... stellt jedoch eine zulässige Bestimmung des Inhalts und der Schranken des Eigentums i.S. von Art. 14 I 2 GG dar.” (Translation: § 11 Nr 2 constitutes a permissible regulation of the content and limitation of property) - supra 3.4.4.4.

⁶³⁶ supra 3.2.

⁶³⁷ During the consultation on the Convent on the EU Charter this provision was titled as “provision on the social function of property” - Norbert Bernsdorff in Jürgen Meyer (ed), *Charta der Grundrecht der Europäischen Union* (3rd edn, Nomos 2011) Artikel 17[21].

4.4.4 The Public Interest in interfering with property/possessions

Both the deprivation and regulation of property must be justified. Article 17 (1) Charter, as well as Article 1 of the 1st Protocol to the ECHR, provide for conditions that need to be present when interfering with property. One of these conditions is that the interference must be conducted in accordance with the law. Additionally, it must be based on a legitimate aim, in other words public or general interest considerations.⁶³⁸ Finally, as an unwritten condition, the interference must be proportionate, i.e. it must follow a fair balancing of the interests involved in protecting the property.⁶³⁹ The interests involved are those of the proprietor and that of the public.

The absence of such a legitimate aim, i.e. the lack of a public interest underlying the interference, would violate Article 1 of the Protocol.⁶⁴⁰ What is important is that the Court has left it to the state to identify what the public or common interest is that the interference is based on.⁶⁴¹ Furthermore and equally important, the Court has held that States have a considerable margin of appreciation in assessing what lies within the public interest.⁶⁴² These findings can also be transposed to the situation within the EU Charter.⁶⁴³ A wide margin of appreciation is particularly provided in the political, social and economic fields.⁶⁴⁴

This wide scope that public authorities or national legislator can apply are based on the fact that it was acknowledged that the question of what constitutes the public interest can be better assessed by national authorities.⁶⁴⁵ In relation to the human rights framework that the ECHR sets up, this can be explained by the fact that its protection is considered as a subsidiary to

⁶³⁸ The Court tends to use these two terms largely synonymously - Doris König, 'Der Schutz des Eigentums im europäischen Recht' in Otto Depenheuer (ed), *Eigentum – Ordnungsidee, Zustand, Entwicklungen* (Springer 2005) 121. See also - David Harris, Michael O'Boyle and Colin Warbrick, *Law of the European Convention on Human Rights* (2nd edn, OUP 2009) 668.

⁶³⁹ *Case of Spjornog and Lönnroth v. Sweden* App no 7151/75, 7152/75 (ECtHR, 23 September 1982) [69]

⁶⁴⁰ David Harris, Michael O'Boyle and Colin Warbrick, *Law of the European Convention on Human Rights* (2nd edn, OUP 2009) 668.

⁶⁴¹ *ibid* 667.

⁶⁴² *Case of Handyside v UK*, App no 5493/72 (ECtHR, 07 December 1976) [62].

⁶⁴³ Norbert Bernsdorff in Jürgen Meyer (ed), *Charta der Grundrecht der Europäischen Union* (3rd edn, Nomos 2011) Artikel 17[22].

⁶⁴⁴ Karen Kaiser in Ulrich Karpenstein and Franz C. Mayer (eds), *EMRK – Kommentar zum Schutz der Menschenrechte und Grundfreiheiten* (C.H. Beck 2012) Art. 1 ZP I [36].

⁶⁴⁵ "..., State authorities are in principle in a better position than the international judge to give an opinion on the exact content of these requirements as well as on the "necessity" of a "restriction" or "penalty" intended to meet them." – *Case of Handyside v UK* App no 5493/72 (ECtHR, 07 December 1976) [48].

national fundamental rights aiming at protecting human rights.⁶⁴⁶ This means that as long as the legitimate aim “relates to the justification and motives for the actual taking” then the interference would not fall afoul of Article 1.⁶⁴⁷

The public interest can justify the interference where its beneficiaries are not the general public but individuals. The ECtHR held: “(A) taking of property effected in pursuance of legitimate social, economic or other policies may be “in the public interest”, even if the community at large has no direct use or enjoyment of the property taken.”⁶⁴⁸ This means “that states have a wide power to interfere with property rights in the general and social and economic interest, even where the benefits fall to the advantage of particular individuals.”⁶⁴⁹

This is an important point with regards to exceptions to patent rights. It actually enables exception provisions such as those found in § 11 PatG or within Article 60(5) UK Patents Act 1977.⁶⁵⁰ This is because the exempted uses are usually conducted by private individuals or legal entities. A narrow understanding of the term “public interest” would make such private uses difficult if not impossible. What is important is that the purpose of the exception is based on a legitimate public interest which is the case with exceptions to patentee’s rights.⁶⁵¹

What additionally leaves leeway for public interest considerations is the fact that property in the fundamental/human rights context is given a social function.⁶⁵² According to the case law of the ECJ, the right to property does not prevail against other legal interests but must be assessed by bearing its social function in mind.⁶⁵³ In the consultation of the EU Charter, the regulation of the use of property was discussed under the notion social “function of property.”⁶⁵⁴ Streinz argues that since these uses are considered as being based on the social

⁶⁴⁶ S.J. Bailey, J.P.L. Ching and N.W. Taylor, *Smith, Bailey and Gunn on the Modern English Legal System* (5th edn, Sweet and Maxwell 2007) [8-004].

⁶⁴⁷ David Harris, Michael O’Boyle and Colin Warbrick, *Law of the European Convention on Human Rights* (2nd edn, OUP 2009) 669 referring to *Lithgow v United Kingdom* App no 9006/80; 9262/81; 9263/81; 9265/81; 9266/81; 9313/81; 9405/81 (ECtHR, 08 July 1986).

⁶⁴⁸ *Case of James and Others v United Kingdom* App no 8793/79 (ECtHR, 21 February 1986) [39-45].

⁶⁴⁹ David Harris, Michael O’Boyle and Colin Warbrick, *Law of the European Convention on Human Rights* (2nd edn, OUP 2009) 695.

⁶⁵⁰ See Chapter 3.

⁶⁵¹ *supra* 3.6.

⁶⁵² Christophe Geiger and Elena Izyumenko, ‘Copyright on the Human Rights’ Trial: Redefining the Boundaries of Exclusivity Through Freedom of Expression’ [2014] IIC 316, 333.

⁶⁵³ “If rights of ownership are protected by the constitutional law of all the Member States and if similar guarantees are given in respect of their right freely to choose and practice their trade or profession, the rights thereby guaranteed, far from constituting unfettered prerogatives, must be viewed in the light of the social function of the property and activities protected thereunder.” - Case 4/73 *Nold* [1974] ECR 491 [14].

⁶⁵⁴ Norbert Bernsdorff in Jürgen Meyer (ed), *Charta der Grundrecht der Europäischen Union* (3rd edn, Nomos 2011) Article 17 [21].

function, no compensation needs to be paid to the owner.⁶⁵⁵ This could explain the fact that purpose of unremunerated exceptions to patent rights as fulfilling a purpose in the public interest.

4.5 Collision of fundamental rights

The individual interests surrounding the third party use of a patent which are considered to be in the public interest can now themselves be based on a fundamental right. In this scenario two fundamental/human rights conflict with one another. And such conflicts can commonly be placed within the patent rights and exceptions conundrum, especially with regards to the research exception that has been discussed as a case study throughout this work. With this respect, the German Federal High Court explained in its *Clinical Trials I* Decision that patent protection is not unlimited.⁶⁵⁶ It has specifically held that the drafters of the Community Patent Convention have balanced the interest of the patent holder with the public interest by having taken account of “the principle of freedom of research”⁶⁵⁷ with Article 31 CPC 1975.

This intrinsic conflict of human or fundamental rights in relation to patent rights and freedom of research is already stipulated within the ICESCR. The Convention provides that “the freedom indispensable for scientific research and creative activity” would need to be respected by the States Parties within its Article 15(3). Some EU Member States have for instance positively codified a fundamental right for scientific freedom⁶⁵⁸ but the scope and the extent of the freedom of scientific research however varies substantially.⁶⁵⁹ In some instances, the subject matter of scientific freedom is regulated within ordinary laws.⁶⁶⁰ Since the scope of the rights throughout EU Member States differs and a clear template deriving

⁶⁵⁵ Rudolf Streinz in Rudolf Streinz (ed), EUV/AEUV - Vertrag über die Europäische Union und die Arbeitsweise der Europäischen Union (2nd edn, C.H. Beck 2012) 2813.

⁶⁵⁶ supra 3.4.4.4.

⁶⁵⁷ BGH, GRUR 1996, 109 (114) - Klinische Versuche I = BGH, RPC 1997, 623 (643) - Clinical Trials I.

⁶⁵⁸ For instance Italy (Article 33 of the Constitution of the Italian Republic), Spain (Article 20(1)(c) of the Spanish Constitution), Germany (Article 5(3) of the German Basic Law).

⁶⁵⁹ Sebastian M. Heselhaus and Carsten Nowak, *Handbuch der Europäischen Grundrechte* (C.H. Beck Verlag 2006) § 26 [49].

⁶⁶⁰ *ibid* § 26 [49].

from the ECHR is missing, scientific freedom cannot be considered to be as a common source of constitutional traditions within EU Member States that the ECJ often refers to.⁶⁶¹

In relation to the ECHR and the EU Charter, this conflict is also present. Regarding the ECHR, the freedom of expression in Article 10 only contains certain aspects relating to the freedom of science. It was acknowledged that Article 10 ECHR would cover the communicative aspects of the freedom of science of scientists in receiving and disseminating ideas and information.⁶⁶² Since patent laws generally require that the patented invention needs to be disclosed and available, this aspect is covered by the ordinary law. The disclosure of the patented invention is at the heart of patent law.

Grabenwarter and Pabel however, state that Article 10 not just covers the freedom of the scientist of scientific expression by publications and lectures.⁶⁶³ The freedom is more extensive as it does not just cover the communicative element of research in receiving and imparting information but moreover the activities to achieve scientific findings.⁶⁶⁴ This interpretation would make it possible to regard experimental use of a patented invention as being covered by the fundamental right of freedom of expression. This stipulates that the conflict that the German Federal High court analysed could also occur within the Convention.⁶⁶⁵ But such an interpretation of the freedom of expression has not yet been discussed by the ECtHR as of yet.⁶⁶⁶ And Mensching argues against such an interpretation as pure research activities would lack a communicative act which would constitute the protected acts in Article 10.⁶⁶⁷

A wide interpretation of the freedom of expression is not unthinkable. It could be based on the principle that the ECHR is as living instrument. The court applies a dynamic-teleological interpretation of the ECHR which means that it analyses the provisions under its current

⁶⁶¹ Sebastian M. Heselhaus and Carsten Nowak, *Handbuch der Europäischen Grundrechte* (C.H. Beck Verlag 2006) § 26 [50]. It is however argued that the core of scientific freedom is acknowledged to be a European fundamental right.

⁶⁶² *ibid* § 26 [9].

⁶⁶³ Christoph Grabenwarter and Katerina Pabel, *Europäische Menschenrechtskonvention* (5th edn, C.H. Beck, 2012) § 23 [12].

⁶⁶⁴ *ibid* § 23 [12]; Anne Peters and Tilmann Altwicker, *Europäische Menschenrechtskonvention* (2nd edn, C.H. Beck 2012) § 13 [1].

⁶⁶⁵ The EU Charter has a special provision protecting the freedom of science in its Article 13.

⁶⁶⁶ Peters and Altwicker link this to the fact that research is still primarily organised nationally - Anne Peters and Tilmann Altwicker, *Europäische Menschenrechtskonvention* (2nd edn, C.H. Beck 2012) § 13 [1].

⁶⁶⁷ Christian Mensching in Ulrich Karpenstein and Franz C. Mayer (eds), *EMRK – Kommentar zum Schutz der Menschenrechte und Grundfreiheiten* (C.H. Beck 2012) Art. 10 [24].

rationale and purpose.⁶⁶⁸ Additionally, the explanation of the freedom of science regulated within Article 13 of the EU Charter saw this right as being “deduced primarily from the right to freedom of thought and expression.”⁶⁶⁹ This renders the freedom of science as being originally based on the freedom of expression. Perceived as subsequent development, this could lead to an extensive interpretation of Article 10 ECHR as including research activities.

While the subsumption of research activities under Article 10 of the ECHR remains questionable, the Charter provides for a specific fundamental right of freedom of science in its Article 13. It has been argued that this right would cover all activities relating to research including preparatory and assisting activities, but exclude activities that entail the sheer application of already available knowledge.⁶⁷⁰ It is questionable whether this freedom would contain the commercial exploitation of the results of research.⁶⁷¹

It is submitted that a collision of the right of the patent holder based on his property right and that of the user wishing to enjoy freedom of science is generally possible on the human/fundamental right level. This requires the conflict between these fundamental rights to be accommodated in a proportionate manner.⁶⁷² The doctrine of proportionality is covered within Article 52 (1) of the Charter and is case law within the Convention.⁶⁷³ It undertakes its proportionality test not by analysing whether the interference is suitable and necessary, but only assesses the proportionality in *strictu sensu*, i.e. whether the interference establishes a fair balance between the public interest and the right of the property owner.⁶⁷⁴

This proportionality test has been discussed in cases involving intellectual property. In *Promusicae*,⁶⁷⁵ the CJEU has held that “Member States must, when transposing the directives mentioned above, take care to rely on an interpretation of the directives which allows a fair

⁶⁶⁸ *Case of Golder v United Kingdom* App no 4451/70 (ECtHR, 21 February 1975) [36].

⁶⁶⁹ Official Journal of the European Union 14.12.2007, C 303/22.

⁶⁷⁰ Hans D. Jarass, *Charta der Grundrechte der Europäischen Union* (2nd edn, C.H. Beck 2013) Art. 13 [7].

⁶⁷¹ *ibid* Art. 13 [7].

⁶⁷² “[A]ny claim by an author or inventor to a ‘human right’ benefit from her work must be limited by the countervailing human rights of the public.” - Wendy J. Gordon, ‘Current patent law cannot claim the backing of human rights’ in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) 159.

⁶⁷³ *supra* 4.4.1.

⁶⁷⁴ Doris König, ‘Der Schutz des Eigentums im europäischen Recht’ in Otto Depenheuer (ed), *Eigentum – Ordnungsidee, Zustand, Entwicklungen* (Springer 2005) 121-122.

⁶⁷⁵ Case C-275/06 *Productores de Música de España (Promusicae) v Telefónica de España SAU* (ECJ 29 January 2008).

balance to be struck between the various fundamental rights protected by the Community legal order.”⁶⁷⁶

In *SABAM*, the Court revisits its argumentation from *Promusicae* when it states that “the protection of the fundamental right to property, which includes the rights linked to intellectual property, must be balanced against the protection of other fundamental rights.”⁶⁷⁷

In paragraphs 45 and 46, the court elaborates on the notion in *Promusicae* that a balance needs to be established between the intellectual property right and other conflicting fundamental rights. It adds: “More specifically, it follows from paragraph 68 of that judgment that, in the context of measures adopted to protect copyright holders, national authorities and courts must strike a fair balance between the protection of copyright and the protection of the fundamental rights of individuals who are affected by such measures.”⁶⁷⁸

If one applies the understanding of the fundamental right discourse of property in the property/interference to patent rights and exceptions thereof, then one can see the balancing exercise that legislators had in mind. The proportionate balancing of the interests between patent holder and third parties where both interests are grounded on fundamental rights ultimately serves the public interest.⁶⁷⁹ It accommodates the conflicting interests and wishes to alleviate tensions between these interests. Van Overwalle states that “[h]uman rights can be factored in to patent law, through the gateway of public interest. A post-modern interpretation of public interest will prove to offer a more than skeletal basis for taking into account human rights in patent law, and to have prompted new human rights standards in the patent law system.”⁶⁸⁰ Additionally, Vaver and Basheer add that “[h]uman rights may adjust to intellectual property in some respects, but so must intellectual property rights adjust to them.”⁶⁸¹

⁶⁷⁶ Case C-275/06 *Productores de Música de España (Promusicae) v Telefónica de España SAU* (ECJ 29 January 2008) [68].

⁶⁷⁷ Case C-70/10 *Scarlet Extended SA v SABAM* (CJEU 24 November 2011) [44].

⁶⁷⁸ *ibid* [45].

⁶⁷⁹ In relation to German law - *supra* 3.4.4.6.

⁶⁸⁰ Geertrui van Overwalle, ‘Human rights’ limitation in patent law’ in Willem Grosheide (ed), *Intellectual Property and Human Rights – A Paradox* (Edward Elgar 2010) 238.

⁶⁸¹ David Vaver and Shamnad Basheer, ‘Popping patented pills: Europe and a decade's dose of TRIPs’ [2006] EIPR 290.

4.6 Shifting the discourse - Property as interferences of human rights

The ordinary IP and human rights discourse is led from the starting point with the right to property that is being interfered with. In patent terms, this would translate that exceptions interfere with the patent right. As already mentioned, this could lead to a certain bias in favour of safeguarding the human right of the patent holder which is based, for instance, on the fact that Article 1 of the Protocol sets out the common principle that property is to be respected.⁶⁸² The other two principles, which provide for the possibility to interfere with the right to property, however need to acknowledge this principle as they “are to be construed in the light of the general principle laid down in the first rule.”⁶⁸³

What may change the discourse is the fact that there is no hierarchy between fundamental/human rights as each share equal importance. Often, the underlying interests of a third party can be based on a fundamental right itself as has been elaborated. This leads to the above mentioned collisions of fundamental rights and then to balance both interests proportionally. But a recent development may alter the classical discourse fundamentally. The ECtHR has recently assessed the IP/Human Rights discourse not from the classical perspective of possessions/interference but rather has seen intellectual property and its enforcement as interferences with other fundamental rights, i.e. freedom of expression.⁶⁸⁴

*Ashby Donald v France*⁶⁸⁵ is such a case. Rather than in previous cases before the ECtHR that dealt with intellectual property, it did not discuss as to whether intellectual property would fall or whether there would be an interference with that right which needed justification. *Ashby Donald v France* argued that the enforcement of intellectual property rights could constitute an interference with the right to freedom of expression. For the first

⁶⁸² Anne Peters and Tilmann Altwicker, *Europäische Menschenrechtskonvention* (2nd edn, C.H. Beck 2012) § 32 [2]; Jens Meyer-Ladewig, *EMRK – Europäische Menschenrechtskonvention* (3rd edn, Nomos 2011) Zusatzprotokoll zur EMRK Artikel 1 [2].

⁶⁸³ *Case of the Former King of Greece and others v. Greece* App no 25701/94 (ECtHR (Grand Chamber) 23 November 2000) [50].

⁶⁸⁴ Helfer states “that Strasbourg judges may one day conclude that national IP laws transgress these principles and thus violate the right to freedom of expression protected by the European Convention on Human Rights (ECHR)” – Lawrence Helfer, ‘Mapping the interface between human rights and intellectual property’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 7.

⁶⁸⁵ *Case of Ashby Donald and others v France* App no 36769/08 (ECtHR, 10 January 2013).

time the Court discusses whether copyright interferes with freedom of expression.⁶⁸⁶

Torremans states that based on this decision that:

There has to be a balancing exercise between the fundamental rights involved. The fact that copyright has internalised aspects of freedom of expression does not eliminate the need for a balancing exercise. It merely reduces the problem, cuts off some sharp edges and makes the outcome predictable in a large number of cases.⁶⁸⁷

Geiger and Izyumenko observe that “the ECtHR’s pronouncement that even illegal and profitmaking sharing of copyright-protected material is not deprived of freedom of expression guarantees denotes a prominent and important shift.”⁶⁸⁸ By this, they mean that the Court’s approach in *Ashby* could mean that “the often alleged immunity of IP from any external freedom of expression scrutiny is progressively being dislodged.”⁶⁸⁹ Geiger and Izyumenko pinpoint the Courts’ new approach out by saying that “the rule becomes the exception and the exception becomes the rule.”⁶⁹⁰ What the court meant is that freedom of expression may sometimes be provided even when the use is considered to be illegal, i.e. infringing.

This could mean that even where a use is infringing according to IP legislation, it may be covered by freedom of expression and hence may warrant the modification of the exclusive rights of IP rights holders. Both *Ashby* and the subsequent case with this regards *Frederik Neij and Syunde Kolmisoppi v Sweden*⁶⁹¹ (the Pirate Bay case) stipulate that the responding state would have to balance the right of the IP holder with that of the user.⁶⁹² Additionally, both cases maintain that the state has a wider margin of appreciation to with this balancing

⁶⁸⁶ Geiger and Izyumenko state with this regards that “[m]eanwhile, unconditionally equating IP protection with the Convention-granted right to property disregards the idea of the “restrictive coverage” of the human right to property. In fact, the latter should not extend to “all forms of economic rights as protected in the existing intellectual property system, but rather [to] the limited interests of authors and inventors in obtaining just remuneration for their intellectual labour.” - Christophe Geiger and Elena Izyumenko, “Copyright on the Human Rights’ Trial: Redefining the Boundaries of Exclusivity Through Freedom of Expression” [2014] IIC 316, 331.

⁶⁸⁷ Paul Torremans, ‘Ashby Donald and others v France, application 36769/08, EctHr, 5th section, judgment of 10th January 2013’ [2014] QMJIP 95, 98.

⁶⁸⁸ *ibid* 339.

⁶⁸⁹ *ibid* 339.

⁶⁹⁰ *ibid* 325.

⁶⁹¹ *Case of Frederik Neij and Sunde Kolmisoppi v Sweden* App no 40397/12 (ECtHR 19th February 2013).

⁶⁹² Henning Grosse Ruse-Khan, ‘Overlaps and conflict norms in human rights law: Approaches of European courts to address intersections with intellectual property’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 87.

exercise.⁶⁹³ This may lead to the mentioned shift away from the old rule exception paradigm⁶⁹⁴ to a more unbiased assessment of conflicting rights.⁶⁹⁵

The question remains how this new approach alters the assessment of public interest considerations with regards to exceptions affects national patent policy. Grosse Ruse-Khan posits the wide margin of appreciation given to Convention States in order to balance competing fundamental rights would “prioritise the balancing conducted on the national level and thereby the norms national authorities rely on.”⁶⁹⁶ It appears that the human rights discourse before the ECtHR would then not substantively curtail Convention States to adopt public interest considerations within their exception provisions.

This new approach would render Ottolito’s remark obsolete whereby the fundamental rights discourse would not aim at providing an “interpretive balance”⁶⁹⁷ that would lead to “a reason to modify existing law but to assess the legality of a pre-existing national limitation.”⁶⁹⁸ What would be possible is that the underlying purposes of exception provisions would not need to be assessed narrowly. Rather, it seems that when the purpose of an exception can be based on a fundamental right then it is mandated to apply the right and aiming at providing a proportionate balance with the right of the patent holder.

⁶⁹³ *Frederik Neij and Sunde Kolmisoppi v Sweden* App no 40397/12 (ECtHR 19th February 2013).

⁶⁹⁴ Geiger and Izyumenko criticise “the generality of the premise that copyright is protected by the human right to property and the overall protection that seems to be granted to all aspects of IP.” - Christophe Geiger and Elena Izyumenko, ‘Copyright on the Human Rights’ Trial: Redefining the Boundaries of Exclusivity Through Freedom of Expression’ [2014] IIC 316, 332.

⁶⁹⁵ By referring to case law of the ECtHR, the European Copyright Society has mentioned with this regards that “any exception to freedom of expression under the Convention, including the protection of copyright, must itself “be narrowly interpreted” and the necessity for any restrictions must be convincingly established.” - Christophe Geiger, Jonathan Griffiths, Martin Senftleben, Lionel Bently and Raquel Xalabarder, ‘Limitations and Exceptions as Key Elements of the Legal Framework for Copyright in the European Union – Opinion of the European Copyright Society on the Judgment of the CJEU in Case C-201/13 Deckmyn’ [2015] IIC 93, 98.

⁶⁹⁶ Henning Grosse Ruse-Khan, ‘Overlaps and conflict norms in human rights law: Approaches of European courts to address intersections with intellectual property’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 87.

⁶⁹⁷ Andrea Ottolito, *The Public Interest and Intellectual Property Models* (G. Giappichelli Editore 2010) 135.

⁶⁹⁸ *ibid* 136.

4.7 Application of the Human Rights Act 1998 to intellectual property law in the UK

4.7.1. Introduction

The Human Rights discourse within the ECHR is of particular importance in the UK. However, the impact that the Human Rights Act 1998 would have on intellectual property law in general and patent law in particular in the United Kingdom was uncertain. Its influence in the jurisprudence of courts has however become noticeable: British Courts have handed down decisions that consider the Human Rights Act 1998 in relation to intellectual property rights. There is however, no case in relation to patent law as of yet that discusses the fundamental rights discourse between patent rights and exceptions applying the HRA 1998. Yet, there have been cases decided in relation to copyright law that can be applied, though with the necessary caution that analogies to patent law may not be easily established.

4.7.2 Ashdown v Telegraph Ltd

In relation to copyright law, an important decision was handed down by the Court of Appeal in *Ashdown*⁶⁹⁹ which discusses the influence of the HRA 1998 on exception provisions.⁷⁰⁰ The decision surrounded the publication of a diary of Paddy Ashdown, the former party leader of the Liberal Democrats. The newspaper that obtained the diary and subsequently published it was sued by Paddy Ashdown *inter alia* for copyright infringement. Since the Human Rights Act 1998 had come into force the defendants argued that the defences based on fair dealing for reporting current news events (Section 30(2) CDPA 1988) and the public interest defence (Section 171(3) CDPA 1988) had to be interpreted in the light their freedom of expression as provided in Article 10 ECHR. This was because of the reference made within Article 3 of the Human Rights Act 1998.

The judge in the first instance proceedings acknowledged that the defendant's actions would fall within the scope of Article 10 ECHR.⁷⁰¹ The freedom of expression would need to be

⁶⁹⁹ *Ashdown v Telegraph Ltd* (2002) RPC 5.

⁷⁰⁰ Birnhack emphasises the importance of the case as he states that it was “the first time in English law freedom of expression has gained an explicit status in the legal landscape.” - Michael Birnhack, ‘Acknowledging the conflict between copyright law and freedom of expression under the Human Rights Act’ [2003] Entertainment Law Review 24, 24.

⁷⁰¹ *Ashdown v Telegraph Ltd* (2001) RPC 34 [12].

balanced with the conflicting property right of the copyright holder. Importantly, he held that such balance has already been struck by the provisions of the CDPA 1988. The court held it unnecessary to “examine whether on the fact of [each particular] case it was necessary in a democratic society to provide from exceptions, exemptions and defences over and above those permitted by the legislation.”⁷⁰² Based on the facts of the case, the judge found that the fair dealing defence of Section 30(2) CDPA 1988 did not apply.⁷⁰³

This approach suggests that the framework set by the CDPA 1988 would already strike a balance between the exclusive right of the author and the freedom of expression of the newspaper. The court denied applying any further considerations as to whether the provisions would be influenced by fundamental rights. As Griffiths states, such approach regarding the balance between interests as Article 10 would be “untenable.”⁷⁰⁴ A court cannot reach a finding that “an overall legal framework secures compliance regardless of the application to the fact of a particular case.”⁷⁰⁵ The Convention would rather mandate an application of whether a balance has been achieved in the individual case and adds that “[s]uch an approach cannot serve to protect individual rights.”⁷⁰⁶

The decision was appealed to the Court of Appeal which then issued a judgment that appears to embrace the impact of the Human Rights Act on the CDPA 1988 more. The Court applied Article 10 ECHR in relation to the public interest exception and held that “[n]ow that the Human Rights Act is in force, there is the clearest public interest in giving effect to the right of expression in those rare cases where this right trumps the rights conferred by the Copyright Act.”⁷⁰⁷ It also held that considerations as to fairness within the fair dealing provisions would entail that “considerations of public interest are paramount.”⁷⁰⁸ What the court basically did was to apply the defendant’s freedom of expression through the conduit of the public interest defence in Section 171 (3) CDPA 1988.⁷⁰⁹

⁷⁰² *Ashdown v Telegraph Ltd* (2001) RPC 34 [13].

⁷⁰³ *ibid* [31].

⁷⁰⁴ Jonathan Griffiths, ‘Copyright law after Ashdown - time to deal fairly with the public’ [2002] IPQ 240, 244.

⁷⁰⁵ *ibid* 244.

⁷⁰⁶ *ibid* 244.

⁷⁰⁷ *Ashdown v Telegraph Ltd* (2002) RPC 5 [58].

⁷⁰⁸ *ibid* [71].

⁷⁰⁹ In other words this means that through Section 171 (3) CDPA 1988 the Court of Appeal internalised the human rights considerations into the CDPA 1988 - Michael Birnhack, ‘Acknowledging the conflict between copyright law and freedom of expression under the Human Rights Act’ [2003] Entertainment Law Review 24, 32.

With regards to the court's holding of how the HRA 1988 would influence the fair dealing defences, it took a more conservative approach. It did not interpret the provisions in the light of the HRA 1998. With this regards, Griffiths criticises the Court's application of the Laddie Factors⁷¹⁰ as being conducted "in a formulaic manner."⁷¹¹ It held that newspapers were commercially competing with copyright holder which would taint the dealing as being unfair. Griffiths criticises this as newspapers are profit orientated and disallowing this would taint their job as a watchdog.⁷¹²

The approaches taken by the courts in incorporating human rights considerations seem to suggest that ECHR rights do influence their assessment. It is noticeable that the interpretation of provisions is now being done by bearing Article 3 of the Human Rights Act 1988 in mind. This provision mandates that court rulings need to be as far as possible compatible with the Convention as mentioned. In relation to exceptions to copyright, the *Ashdown* decision shows that compatibility with ECHR rights was aimed through two ways: First, the Court applied ECHR-Rights considerations in relation to the assessment of fairness through the Laddie factors within fair dealing exceptions.⁷¹³ Additionally, it applied these considerations to the abstract terms of the public interest exceptions as laid out in Section 171(3) CDPA 1988.⁷¹⁴

With this regards, it appears that the abstract wording of the provision with the term "public interest" made it easier for the Court to incorporate Convention principles. Similarly, the assessment of fair dealing as laid out in the Laddie factors is a "cooking pot" test that allows the consideration of multiple factors. This also serves as a gateway to incorporate considerations of the Convention without too much effort. This could mean in relation to such exceptions that verbatim allow the use of a patented invention in the public interest to follow the ruling of *Ashdown* in the Court of Appeal.

⁷¹⁰ *Ashdown v Telegraph Ltd* (2002) RPC 5 [20], [70].

The so-called Laddie factors derive from the CDPA commentary Laddie, Vitoria and Prescott (Laddie, Prescott & Vitoria, *The Modern Law of Copyright and Designs* (3rd edn, Sweet & Maxwell 2000) [20.16]). They provide for three factors that need to be assessed for a finding to the question whether the talking by the infringer can be considered to be fair. The Court of Appeal summarises the factors which ask ". . . (1) whether the alleged fair dealing is in commercial competition with the owner's exploitation of the work, (2) whether the work has already been published or otherwise exposed to the public and (3) the amount and importance of the work which has been taken." - *Ashdown v Telegraph Ltd* (2002) RPC 5 [20].

⁷¹¹ Jonathan Griffiths, 'Copyright law after Ashdown – time to deal fairly with the public' (2002) IPQ 240, 250. Angelopoulos states the Court's interpretation was "remarkably strict" - Christina J. Angelopoulos, 'Freedom of expression and copyright: the double balancing act' [2008] IPQ 328 343.

⁷¹² Jonathan Griffiths, 'Copyright law after Ashdown - time to deal fairly with the public' [2002] IPQ 240, 252.

⁷¹³ *Ashdown v Telegraph Ltd* (2002) RPC 5 [78-84].

⁷¹⁴ *ibid* [47-60].

4.7.3 The Human Rights Act 1998 and its influence on exceptions to patent rights

The application of ECHR principles through the HRA 1998 towards exceptions to patent rights would be twofold: First, it would require Parliament to consider the case law of the ECtHR with regards to the fundamental rights discourse. This would mean that patent rights would be protected by Article 1 of the 1st Protocol and interferences with it (i.e. exceptions) would need to follow the template that Article 1 provides for.⁷¹⁵ Aside from the impact on legislation, the HRA 1998 could affect the courts assessment and interpretation of an exception provisions similarly as in the *Ashdown* decision.

4.7.3.1. Legislating exceptions

The incorporation of ECHR rights influences Parliament to provide legislation that is compatible with ECHR principles. It is now held to consider the ECtHR's assessment on the matter when legislating for exceptions to patent rights since they are considered as possessions. It is now necessary to base the exception on a legislative measure. Parliament then would need to consider whether the exception provision would be in the public interest. As seen, the ECHR permits legislators a wide margin of appreciation with this regard. Where the exception is based on another fundamental right then Parliament will need to apply the proportionality test in order to accommodate the conflicting fundamental rights.

The United Kingdom has recently provided for new legislation with regards to the scope of the research exception.⁷¹⁶ This would mean that there would have been scrutinised as to whether there is compatibility with ECHR rights.⁷¹⁷ The British legislator has also been

⁷¹⁵ Section 1 (1) (b) of the HRA 1998 states that Article 1 of the 1st Protocol to the ECHR is within the ambit of the HRA 1998.

⁷¹⁶ Based on the Legislative Reform (Patents) Order 2014, the Sections 60 (6D) – (6F) were added to the UK Patents Act 1977. The Order aims at clarifying what activities with regards to the assessment of medicinal products would fall with the scope of Article 50 (5) (b) UK Patents Act. See: <<https://www.gov.uk/government/news/changes-to-the-patents-research-exceptions>> assessed: 31.03.2015>. The amendments are introduced through secondary legislation (based on the Legislative and Regulatory Reform Act 2006). Such subordinate legislation however also needs to comply with Convention Rights, Section 3 (1) HRA 1998. The responsible Minister has provided the statement of compatibility with regards to this amendment to the UK Patents Act 1977 - 'The Legislative Reform (Patents) Order 2014 - Explanatory document by the Intellectual Property Office, an Executive Agency of the Department for Business, Innovation and Skills' (2014) 14 <http://www.legislation.gov.uk/ukxi/2014/1997/pdfs/ukxi0d_20141997_en.pdf> .accessed 23 May 2015.

⁷¹⁷ Section 19 HRA 1998 requires any Minister in charge of a Bill to provide Parliament before the Second Reading of the Bill with a statement of compatibility with human rights considerations. Within this statement the Minister either indicates his or hers view that the Bill is compatible with human rights. Otherwise, the Minister states that it is not compatible but that Government still wishes to proceed with the Bill.

active in providing exception provision in the field of copyright law. Prominently, an exception for private copying has been legislated within Section 28B of the CDPA 1988. The Parliamentary Under-Secretary of State for Business has provided the statement that this would not have any issues with compatibility with the ECHR.⁷¹⁸ This however, remains doubtful since many European States have similar provisions but provide for right holders to be remunerated.⁷¹⁹ Whether an unremunerated exception would pass muster of the ECHR remains to be seen.

4.7.3.2. Application by courts

The HRA 1998 is likely to influence the interpretation of exception provisions. What remains to be seen is whether courts would apply these considerations where the wording of a provision is relatively concrete. The exception provisions within Article 60(5) UK Patents Act 1977 provide for more or less concrete purposes. What appears to be possible from the jurisprudence of the courts is an increased willingness to interpret provisions in the light of the Convention based on the principle of compatibility with ECHR principles.

Traditionally, English courts have followed a more textual interpretation of statutory provisions. Generally this is because of the Supremacy of Parliament.⁷²⁰ We have seen that the court in *Monsanto v Stauffer* has applied a rather textual interpretation in comparison to the German Federal High Court in the *Clinical Trials* decisions.⁷²¹ But such teleological approach which focusses on giving the statutory provision “its presumed legislative intent” is not unfamiliar with English courts. It is more akin to interpretation within common law.

However, the statutory interpretation in the UK has moved from being merely literal to being purposive. Through the inception of the HRA 1998 and with it the full body of ECtHR jurisprudence which pays more tribute to the purpose of the law rather than its literal meaning, it can be argued that “the balance is likely to swing more firmly yet in the direction

⁷¹⁸ Explanatory Memorandum to the Copyright and Rights in Performances (Personal copies for Private Use) Regulations 2014 (No. 2361) and the Copyright and Rights in Performances (Quotation and Parody) Regulations 2014 (No. 2356) 6 <http://www.legislation.gov.uk/ukxi/2014/2361/pdfs/ukxiem_20142361_en.pdf> accessed 23 May 2015.

⁷¹⁹ So for instance in Germany where a levy system has been set up to remunerate right holders for private copies in §§ 53 and 54 of the German Authors’ Rights Act.

⁷²⁰ supra 3.3.3 and 3.5.3.

⁷²¹ supra Chapter 3.

of the purposive approach.”⁷²² Exceptions serve to establish fundamental freedoms of users of the patented invention.⁷²³ Hence, the acknowledgement of this fundamental right position is therefore a purposive interpretation of the exception provision.⁷²⁴ Such an approach would also discard the *singularia* rule which mandates that exceptions have to be interpreted narrowly.⁷²⁵

Such an approach can be seen in the development of the *Ashdown* decisions. In discarding the Vice-Chancellor, the Court of Appeal gave effect of the fact an individual assessment of the facts of the case when assessing compatibility of copyright legislation with the ECHR. Previously, the High Court judgment perceived that the balance between copyright protection and freedom of expression was already been conducted by the present exceptions within the CDPA 1988.⁷²⁶ This was based on the fact that the UK would have a margin of appreciation conveyed by the Convention.

The Court of Appeal, however, acknowledged that there are instances where the statutory exceptions do not suffice and held that:

[R]are circumstances can arise where the right of freedom of expression will come into conflict with the protection afforded by the Copyright Act, notwithstanding the express exceptions to be found in the Act. In these circumstances, we consider that the court is bound, insofar as it is able, to apply the Act in a manner that accommodates the right of freedom of expression. This will make it necessary for the Court to look closely at the facts of individual cases (as indeed it must whenever a 'fair dealing' defence is raised).⁷²⁷

The Court acknowledged that there are circumstances where the exception provisions of the CDPA might not fully be able to accommodate to safeguard human rights considerations. Griffiths notes that the court acknowledged that ECHR rights were given precedence.⁷²⁸ The Court found a way out to accommodate by not granting injunctive relief where freedom of

⁷²² Lord Irvine of Lairg LC, The Tom Sargent Memorial Lecture, ‘The development of Human rights in Britain under an Incorporated Convention on Human Rights’ (16 December 1997) printed in: Michael J. Allen and Brian Thompson, *Cases and Materials on Constitutional and Administrative Law* (10th edn, OUP 2011) 473.

⁷²³ Alexander Peukert, ‘The fundamental right to (intellectual) property and the discretion of the legislature’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 145.

⁷²⁴ Additionally, the CJEU has generally approved of a purposive interpretation of exception provisions. It has held in a decision on copyright exceptions that the purpose of such an exception needs to be observed when interpreting it - Joined Cases C-403/08 and C-429/08, *Football Association Premier League and Others* [2011] ECR I-09083, [162]-[163].

⁷²⁵ Thomas Hoeren, ‘Access Right as a postmodern symbol of Copyright Deconstruction?’ in APDI - Associação Portuguesa de Direito Intelectual, *Direito da Sociedade da Informação - Volume VI* (2006) 489.

⁷²⁶ Griffiths criticises the fact that the court was unwilling to apply ECHR aspects to the case by concluding that the balance between the interests had already been made by legislating the defence provisions of the CDPA - Jonathan Griffiths, ‘Copyright law after *Ashdown* - time to deal fairly with the public’ [2002] IPQ 240, 244.

⁷²⁷ *Ashdown v Telegraph Ltd* (2002) RPC 5 [45].

⁷²⁸ Jonathan Griffiths, ‘Copyright law after *Ashdown* - time to deal fairly with the public’ [2002] IPQ 240, 244.

expression would prevail over the copyright holder's interest.⁷²⁹ This might resolve the clash of interest between the copyright holder and the newspaper that wish to publish the work.

Transposed to the patent scenario, it is doubtful whether this would be sufficient. While injunctive relief is a strong weapon against the infringer, it appears that the claim for damages would produce a "chilling effect" with regards to the scientist's freedom of expression which could be subsumed under Article 10 ECHR.⁷³⁰ The Court acknowledged such an approach. Rather than accommodating Article 10 within the existing fair dealing provisions of the CDPA 1988, it was relied on Article 171 (3) of the CDPA 1988. The provision served as a gateway provision⁷³¹ to allow freedom of expression to be taken into consideration in the case at hand.⁷³² This could stipulate that the Court of Appeal came to the finding that a human right, there freedom of expression and its application, was in the public interest. Further, this could mean that the application of a human right is in the public interest.

On the other hand, the court took a very fact specific approach which would mean that not all cases where freedom of expression is being raised would be considered to be in the public interest. Rather, this would be the specific contents of the infringed work. And indeed, the court emphasised that there was the public interest in the disclosure of Paddy Ashdown's notes. The question then remains how such considerations are applied where such a gateway provision is lacking. The UK Patents Act 1977 does not provide for a provision within its text resembling Article 171 (3) CDPA 1988.

The Human Rights Act 1998 has influenced the adoption of the proportionality test applied by the ECtHR.⁷³³ When two human rights conflict with one another then the ECHR seeks to apply a test of proportionality in order to accommodate the conflict.⁷³⁴ In *Ashdown*, the court did not let freedom of expression prevail over the copyright holder's right. Rather, it applied not expressly but tacitly, a proportionality test in relation to the specific case. It argued that based on the specific facts of the case, an injunctive relief was not a proportionate measure.

⁷²⁹ *Ashdown v Telegraph Ltd* (2002) RPC 5 [46].

⁷³⁰ *supra* 4.5.

⁷³¹ Charlotte Waelde and Abbe E.L. Brown, 'A practical analysis of the human rights paradox in intellectual property law: Russian Roulette' in Willem Grosheide (ed), *Intellectual Property and Human Rights – A Paradox* (Edward Elgar 2010) 198.

⁷³² With this regards Angelopoulos states that "the common law "public interest" defence would come to the rescue" - Christina J. Angelopoulos, 'Freedom of expression and copyright: the double balancing act' [2008] IPQ 342. Sims holds that the public interest defence would work "as a safety valve" - Alexandra Sims, 'The public interest defence in copyright law: myth or reality?' [2006] EIPR 343.

⁷³³ *R v. Secretary of State for the Home Department, Ex Parte Daly* [2001] UKHL 26; see also - Orit Fischman Afori, 'Proportionality – A New Mega Standard in European Copyright Law' [2014] IIC 896.

⁷³⁴ *supra* 4.4.4.

Waelde and Brown see in this that the question of whether there is an infringement is not “accorded pre-eminence.”⁷³⁵ What the court did was to deny copyright its feature as an exclusive right and rendered it into a liability rule.

Thus, countervailing human rights are being considered by the courts. Furthermore, freedom of expression could be applied when arguing a case with regards to the research exception as a possible interpretation.⁷³⁶ Pinto however, applies a narrow interpretation to freedom of expression by referring to Article 10’s protected uses of information, namely to impart and receive such information.⁷³⁷ The infringement provisions of patent law relate *inter alia* to using information. He sees such use as not falling within the protected uses of Article 10 ECHR.⁷³⁸ The fact that a scientist requires to test of a hypothesis on order to generate new knowledge stipulates that the freedom requires him or her to use the information to create such knowledge. Hence, a narrow interpretation does not suffice to guarantee scientific freedom of expression.⁷³⁹

4.7.4 Summary

The HRA 1998 could impact patent law in the United Kingdom to a certain degree. It already does with regards to legislating IP law in the UK and has gradually been applied within the case law. This is a process that will take more time. As Griffiths said “[i]n order to adopt the HRA/ECHR into copyright they need a “certain amount of disruption.”⁷⁴⁰ The same applies to patent law. With regards to public interest considerations, this is a laudable development. The application of human rights considerations is itself in the public interest and the proportionate balancing of the colliding interests surrounding the patent right would also be a task which is in the public interest.

It however, has to be noted that there is still leeway to deviate from ECHR considerations. Parliament can decide not to follow the rulings of the ECtHR as courts are not bound to follow the ECHR jurisprudence but just to take account of it. What however, can be seen is

⁷³⁵ Charlotte Waelde and Abbe E.L. Brown, ‘A practical analysis of the human rights paradox in intellectual property law: Russian Roulette’ in Willem Grosheide (ed), *Intellectual Property and Human Rights – A Paradox* (Edward Elgar 2010) 199.

⁷³⁶ *supra* 4.5.

⁷³⁷ Timothy Pinto, ‘The influence of the European Convention on Human Rights on intellectual property rights’ [2009] EIPR 209, 219.

⁷³⁸ *ibid* 219.

⁷³⁹ *supra* 4.5.

⁷⁴⁰ Jonathan Griffiths, ‘Copyright law after Ashdown - time to deal fairly with the public’ [2002] IPQ 240, 264.

that there is an increased awareness and through influence of ECHR rights on British legislation and jurisprudence.

4.8 Conclusions

The chapter has shown that intellectual property is being considered as a fundamental right, both by the ECHR and the EU Charter on fundamental rights. The right holder should be protected from arbitrary interferences with their right. This approach seems to reinvigorate a natural law (or property theory) justification of patent rights. If one considers fundamental rights as a natural law that have been transposed into positive law then this influences the way that legislators can “justify” a deviation or interference of the fundamental right to property. Arguably, the elevation of intellectual property to the human/fundamental rights level entails a curtailment of the legislator’s prerogative to assess public interest.

The fact that the patent rights are protected by fundamental rights under the ECHR however, does not appear to restrict national legislators in applying public interest considerations substantially.⁷⁴¹ The fundamental/human rights framework of the ECHR and the Charter of Fundamental Rights permits legislators to provide for regulations of the property. Such a regulation can be conducted when public interest considerations apply. In relation to the ECHR, the margin of appreciation that legislator can apply is substantial.⁷⁴² In order not to render the fundamental right to property meaningless, the legislator is mandated to find an appropriate balancing of the conflicting interests. This puts the interference under conditions that need to be adopted.

What the fundamental/human rights discourse then stipulates is a balanced approach to the interests concerned: On the one hand, it aims at leaving governments the opportunity to establish economic and social policies without having to compensate the owner. On the other hand, it prevents the right to property from being deprived arbitrarily. The legislator is held to balance the conflicting rights. This is particularly the case where exceptions provisions are based on other fundamental rights that conflict with the right to property of the patent owner. This obligation relates to the legislator when drafting exceptions. It also extends to courts that

⁷⁴¹ This is because Article 1 Protocol does not provide an institutional guarantee, as does Article 14 of the German Basic Law, as it is not part of a national property and economic order.

⁷⁴² *supra* 4.4.

apply exceptions which means that courts need to consider the conflicting fundamental rights when interpreting exceptions. Exceptions to patent rights are then an internal measure within patent law serving this balancing exercise.

It can be said that the ECHR framework will not affect the German patent law as much as the United Kingdom's. This is because of the existing fundamental right's framework that exists there.⁷⁴³ Interferences with the Article 1 of the Protocol are possible in a wider ambit⁷⁴⁴ and where the scope of protection goes further than that of Article 14 of the Basic Law other fundamental rights, such as Article 12, may supplement a possible gap in protection.⁷⁴⁵ Conversely, due to the Human Rights Act 1998, the ECHR jurisprudence is of a heightened relevance for patent law in the United Kingdom.⁷⁴⁶ The UK courts have yet to consider patent rights within the ambit of the Human Rights Act 1998. What the decided case law in other fields of intellectual property stipulate is a general willingness to adopt such considerations in interpreting the law. What might not occur in English courts is that the conflict between right holder and unauthorised user to be constructed as a conflict between two holders of fundamental rights as in Germany. The evolving case law in the United Kingdom adopting ECHR principles, along with the balancing of interest and the doctrine of proportionality is a promising step in providing equitable solutions. The effect and scope of the EU Charter, where applicable, will need to be carefully established and the CJEU's reasoning within *Fransson* applied.

It is submitted that the human/fundamental rights discourse actively serves the public interest in the United Kingdom. It is achieving equitable solutions for conflicting interests surrounding patent rights by providing a mechanism that establishes proportionality.⁷⁴⁷ With regards to patent law, this is done by regarding the conflict between patent holder and users as a conflict of interests. Both interests as being equally protected through fundamental rights

⁷⁴³ *supra* 3.4.4.

⁷⁴⁴ This may be based on the fact that in contrast to the German Constitutional Court the ECtHR does not delineate between the different types of interferences as rigorously - Hans Joachim Cremer in Oliver Dörr, Rainer Grote and Thilo Marauhn (eds), *EMRK/GG – Konkordanzkommentar zum europäischen und deutschen Grundrechtsschutz Band II* (2nd edn, Mohr Siebeck 2013) 1484.

⁷⁴⁵ Karen Kaiser in Ulrich Karpenstein and Franz C. Mayer (eds), *EMRK – Kommentar zum Schutz der Menschenrechte und Grundfreiheiten* (C.H. Beck 2012) Art. 1 ZP I [6].

⁷⁴⁶ The jurisprudence of the ECHR as well as other states that have a developed fundamental rights doctrine and case law could be used as guidance. See: Jürgen Kühling, 'Fundamental Rights' in Armin von Bogdandy and Jürgen Bast (eds), *Principles of European Constitutional Law* (2nd edn, Hart Publishing, C.H. Beck 2008) 490.

⁷⁴⁷ Uerpmann regards the public interest in general welfare in being established when all relevant interests are brought into balance - Robert Uerpmann, *Das öffentliche Interesse: seine Bedeutung als Tatbestandsmerkmal und als dogmatischer Begriff* (Mohr Siebeck 1999) 36.

and then are brought into proportionate balance.⁷⁴⁸ Additionally, the human rights discourse could provide a yardstick for adjusting the approach towards the surrounding interests as legislators and courts need to take the interests into account that are currently prevalent.⁷⁴⁹

Ottolia however, notes that the mechanism of rule (property) versus exceptions (limitation of the property right) would not be able to contain intellectual property rights in the public interest.⁷⁵⁰ He provides an example from the *Smith Kline v the Netherlands* decision where the court does not use the public interest in fostering technological advance “to modify an existing law but to assess the legality of a pre-existing national limitation.”⁷⁵¹ What he means is that the human rights discourse functions retroactively by assessing the validity of a measure of not to advance it. But as we have seen, the patent right/exception paradigm has been broken on the fundamental rights level by the *Ashby* decision of the ECHR. Even an *ante* infringing use may be covered by freedom of expression. Hence, this will provide a fresh approach.

⁷⁴⁸ supra 4.4.4.

⁷⁴⁹ supra 2.4 and 3.6.

⁷⁵⁰ Andrea Ottolia, *The Public Interest and Intellectual Property Models* (G. Giappichellie Editore 2010) 134, 135.

⁷⁵¹ Andrea Ottolia, *The Public Interest and Intellectual Property Models* (G. Giappichellie Editore 2010) 135, 136.

Chapter 5: The TRIPS Agreement

5.1 Introduction

The international agreement that probably had and has the most impact on national IP legislation in general, and patent law in particular, is the Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) which is governed by the World Trade Organisation (WTO). The Agreement represents the legal text that achieved the most substantial amount of harmonisation within patent legislation of WTO Member States. Having said that, it is not the first international measure to align intellectual property rights on a global level⁷⁵² but TRIPS's impact is more substantial and fundamental in comparison to these preceding measures.⁷⁵³

The impact of the TRIPS Agreement on national IP legislation is best explained by its main objective: It aims at setting minimum standards in relation to the protection of intellectual property rights.⁷⁵⁴ Such minimum standards set out thresholds that national intellectual property legislation needs to adopt when implementing the Agreement.⁷⁵⁵ This then potentially limits the choice and scope for legislators to provide for individually customised legislation, and hence policy making.⁷⁵⁶

⁷⁵² The Agreement does not constitute the first international convention with regards to intellectual property rights. Most notably the Paris Convention which is administered by the World Intellectual Property Organisation (WIPO) has set an international framework in relation to industrial property rights and has for instance provided with regards to exceptions to patent protection a provision for compulsory licensing in Article 5 (A) (4).

⁷⁵³ The TRIPS Agreement provides a comprehensiveness “unprecedented in international intellectual property law” - Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (OUP 2012) 6; similarly - Thomas Cottier, *Trade and Intellectual Property Protection in WTO Law* (Cameron May 2005) 81.

⁷⁵⁴ See Article 1(1) TRIPS. This has also been the aim of conventions administered by WIPO such as the Berne and the Paris Convention, see: Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPS Agreement* (Routledge 2001) 46. Similarly to the TRIPS Agreement, the Berne and the Paris Convention allow its Member States to provide for greater protection than mandated - Susy Frankel, ‘The WTO’s Application of ‘The Customary Rules of Interpretation of Public International Law’ to Intellectual Property’, [2005-2006] *Virginia Journal of International Law* 365, 385.

⁷⁵⁵ Most notably this restriction has been vocally criticised as especially not providing developing countries with enough scope to tailor legislation for their local needs and economic situation.

⁷⁵⁶ Antony Tubman, *A practical guide to working with TRIPS* (OUP 2011) 105. See also - Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘An international *acquis*: Integrating regimes and restoring balances’ in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 125.

But the Agreement's impact on national legislation cannot be fully explained solely through the setting of such minimum standards. It is rather the mechanism that TRIPS provides to ensure compliance with these standards. The Agreement is embedded within WTO law which provides for an effective framework of enforcing compliance with its rules. This holds Member States of the WTO to effectively implement its provisions⁷⁵⁷ as any non-compliance with the rules may trigger a Dispute Settlement Procedure.⁷⁵⁸ Such Dispute Settlement Procedure can be called upon by a Member State of the WTO that believes that another Member State does not comply with provisions of the TRIPS Agreement.⁷⁵⁹ This mechanism arguably ensures compliance with provisions of TRIPS which has led to the commonly used figure of speech that the Agreement has "teeth."⁷⁶⁰

⁷⁵⁷ "[T]he addition of a compliance mechanism is perhaps its most significant contribution to international intellectual property law."; Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (OUP 2012) 50.

Both, the Berne and the Paris Convention provide for disputes between Union States on the interpretation and application of the Convention to be adjudicated before the International Court of Justice (Article 28 (1) Paris Convention, Article 33 (1) Berne Convention). Kunz-Holstein notes that in relation to the Paris Convention the system was however practically not applied by Union States - Hans Peter Kunz-Holstein, 'The United States Proposal for a GATT Agreement on Intellectual Property and the Paris Convention for the Protection of Industrial Property' [1989] *Vanderbilt Journal on Transnational Law* 265, 282. See also - Henning Grosse Ruse-Khan, 'Proportionality and Balancing within the Objectives for Intellectual Property Protection' in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 166.

This system therefore did not appear to be "sufficiently operational" and the perceived lack of enforceability gave momentum to include intellectual property under the auspices of GATT - Thomas Cottier, *Trade and Intellectual Property Protection in WTO Law* (Cameron May 2005) 20.

⁷⁵⁸ Article 64(1) TRIP refers to the Understanding on Rules and Procedures Governing the Settlement of Disputes as governing disputes in relation to the TRIPS Agreement.

⁷⁵⁹ The Dispute Settlement Understanding (DSU) urges Member States to first seek consultations with the Member State that it believes is in breach with provisions of the Agreement. When such consultations are not completed successfully the complaining Member State may request the establishment of a panel pursuant to Article 4.7. In case where a violation has been found and when the recommendations issued by the Dispute Settlement Panel are not incorporated within a reasonable time frame, the panel may allow the complaining Member State to seek for compensation or to "retaliate" by being allowed to "suspend trade concessions or other WTO obligations to the Member that has been found to be in breach." - Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPs Agreement* (2001 Routledge) 88; see also - United Nations High Commissioner for Human Rights, *The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, 27 June 2001, E/CN.4/Sub.2/2001/13 [7]; James Harrison, *The Human Rights Impact of the World Trade Organisation* (Hart Publishing 2007) 10.

The suspension of such concessions therefore allows the complainant Member to impose trade sanctions the other Member.

⁷⁶⁰ Lawrence R. Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' [2004] *Yale Journal of International Law* 1, 2.

The effectiveness of trade sanctions as a sanction for non-compliance can be disputed. The panel in the EC-US decision held that Subparagraph (B) of Section 110(5) of the US Copyright Act was in conformity with the TRIPS Agreement and the United States was requested to ensure sure conformity - *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.1, 7.2]. The United States however have yet to amend their copyright act with respect to the findings of the panel - Dalinyebo Shabalala, 'United States-section 110(5) of the US Copyright Act: summary and analysis' in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume II* (Edward Elgar 2010) 177-178). It can therefore be argued that such

The Agreement however does not constitute a “model IP law”, which needs to be copied and pasted into national IP legislation.⁷⁶¹ This means that legislators are able to provide for individualised provisions as long as the minimum standards that the Agreement sets out are met.⁷⁶² In relation to exceptions to patent infringement however, the Agreement sets out a three-partite test within its Article 30.⁷⁶³ The wording of this section sets out conditions which need to be met by exceptions to patent infringement with the patent laws of WTO Member States. A national exception provision which another WTO Member State deems not to comply with Article 30 TRIPS may be adjudicated within a Dispute Settlement Procedure. And indeed, Article 30 was already put under the scrutiny of a dispute settlement procedure in the *Canada – Patent Protection of Pharmaceuticals* case.⁷⁶⁴ This decision sheds some light on how the Dispute Settlement Body (DSB) approached and interpreted Article 30 which provides some guidance on how exceptions ought to be modelled according to the DSB.

The approach that the Dispute Settlement Body took in interpreting Article 30 has widely been criticised by commentators as not providing enough scope to legislators to shape their exception provisions.⁷⁶⁵ Furthermore, a more general discomfort has been uttered as to the

disputes can be ignored if the opposing party has enough of bargaining power to ignore possible trade sanctions or the dispute is settled between the parties after the dispute settlement procedure.

⁷⁶¹ Antony Taubman, *A practical guide to working with TRIPS* (Oxford University Press 2011) 45.

Dinwoodie and Dreyfuss regard the Agreement rather “as defining the parameters of national autonomy”, Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (Oxford University Press 2012) 6. Susy Frankel states that the Agreement is “a ‘low-level’ harmonization agreement.” - Susy Frankel, ‘The WTO’s Application of ‘The Customary Rules of Interpretation of Public International Law’ to Intellectual Property’, [2005-2006] *Virginia Journal of International Law* 365, 375.

⁷⁶² See: Article 1(1) TRIPS: “Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”.

⁷⁶³ With regards to this three-partite test in the field of copyright law, Geiger, Gervais and Sentfleben argue that “the three-step test became one of the main, if not *the main* issue, when trying to find a fair balance of interest in copyright law and policy.” - Christophe Geiger, Daniel J. Gervais and Martin Sentfleben, ‘Understanding the “three-step test”’ in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 173.

⁷⁶⁴ WT/DS114/R.

⁷⁶⁵ Max Planck Institute for Innovation and Competition, Declaration on Patent Protection, [22] <http://www.ip.mpg.de/fileadmin/user_upload/Patent_Declaration_en.pdf > accessed 23 May 2015); Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (OUP 2007) pp. 305; Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 280; Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ [2008-2009] *Richmond Journal of Global Law and Business* 287, 339; Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (4th edn,

fact that national IP legislation, i.e. its IP policy, is partly governed by WTO law which would reinforce intellectual property as a trade commodity rather than having a more holistic approach.⁷⁶⁶ With a view on the question posed in this thesis of what constitutes the public interest in relation to exceptions to patent rights and how such public interest considerations are adopted, the Agreement and its Article 30 are therefore of great significance. In particular, the question: To what extent the Agreement restricts national legislators to apply domestic public interest considerations within their exception provisions?⁷⁶⁷

This chapter will analyse the impact that the TRIPS Agreement has had on patent legislation in general and in relation to providing for exceptions to patent infringement in particular. First, it will analyse how a transnational legal instrument, such as the TRIPS Agreement may influence national IP legislation in general. Then, the potential scope that Article 30 provides will be set out by analysing its jurisprudence and scholarly commentary. This will clarify to what extent legislators are curtailed by the Agreement and whether and how considerations of public interest can be adopted if one seeks to be TRIPS-compliant.

5.2 Trans-national intellectual property law v national public interest considerations

The underlying reason for establishing a transnational framework for intellectual property law such as the TRIPS Agreement is based on the increasingly globalised operation of economic markets. The starting point of globalisation with its wide reaching ramifications can be traced back to the emerging trade of European Countries that started to operate globally in the era of colonisation. The current level of globalisation was spurred by “the growing international basis of knowledge and technology, shorter production cycles, high

Wolters Kluwer 2014) [30.1] – [30.17]; Edson Beas Rodrigues Jr., ‘The General Exception Clauses of the TRIPS Agreement’ (Cambridge University Press 2012) 90-107; Robert Howse, ‘The Canadian Generic Medicines Panel – A dangerous precedent in dangerous times’ (2000) *The Journal of World Intellectual Property* 493, 494.

⁷⁶⁶ See generally - Rochelle C. Dreyfuss and Susy Frankel, ‘From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property’ [2014] *New York University Public Law and Legal Theory Working Papers Paper 478* <http://lsr.nellco.org/nyu_plltwp/478> accessed: 23 May 2015.

⁷⁶⁷ With this regards Howse states that “[t]he area where the WTO does interfere most explicitly in the ability of governments to strike a balance in their policies between diverse public values is that of intellectual property” - Robert Howse, ‘The Canadian Generic Medicines Panel – A dangerous precedent in dangerous times’ (2000) *The Journal of World Intellectual Property* 493, 493.

market entry costs as a result of high intensity of capital and the significance of non-price factors for competitiveness (R&D, design, marketing).”⁷⁶⁸

The global operation of markets leads to the question on how legal regulation of such markets could be achieved. An avenue to provide for regulation of the globalised economy and critically important for the analysis of this thesis is the creation of transnational laws adjudicated by transnational bodies such as the WTO.⁷⁶⁹ In comparison to the rules of public international law, such transnational bodies operate to a large extent independently from the nation states that established them.⁷⁷⁰ Furthermore, such transnational bodies engage in norm setting activities.⁷⁷¹ This creation of norms outside the ambit of the nation state has led to two developments according to Calliess and Zumbansen: “[O]n the one hand, it suggests the emergence of an autonomous or, at least semi-autonomous legal order.”⁷⁷² Additionally, the question would arise which role the nation state would take when norm setting takes place outside of its ambit.⁷⁷³ The latter notion somehow questions the relevance of the nation state in setting norms. In particular, it challenges the central role of the national legislator in applying domestic public interest considerations. With this regard, it has been said that globalisation does not mean that the role nation state becomes irrelevant.⁷⁷⁴ Its role rather changes: It “is mutating from a monopolist of power to a manager of power.”⁷⁷⁵

⁷⁶⁸ Josef Straus, ‘Implications of the TRIPs Agreement in the Field of Patent Law’ in Friedrich-Karl Beier and Gerhard Schricker (eds), *From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights* (1996 VCH Verlagsgesellschaft) 164.

⁷⁶⁹ Andreas Fischer-Lescano and Gunther Teubner, ‘Regime-Collisions: The vain Search for legal Unity in the fragmentation of Global Law’ [2004] *Michigan Journal of International Law* 999, 1000; Holger Hestermayer, *Human Rights and the WTO – The Case of Patents and Access to Medicines* (OUP 2007) 171.

⁷⁷⁰ Other examples are for instance the OECD, OPEC, the EU and the UN.

⁷⁷¹ Andreas Fischer-Lescano and Gunther Teubner, ‘Regime-Collisions: The vain Search for legal Unity in the fragmentation of Global Law’ [2004] *Michigan Journal of International Law* 999, 1010.

⁷⁷² Graf-Peter Callies and Peer Zumbansen, *Rough Consensus and Running Code – A Theory of Transnational Private Law* (Hart Publishing 2010) 18-19.

⁷⁷³ Graf-Peter Callies and Peer Zumbansen, *Rough Consensus and Running Code – A Theory of Transnational Private Law* (Hart Publishing 2010) 19.

⁷⁷⁴ Braun argues that while the state’s function of maintaining order is not dispensable, its influence has decreased in relation to the internationalised economy - Johann Braun, *Rechtsphilosophie des 20. Jahrhundert – Die Rückkehr der Gerechtigkeit* (C.H. Beck 2001) 11.

⁷⁷⁵ Martin Schulte, *Eine soziologische Theorie des Rechts* (Duncker & Humblot 2011) 14.

Under this new premise, nation states do not hold a monopoly-like competence within their jurisdiction but would increasingly be engaged in integrating and coordinating the acts of sectorial disparate international organisations.

One challenge that such transnational bodies set for the nation state and its domestic norm setting is the fact these have been created to administer a particular area of society.⁷⁷⁶ With respect to the WTO, this is trade or more generally an economic rationality.⁷⁷⁷ The classical stance of the role of the nation state is that it conversely is responsible for all sectors of society. The specialisation, in other words differentiation, of transnational bodies leads to “interest driven emergence of specialised legal frameworks”.⁷⁷⁸

Two questions then arise from such a development in relation to public interest considerations surrounding exceptions to patent rights: First, how can such considerations which can be based on an array of different societal interests be addressed and acknowledged within an transnationally operating, specialist legal framework? The TRIPS Agreement’s influence could lead to a certain bias towards a solely economical understanding of IP rights which may not allow the possibility to fully appreciate other societal interests.⁷⁷⁹

Another, related challenge that transnational law poses to public interest considerations is whether these norms circumvent traditional forms of hierarchy within national laws.⁷⁸⁰ In many circumstances public interest considerations that nation states take are mandated by superior, often constitutional law.⁷⁸¹ Therefore, the question can be raised whether transnational legal frameworks alter such hierarchies and possibly restrict nation states in providing exceptions in the public interest.

5.2.1 Intellectual Property Rights within the WTO framework - The inception of TRIPS

The emerging globalisation of the economy was inevitably prone to affect intellectual property rights.⁷⁸² The first instances where multilateral international collaboration in the

⁷⁷⁶ Fischer-Lescano and Teubner refer to this as sectorial fragmentation - Andreas Fischer-Lescano and Gunther Teubner, ‘Regime-Collisions: The vain Search for legal Unity in the fragmentation of Global Law’ [2004] Michigan Journal of International Law 999, 1008.

⁷⁷⁷ *ibid* 1030.

⁷⁷⁸ Graf-Peter Callies and Peer Zumbansen, *Rough Consensus and Running Code – A Theory of Transnational Private Law* (Hart Publishing 2010) 56.

⁷⁷⁹ Feintuck points out that the notion of public interest stipulates that it requires being in line with “the dominant values of the society” - Mike Feintuck, *The Public Interest in Regulation* (OUP 2004) 25.

Similarly, Robert Uerpman, *Das öffentliche Interesse: seine Bedeutung als Tatbestandsmerkmal und als dogmatischer Begriff* (Mohr Siebeck 1999) 27.

⁷⁸⁰ Andreas Fischer-Lescano and Gunther Teubner, ‘Regime-Collisions: The vain Search for legal Unity in the fragmentation of Global Law’ [2004] Michigan Journal of International Law 999, 1002.

⁷⁸¹ See the discussion within Chapter 3 with regards to Germany.

⁷⁸² This can be attributed to the advances in science according to Dinwoodie and Dreyfuss:

field of intellectual property occurred can be traced back to the late 19th century with the inception of the Paris Convention in 1883 and the Berne Convention in 1886.⁷⁸³ Both Agreements introduced the concept of equal treatment of nationals of other Convention Member states.⁷⁸⁴

The TRIPS Agreement came into effect in 1995 and has made intellectual property “a key issue for international trade.”⁷⁸⁵ The on-going global integration of the economy urged for further integration of international trading rules.⁷⁸⁶ Along with the negotiations relating to establishing the WTO, the need to secure common rules with regards to intellectual property became apparent.⁷⁸⁷ The mandate to elaborate an agreement on intellectual property under the auspices of the General Agreement on Tariffs and Trade (GATT) had the objective to establish viable and appropriate rules for protecting intellectual property while these rights should not themselves constitute a trade barrier.⁷⁸⁸

The momentum to place intellectual property into the agenda of GATT rather than under those of WIPO⁷⁸⁹ was launched by the United States; an effort that was later supported by the

“Advances in such fields as electronics, biotechnology, computer science, information technology, materials science, remote monitoring and imaging, digitization, and networking technologies ushered in the so-called Third Industrial Revolution and, with it, a Knowledge Economy heavily dependent on Information and science-intensive products. Not necessarily tied to physical object, the knowledge components of these goods could be widely distributed with exceptional ease.”

Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (OUP 2012) 3-4.

The authors submit that these creative industries were increasingly dissatisfied with the different levels of protection in states which would lead to trade distortions which eventually lead to addressing this issue on an intergovernmental level.

⁷⁸³ The conclusion of both Agreements is based on the rapidly increasing of industrialisation of its Member States. The Paris Convention, for instance, introduced the concept of national treatment which allowed inventors to receive patent protection in other Convention States. The Convention was the result of many foreign traders effusing to attend the International Exhibition of Inventions in Vienna in 1873 as they were of the belief that their inventions would have been appropriated by others - Charles Clift, ‘Why IPR issues were brought to GATT: a historical perspective on the origins of TRIPS’ in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 3.

⁷⁸⁴ Article 2 Paris Convention; Article 5 Berne Convention.

⁷⁸⁵ Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPs Agreement* (Routledge 2002) 7.

⁷⁸⁶ This was accommodated by the creation of the General Agreement on Trade and Tariffs.

⁷⁸⁷ The push to include intellectual property considerations into the realm of GATT has been based on the perceived “toothlessness” of the international treaties administered by the World Intellectual Property Organisation (WIPO) - Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet and Maxwell 1996), Preface.

⁷⁸⁸ Christoph Herrmann, Wolfgang Weiß and Christoph Ohler, *Welthandelsrecht* (2nd edn, C.H. Beck 2007) [913].

⁷⁸⁹ A point that was argued by the Governments of India and Brazil that held that WIPO had exclusive jurisdiction in relation to intellectual property when the US proposed an inclusion of IP matters within the GATT framework at the Ministerial Meeting in Geneva in 1982 - Jane A. Bradley, ‘Intellectual Property Rights,

European Communities.⁷⁹⁰ It is however important to note that the initiative was initially promoted by private, multinational companies that lobbied for such an agreement.⁷⁹¹ Their support, i.e. of the right holders to integrate intellectual property under the WTO umbrella stipulates that they perceived benefits in this arrangement.⁷⁹²

Eventually, the TRIPS Agreement came into existence as an annex to the WTO Agreement and establishes an international framework that regulates both substantive and procedural matters in relation to intellectual property.⁷⁹³ The states that wanted to benefit from the free trade umbrella of the WTO had to adhere to the rules of the TRIPS Agreement.⁷⁹⁴ As an instrument of international law, the TRIPS Agreement does not require direct application of its provision which enables Member States to accommodate the implementation with their own constitutional order.⁷⁹⁵ It is therefore constitutional law, (or in relation to the European

Investment and Trade in Services in the Uruguay round; Laying the Foundations' [1987] *Stanford Journal of International Law* 57, 66-67; see also - Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet and Maxwell 2012) [1.12].

The negotiations regarding and amendment of the Paris and Berne Convention proved to be difficult as developing countries urged to weaken the rules, developed countries aimed at strengthening them - Charles Clift, 'Why IPR issues were brought to GATT: a historical perspective on the origins of TRIPS' in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 6; Peter K. Yu, 'Currents and crosscurrents in the international intellectual property regime'[2004] *Loyola of Los Angeles Law Review* 323, 357; Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPs Agreement* (Routledge 2002) 12.

⁷⁹⁰ Charles Clift, 'Why IPR issues were brought to GATT: a historical perspective on the origins of TRIPS' in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 5.

⁷⁹¹ Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet and Maxwell 2012) [1.12]; Charles Clift, 'Why IPR issues were brought to GATT: a historical perspective on the origins of TRIPS' in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 5; Peter Drahos, 'Global Property Rights in Information: The story of TRIPS at the GATT' [1995] *Prometheus* 6, 7.

⁷⁹² Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPs Agreement* (Routledge 2002) 18-19.

⁷⁹³ Christoph Herrmann, Wolfgang Weiß and Christoph Ohler, *Welthandelsrecht* (2nd edn, C.H. Beck 2007) [913].

⁷⁹⁴ Developed countries had to be TRIPS compliant within a year; Article 65 (1) TRIPS. Arguably many developed countries were deemed to be ex-ante TRIPS-compliant to a large degree but would still require making some amendments to their laws - Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet and Maxwell 1996) [15.09].

This period was considerably longer for developing and the least developed countries; Article 65 (2) and Article 66 TRIPS. The TRIPS Council subsequently extended the deadline to comply with the Agreement twice: until 01.07.2013 in the Decision of 29th of November 2005 (WTO Document IP/C/40 dated 30.11.2005), and recently until 1st July 2021 in its decision from 11th June 2013 (WTO Document IP/C/64 dated 12 June 2013).

⁷⁹⁵ Josef Drexler, 'The TRIPS Agreement and the EC: What comes next after joint competence?' in Friedrich-Karl Beier and Gerhard Schrickler (eds), *From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights* (1996 VCH Verlagsgesellschaft) 48.

Straus however argues that the provisions of the TRIPS Agreement with regards to "patents set strict limits upon WTO-Members' freedom to legislate in the course of pursuing their national interests." - Josef Straus, 'Implications of the TRIPs Agreement in the Field of Patent Law' in Friedrich-Karl Beier and Gerhard Schrickler (eds), *From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights* (1996 VCH Verlagsgesellschaft) 161. He puts this this statement into perspective when he states that

Union its constitutional order), which informs the way to implement the Agreement into national or regional law respectively.⁷⁹⁶

While the Agreement sought to provide for minimum standard across the jurisdictions of the WTO, it is important to state that its Article 1(1)⁷⁹⁷ provides that Member States have some discretion on how to implement these rules. By this, they are able to implement the Agreement “in ways, best suited to their political, institutional, economic, and social conditions.”⁷⁹⁸ The question remains to what extent this is possible when the Agreement seeks for minimum standards. This is particularly important for the providing exceptions that curtail the IP right and hence could conflict with these minimum standards.⁷⁹⁹

5.2.2 Doctrinal and institutional problems of accommodating national public interest considerations

The subsumption of intellectual property under a legal framework such as that of the WTO may preliminarily pose difficulties for Member States in incorporating public interest considerations within exception provisions. This can be based on two points: First, it could be argued that a legal framework that follows a largely trade-orientated rationale could generate a doctrinal bias towards the trade-related aspects of intellectual property as the very name of the Agreement suggests which would conflict with its wider societal relevance.⁸⁰⁰ The second

legislators are given choice with regards to its implementation but emphasises the unprecedented impact of the Agreement on national patent legislation - *ibid* 1616-162 (in Footnote 4).

⁷⁹⁶ Josef Drexl, ‘The TRIPS Agreement and the EC: What comes next after joint competence?’ in Friedrich-Karl Beier and Gerhard Schrickler (eds), *From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights* (1996 VCH Verlagsgesellschaft) 48.

The CJEU has recently held that it had the sole competence of interpreting the TRIPS Agreement. It based its finding on Article 207(1) of the TFEU which gives the EU exclusive competence over the Union’s common commercial policy. Since the TRIPS Agreement would relate to trade –related aspects of intellectual property its rules “are capable of falling within the concept of ‘commercial aspects of intellectual property’ in Article 207(1) TFEU and hence the field of the common commercial policy” - Case C-414/11 *Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon*, (CJEU 18 July 2013) [52].

⁷⁹⁷ Article 1(1) of the TRIPS Agreement reads: “Member States shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system.”

⁷⁹⁸ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘TRIPs and the Dynamics of Intellectual Property Lawmaking’ [2004] *Case Western Reserve Journal of International Law* 95, 95.

⁷⁹⁹ On this note Kur and Grosse Ruse-Khan propose “binding ceilings in international intellectual property law protection” that would leave sufficient space for domestic IP law making - Annette Kur and Henning Grosse Ruse-Khan, ‘Enough is enough – the notion of binding ceilings in international intellectual property protection’ in Annette Kur & Marianne Levin (eds), *Intellectual Property in a Fair World Trade System – Proposals for Reform of TRIPs* (Edward Elgar 2011) pp 359.

⁸⁰⁰ Grosse Ruse-Khan notes that this perspective tends to be shared by “variously (mainly developing) countries, civil society groups and NGO’s focussing on non-trade interests such as public health, the environment or

point is related to the first point but particularly looks at the institutional design of the Dispute Settlement Procedure. Both of these points warrant a deeper analysis as to whether this may present an obstacle for public interest considerations with regards to exceptions.

5.2.2.1 Doctrinal incompatibility - The nexus between intellectual property, trade and public interest considerations

The outreach of the TRIPS Agreement is far reaching as it pushes towards formulating substantial and procedural individual rights within all WTO Member States. The emphasis on the trade-related aspects of intellectual property rights was aimed to diminish the distortions to trade.⁸⁰¹ This firmly established intellectual property in a nexus with trade:⁸⁰² Since “[t]he focus of the WTO is trade, the TRIPS Agreement tends to view intellectual property very much as a commodity”.⁸⁰³ With this view, a more holistic approach to assessing intellectual property rights within their societal framework becomes difficult.⁸⁰⁴ This is because setting

human rights.” - Henning Grosse Ruse-Khan, ‘Proportionality and Balancing within the Objectives for Intellectual Property Protection’ in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 162.

⁸⁰¹ Interesting in this respect is the different approach on what would distort trade: The US held in a submission to the Uruguay Round negotiations that “deficiencies in protection of intellectual property rights distort trade in goods and services” - Uruguay Round - Group of Negotiations on Goods (GATT) - Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, ‘Submissions from Participants on Trade Problems Encountered in Connection with Intellectual Property Rights’ (GATT Document MTN.GNG/NG11/W/7, 29th May 1987) 30. India, on the other hand, was “of the view that it is only the restrictive and anti-competitive practices of the owners of intellectual property rights that can be considered to be trade-related because they alone distort or impede international trade.” - Uruguay Round - Group of Negotiations on Goods (GATT) - Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods - Standards and Principles concerning the Availability Scope and Use of Trade-Related Intellectual Property Rights ‘Communication from India’ (GATT Document MTN.GNG/NG11/W/37, 10th July 1989), 2. For Frankel these two countervailing approaches have been accommodated with in the TRIPS Agreement as its preamble stipulates, see - Susy Frankel, ‘Some Consequences of Misinterpreting the Trips Agreement’ [2009] *The WIPO Journal* 35, 39.

⁸⁰² Susy Frankel, ‘Some Consequences of Misinterpreting the Trips Agreement’ [2009] *The WIPO Journal* 35, 37; Henning Grosse Ruse-Khan, ‘Proportionality and Balancing within the Objectives for Intellectual Property Protection’ in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 166.

Combining trade with intellectual property rights provided the United States leverage for negotiating the Agreement with lesser developed countries as Drahos highlights; See: Peter Drahos, ‘Global Property Rights in Information: The story of TRIPS at the GATT’ [1995] *Prometheus* 6, 7.

⁸⁰³ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘Enhancing global innovation policy: the role of WIPO and its Conventions in interpreting the TRIPS Agreement’ in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 115.

⁸⁰⁴ The establishment of the TRIPS Agreement can also be regarded as a consequence of the rationality maximization of societal systems, here that of the economic system as described by Niklas Luhmann - Andreas Fischer-Lescano and Gunther Teubner, ‘Regime-Collisions: The vain Search for legal Unity in the fragmentation of Global Law’ [2004] *Michigan Journal of International Law* 999, 1007. Teubner states with regards to rationality maximisation that “[a]ccording to Luhmann and Habermas social systems have developed

intellectual property law within a framework that is concerned with the promotion of trade⁸⁰⁵, such as the WTO's and its TRIPS Agreement, entails the risk of neglecting third party interest in "protectionist biases in WTO law."⁸⁰⁶

A second point is relevant with this regard: The Agreement has been established to provide for a globalised framework among the member states of the WTO. This required an approximation of the legal standards in relation to intellectual property laws in order to provide for a more or less coherent framework. This however, means that the standard of protection is likely to be increased. Dreyfuss states that such harmonisation would converge towards the standard of the jurisdiction with the highest level of protection:⁸⁰⁷ It would be "harder to disappoint those who made specific investments in reliance on exclusive rights than it is to undermine vague expectations that a work will become less expensive."⁸⁰⁸

Additionally, the general doctrinal framework surrounding trade law may not be easily compatible with that of intellectual property. The free trade dictum that surrounded the GATT cannot seamlessly be transposed to intellectual property:⁸⁰⁹ Free trade, as promoted by the GATT, is considered to be beneficial to the majority or people, i.e. the consumers and seeks to curtail the protectionist tendencies of some producers.⁸¹⁰ The TRIPS Agreement however, goes the converse route as it specifically provides minimum standards of protection to few producers rather than benefitting the interests of third parties which are being constrained by the Agreement.⁸¹¹ This "double standard"⁸¹² does not fit well if one regards

such powerful and uncontrollable internal dynamics that they not only overburden individuals and harm the ecology, but also have disintegrating effects upon one another." - Gunther Teubner, 'Altera Pars Audiatur: Law in the Collision of Discourses' in Richard Rawlings (ed), *Law, Society, and Economics - Centenary Essays for the London School of Economics and Political Science 1895-1995* (OUP 1997) 155-156.

⁸⁰⁵ The preamble describes the purpose and objectives of the Agreement. Therefore, the trade focus will compulsory be applied when interpreting the Agreement.

⁸⁰⁶ Ernst-Ulrich Petersmann, 'Constitutionalism and WTO law: From a state-centred approach towards a human rights approach in international economic law' in Daniel L.M. Kennedy and James D. Soutwick (eds), *The Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec* (Cambridge University Press 2002) 55.

⁸⁰⁷ Rochelle C. Dreyfuss, 'Patents and human rights; where is the paradox' in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) 85.

⁸⁰⁸ Rochelle C. Dreyfuss, 'Patents and human rights; where is the paradox' in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) 85. As an example for this development Professor Dreyfuss provides the term extension within European Copyright Law (Directive 2006/116/EC of the European Parliament and of the Council of 12 December 2006 on the term of protection of copyright and certain related rights).

⁸⁰⁹ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, 'TRIPs and the Dynamics of Intellectual Property Lawmaking' [2004] *Case Western Reserve Journal of International Law* 95, 120.

⁸¹⁰ *ibid* 120.

⁸¹¹ *ibid* 121.

exceptions as providing a “balance between diverging interests in a world of rapidly changing social-economic conditions.”⁸¹³

5.1.2.2 Institutional design - The Dispute Settlement Procedure

Apart from its trade focused rationale, the adjudication of disputes regarding the TRIPS Agreement may constitute a barrier in the application of national public interest considerations. The strength and viability of its dispute settlement procedure⁸¹⁴ was attractive to the lobbying groups behind the push towards adding intellectual property into the GATT ambit. Generally, the Dispute Settlement Body of the WTO has a comparable role to courts within national legal system as both apply, interpret and develop the law. What however, may constitute an obstacle for the application of public interest considerations apply is that a panel may be biased towards the economic logic of the WTO.

This point is emphasised by the fact that the composition of members of the adjudicating body stands in stark contrast to national courts. The members of a panel are usually formed by Trade experts.⁸¹⁵ This may emphasise a bias towards the “trade-related” aspects on intellectual property⁸¹⁶ while not providing sufficient expertise as to the wider societal

⁸¹² Simon Walker, ‘The TRIPS Agreement, Sustainable Development and the Public Interest: Discussion Paper’. (2001 IUCN, Gland, Switzerland and Cambridge, UK and CIEL, Geneva, Switzerland) 10
<<https://portals.iucn.org/library/efiles/documents/EPLP-041.pdf>> accessed 23 May 2015.

⁸¹³ Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ [2008-2009] *Richmond Journal of Global Law and Business* 287, 327.

⁸¹⁴ Mitsuo Matasusita, Thomas J. Schoenbaum and Petros C. Mavroidis, *The World Trade Organization-Law, Practice, and Policy* (OUP 2003)18; Marco C. E. J Bronckers, ‘Better Rules for a new Millennium: A warning against undemocratic developments in the WTO’ [1999] *Journal of International Economic Law* 547, 548.

⁸¹⁵ See Dispute Settlement Understanding:

“Article 8: Composition of Panels

1. Panels shall be composed of well-qualified governmental and/or non-governmental individuals, including persons who have served on or presented a case to a panel, served as a representative of a Member or of a contracting party to GATT 1947 or as a representative to the Council or Committee of any covered agreement or its predecessor agreement, or in the Secretariat, taught or published on international trade law or policy, or served as a senior trade policy official of a Member.

2. Panel members should be selected with a view to ensuring the independence of the members, a sufficiently diverse background and a wide spectrum of experience.”

Interestingly, a Member of the Member of the Dispute Settlement Procedure on Article 30 was Mihaly Ficsor. For Dinwoodie and Dreyfuss this is an indication of the informal connections between the WIPO and the WTO - Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘Designing a global intellectual property system responsive to change: The WTO, WIPO, and beyond’ [2009-2010] *Houston Law Review*’ 1187, 1194.

⁸¹⁶ Henning Grosse Ruse-Khan, ‘Proportionality and Balancing within the Objectives for Intellectual Property Protection’ in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 166.

impacts of intellectual property protection.⁸¹⁷ Additionally, it has been mentioned that, in comparison to decisions taken within the legal order of a nation state, it does not provide a system of checks and balances.⁸¹⁸ Also, the Appellate Body is the final body to adjudicate the issue at stake within a dispute settlement procedure. If the Appellate Body “errs” then it is unlikely to be altered. In comparison, if a Supreme Court finds the “wrong” decision the legislative branch can accommodate and change the issue. At the WTO, the political branch comprising of the General Council and the Ministerial Conference tend not to do so.⁸¹⁹

A fundamental principle of the Agreement could restrict a balanced national patent legislation by the Dispute Settlement Mechanism: The minimum standard principle of the TRIPS Agreement means that a Dispute Settlement Procedure could only be established where the complaint refers to an alleged reduction of the level of protection.⁸²⁰ A complaint regarding increased protection on the other hand is not possible as Member States have the discretion to provide for more extensive protection within their patent laws than the Agreement mandates.⁸²¹ This favours such legislation that benefits the right holders as these will not be scrutinised by a WTO Panel. Conversely, provisions aiming to benefit third parties which potentially conflict with the interests of the right holders will fall under this scrutiny.⁸²²

Finally, a panel will only assess a particular piece of legislation that allegedly violates the Agreement. This approach does not take its legislative history and reasoning into account. Dinwoodie and Dreyfuss criticise this as often intellectual property legislation is conducted

⁸¹⁷ With this regard, Marceau states that “[i]t is doubtful WTO Members wanted their WTO ‘judges’ to interpret and apply treaties other than that of the WTO (such as human rights treaties etc.) while requiring that such WTO panellist or members of the Appellate Body have mainly an expertise in GATT/WTO and trade matters.” - Gabrielle Marceau, ‘WTO Dispute Settlement and Human Rights’ [2002] *European Journal of International Law* 753, 766.

⁸¹⁸ Mitsuo Matasusita, Thomas J. Schoenbaum and Petros C. Mavroidis, *The World Trade Organization-Law, Practice, and Policy* (OUP 2003) 43; Ernst-Ulrich Petersmann, ‘Constitutionalism and WTO law: From a state-centred approach towards a human rights approach in international economic law’ in Daniel L.M. Kennedy and James D. Soutwick (eds), *The Political Economy of International Trade Law: Essays in Honor of Robert E. Hudec* (Cambridge University Press 2002) 32-67, 55. It can be argued that the Dispute Settlement System is comparable to the judiciary branch within a nation state.

⁸¹⁹ Mitsuo Matasusita, Thomas J. Schoenbaum and Petros C. Mavroidis, *The World Trade Organization-Law, Practice, and Policy* (OUP 2003) 43.

⁸²⁰ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘TRIPs and the Dynamics of Intellectual Property Lawmaking’ [2004] *Case Western Reserve Journal of International Law* 95, 100; Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPs – Resilience of the International Intellectual Property Regime* (OUP 2012) 118.

⁸²¹ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘TRIPs and the Dynamics of Intellectual Property Lawmaking’ [2004] *Case Western Reserve Journal of International Law* 95, 100.

⁸²² *ibid* 100; Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPs – Resilience of the International Intellectual Property Regime* (OUP 2012) 118.

by providing a trade-off by setting stronger rights with a wider array of exceptions or limitations in order to achieve a balanced intellectual property system.⁸²³ These trade-offs within national law are ignored within a dispute settlement procedure.

5.2.3 Summary

The issues raised with regards to doctrinal framework and the institutional design of intellectual property before the WTO raise concerns as to whether exceptions to patent rights and its underlying public interest considerations can adequately be applied by Member States of the WTO. Dreyfuss argues that the globalisation of patent law through TRIPS and its history of right holders' lobbying would become "especially potent in combination"⁸²⁴ and that TRIPS would "alter the dynamics of domestic law making".⁸²⁵

As mentioned, public interest considerations in relation to exceptions are based on an array on societal interests that do not *prima facie* have any affiliation with the trade-related aspects intellectual property. The question then remains whether national legislators are still able to apply such considerations within their patent legislation. This depends on whether the Agreement would allow the adoption of these considerations without regarding them as a violation of TRIPS. Again, it has to be noted that the Agreement does not provide for a model law but provides minimal safeguards as to how TRIPS compliant legislation should look like. This ultimately depends on the scope that Article 30 TRIPS leaves to apply such considerations.

⁸²³ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (OUP 2012) 118.

⁸²⁴ Rochelle C. Dreyfuss, 'Patents and human rights; where is the paradox' in Willem Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (2010 Edward Elgar) 86.

⁸²⁵ *ibid* 86.

5.3 Article 30 TRIPS as threshold to national legislators

The doctrinal and institutional framework that the TRIPS Agreement poses has the potential to limit the application of national public interest considerations. Ultimately, it is the inclusion of the so-called “Three Step Test”⁸²⁶ into Patent Law through Article 30 that constitutes a critical threshold for WTO Member States to pass when providing exceptions to patentee’s rights. The provision reads as follows:

Members may provide limited exceptions to the exclusive rights conferred by a Patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties.

The wording of the provision leaves it to the discretion of Member States to provide for exceptions to patent infringement as the term ‘may’ stipulates.⁸²⁷ However, when legislators provide for exceptions to the exclusive rights of patent holders, they need to fulfil the conditions or steps that have given the provision its ‘nick name’. Non-compliance may attract a WTO Dispute Settlement Procedure which can result in possible trade sanctions.⁸²⁸ This may represent a restriction, or at least a possible deterrent for WTO Member States in fully applying domestic considerations of public interest when legislating exceptions.⁸²⁹ For the purposes of this work, an analysis of this provision is therefore indispensable as the EU and

⁸²⁶ The term “Three-Step-Test” is commonly used nowadays for the provision. See: Andrew Christie and Robin Wright, ‘A Comparative Analysis of the Three-Step Tests in International Treaties’ [2014] IIC 409, 410). It is modelled on the Article 9(2) of the Berne Convention and therefore derives from a provision used within the field of copyright law. While the term “3 Step Test” is commonly applied there are also other references to the provision such as “three part” test by for instance Dinwoodie and Dreyfuss - Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘TRIPs and the Dynamics of Intellectual Property Lawmaking’ [2004] Case Western Reserve Journal of International Law 95, 102. For the purposes of this thesis the term “3 Step Test” will be used. Christie and Wright however state that “the three-step test is a mythical beast. It does not exist.” - Andrew Christie and Robin Wright, ‘A Comparative Analysis of the Three-Step Tests in International Treaties’ [2014] IIC 409, 431. This is based on the fact that while there are significant differences that would be blurred with the reference to “the” three step-test - Andrew Christie and Robin Wright, ‘A Comparative Analysis of the Three-Step Tests in International Treaties’ [2014] IIC 409, 443. It however must be said that the notion of three steps can be regarded as stipulating the method of interpreting and applying the provision. This will be discussed at a later stage.

⁸²⁷ Justin Malabon, Charles Lawson and Mark Davison, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* (Edward Elgar 2014) [30.01]; Andrew Christie and Robin Wright, ‘A Comparative Analysis of the Three-Step Tests in International Treaties’ [2014] IIC 409, 417.

⁸²⁸ See above.

⁸²⁹ Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ [2008-2009] Richmond Journal of Global Law and Business 287, 289.

all of its Member States are members of the WTO⁸³⁰ and are therefore bound to the TRIPS Agreement.⁸³¹

The language and structure of the provision still remains unclear though the Panel decision in the dispute between Canada and the European Communities shed some light on this respect.⁸³² Interestingly, the literature on the “sister provision” of Article 30, Article 13 or indeed its parent provision in the Berne Convention which provide Three-Step-Tests within copyright law is vaster. However, analogies from the copyright discourse of the Three-Step-Test to the situation within patent law need to be applied with caution.⁸³³ This is due to the fact that both areas of law are distinct which generally forbids analogies. The WTO dispute settlement panel itself however has applied such analogies in the Canada decision.⁸³⁴ This implies that some careful analogies can be made. This will demonstrate to what degree Article 30 TRIPS leaves scope for legislators to accommodate public interest considerations within their exceptions *de lege ferenda*; according to the Canada-EC Panel.

5.2.1 Legislative history of Article 30 TRIPS

The current wording of Article 30 TRIPS originates from a template found in relation to copyright law, more precisely the Berne Convention for the Protection of Literary and Artistic Works.⁸³⁵ The provision in question is Article 9 (2) of the Berne Convention⁸³⁶ which was introduced at the Stockholm Conference on the revision of the Berne Convention in 1967.⁸³⁷ It was introduced to enable the introduction of a general right of reproduction within

⁸³⁰ <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> last accessed 16.02.2014

⁸³¹ See above.

⁸³² *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R.

⁸³³ Gervais stipulates that “reference to copyright-related principles here should be limited to terminology and carried out with outmost caution” - Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet & Maxwell 2012) [2.396]; similarly- Martin Senftleben, ‘Towards a Horizontal Standard for Limiting Intellectual Property Rights? - WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law’ [2006] IIC 407, 413.

⁸³⁴ See *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.14].

⁸³⁵

“It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.”

⁸³⁷ Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreement* (Cambridge University Press 2012) 19, citing Bergström 1967; Martin Senftleben, ‘Towards a Horizontal Standard for Limiting

Article 9 (1) Berne Convention.⁸³⁸ The abstract nature of the norm can be regarded as a compromise solution: The copyright legislation and traditions within Member States of the Berne Union differed substantially. This made the alternative suggestion, i.e. to provide for more concrete wording as to what uses were allowed difficult since there was disagreement as to what concrete uses were to be included.⁸³⁹ The diverse nature of limitations and exceptions that were found within the copyright legislation of the Berne Union States could have impaired the inception of a broad remuneration right.⁸⁴⁰ Therefore, a provision with more abstract terminology appeared to be a compromise which seemingly would be provided by the 3 Step Test.⁸⁴¹

The relevance of Article 9 (2) of the Berne Convention in relation to copyright law and intellectual property law in general is based on the fact that it has served as a template for further intellectual property legislation. Since its inception in 1967, it has not only found its way into subsequent EU legislation within the field of copyright⁸⁴² but has also been adopted in national copyright legislation.⁸⁴³ Finally, the inception of the TRIPS Agreement made it relevant to all fields of intellectual property law: The adoption of the TRIPS Agreement has seen the underlying structure and concept of Article 9 (2) being used as a template in relation to exceptions to other intellectual property rights.⁸⁴⁴ Its form was to a larger or lesser extent

Intellectual Property Rights ? - WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law' [2006] IIC 407, 407.

⁸³⁸ Martin Senftleben, 'Towards a Horizontal Standard for Limiting Intellectual Property Rights ? - WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law' [2006] IIC 407, 411.

⁸³⁹ Martin Senftleben, *Copyright, Limitations and the Three Step Test – An Analysis of the Three Step Test in International and EC Copyright Law* (Kluwer Law International 2004) 50-52.

⁸⁴⁰ Annette Kur, 'Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?' [2008-2009] *Richmond Journal of Global Law and Business* 307.

⁸⁴¹ Martin Senftleben, 'Towards a Horizontal Standard for Limiting Intellectual Property Rights ? - WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law' [2006] IIC 407, 411.

⁸⁴² So for instance Article 5 (5) Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society

⁸⁴³ So for instance Article 40 bis of the Spanish Intellectual Property Act:

“Los artículos del presente capítulo no podrán interpretarse de manera tal que permitan su aplicación de forma que causen un perjuicio injustificado a los intereses legítimos del autor o que vayan en detrimento de la explotación normal de las obras a que se refieran.”.

⁸⁴⁴ Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 217.

Additionally, Article 13 utilises the layout of Article 9 (2) of the Berne Convention with regards to limitations and exceptions to copyright law while additionally mandating legislators to additionally consider the rights and interests of right holders when providing of exceptions or limitations. The Berne template only urged to consider the rights and interest of the authors.

transplanted into the fields of trade marks,⁸⁴⁵ industrial designs⁸⁴⁶ and also patents within Article 30 TRIPS.

5.2.2 Legislative purpose and nature of Article 30 TRIPS

The provision of Article 30 provides a test that exceptions to patent infringement within the patent legislations of WTO Member States have to surpass. This may curtail the freedom to provide for exceptions to patent infringement within their jurisdictions⁸⁴⁷ and therefore limit the application of public interest considerations within exceptions to patentees' rights. The preliminary question arises as to whether the test is addressed to legislators or the courts.⁸⁴⁸ Considerations of public interest can be provided by the legislator in providing for exception provisions.⁸⁴⁹ However, they may also be incorporated through interpretation of legal provisions by the courts.⁸⁵⁰ Hence, it is important to identify the addressee of Article 30.

The provision itself states that “[m]embers may provide limited exceptions” and then sets out under which conditions such exceptions are permissive. This would stipulate that the provision is referring to the legislators in the respective Member States as it is the legislative branch that “provides” for exception provisions. This point is supported by the fact that the only Dispute Settlement Panel in relation to Article 30 TRIPS was established to assess the compliance of exception provisions within Canadian Patent Act⁸⁵¹ with the requirements of TRIPS, hence statutory provisions as such and not the interpretation thereof.

In relation to Article 9(2) of the Berne Convention, Geiger states that the provision is “beyond doubt addressed to legislatures in the Union countries and not the judges”.⁸⁵² The provision within the Berne Convention expressly makes it “a matter for legislation”,⁸⁵³ and

⁸⁴⁵ Article 17 TRIPS.

⁸⁴⁶ Article 26 (2) TRIPS.

⁸⁴⁷ Martin Senftleben, ‘Towards a Horizontal Standard for Limiting Intellectual Property Rights? - WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law’ [2006] IIC 407, 411.

⁸⁴⁸ See for instance in relation to the Three-Step Test in Copyright law - Martin Senftleben, *Copyright, Limitations and the Three-Step Test* (2003 Kluwer Law International) 279.

⁸⁴⁹ See chapters 2 and 3.

⁸⁵⁰ See chapters 2 and 3.

⁸⁵¹ Section 55.2(1) and 55.2(2) of the Canadian Patent Act.

⁸⁵² Christophe Geiger, ‘The Three-Step Test, a Threat to a Balanced Copyright Law?’ [2006] IIC 683, 689. He continues that the situation is “considerably less clear” in relation to Article 5 (5) of the Copyright Directive, a transplant of Article 9(2) of the Berne Convention - *ibid* 689.

⁸⁵³ See footnote 577 for the text of the provision.

therefore undoubtedly addresses the legislator. However, where the test has been provided in addition to a set of limitations then this would make the test being addressed to the courts, as Kur stipulates.⁸⁵⁴ Some EU Member States have adopted the version of the 3 Step Test from Article 5(5) of the Infosoc Directive in their national copyright legislation.⁸⁵⁵ This would mean, for instance, that courts in Spain would need to reassess whether a statutory exception and its interpretation would meet the requirements of the Spanish version of the 3 Step Test.⁸⁵⁶ Then the 3 Step Test becomes a template that courts apply in order to assess whether an exception provision has adequately been acceptable.⁸⁵⁷

A provision mirroring Article 30 TRIPS has not been legislated in Germany or the United Kingdom. Both patent acts rather provide for concrete provisions in relation to exceptions to patent infringement.⁸⁵⁸ Hence, the provision of Article 30 TRIPS is addressed at national legislators. This consequently means that when national legislators wish to apply public interest considerations within exception provisions they need to take Article 30 TRIPS into account. This also means that compatibility with Article 30 would have been assessed by the legislator *ex ante*. Courts are therefore not required to assess compliance with Article 30 TRIPS when interpreting an exception provision. It might be that they apply the test as an interpretation guideline.⁸⁵⁹

⁸⁵⁴ Annette Kur, 'Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?' (2008) Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No. 08-04, 11 (in fn 36) <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1317707> accessed 23 May 2015.

⁸⁵⁵ Guido Westkamp, 'The Implementation of Directive 2001/29/EC in the Member States' (2007) Queen Mary Intellectual Property Research Institute) 48 <http://ec.europa.eu/internal_market/copyright/docs/studies/infosoc-study-annex_en.pdf> accessed 23 May 2015.

⁸⁵⁶ Article 40bis of the Law on Intellectual Property. Geiger states with this regard that this is because its' inclusion in national law and provides France, Italy and Greece as other examples that have directly included the three-step test into their copyright legislation - Christophe Geiger, 'The Three-Step Test, a Threat to a Balanced Copyright Law?' [2006] IIC 683, 690.

⁸⁵⁷ "This provision leads judges to consider the specificities (nature and amount of work, technology, purposes, etc.) of each scenario, in order to find *in casu* the right balance between the public or private interests of each exception and that of the author. This application is however limited to the exceptions expressly provided in the wording of the Copyright Act" – Gemma Minero Alejandre, 'Google cache is legal in Spain – Spanish Supreme Court, 3 April 2012, The Megakini.com v Google Spain case (N. 172/2012)' [2013] QMJIP 81, 83.

⁸⁵⁸ *supra* 3.3 and 3.4.

⁸⁵⁹ In some copyright cases in EU Members States the test deriving from the Infosoc Directive has been applied as a general principle of copyright law. See: Guido Westkamp, 'The Implementation of Directive 2001/29/EC in the Member States' (2007) Queen Mary Intellectual Property Research Institute) 48. <http://ec.europa.eu/internal_market/copyright/docs/studies/infosoc-study-annex_en.pdf> accessed 23 May 2015.

The 3 factors or steps that Article 30 TRIPS sets forward are of abstract nature.⁸⁶⁰ This potentially provides for enough interpretive leeway for national legislators to accommodate the requirements of the test with their own domestic necessities. Initially and similarly to the discussions surrounding the inclusion of Article 9 (2) of the Berne Convention in 1967, a draft version of Article 30 TRIPS included a list of exceptions which national legislators could include as well as the flexible format that we now find in the 3-Step-Test.⁸⁶¹ The Dunkel Draft⁸⁶² that largely displays the final and adopted version of the TRIPS Agreement however displays Article 30 TRIPS in its current form.⁸⁶³

The wording of Article 30 TRIPS departs from the original template from the Berne Convention as it makes no reference to “certain special cases” and does insert the term “unreasonably” when compared to the wordings in relation to copyright. Most remarkably is that according to Art. 30 the “legitimate interests of third parties” need to be taken into account.⁸⁶⁴ The addition of the terms “unreasonably” within the second step of Article 30, as well as the notion of third parties can be attributed to the fact that it has to apply to all exception provisions to patent infringement. The original Berne version only related to the exceptions to the right of reproduction.

⁸⁶⁰ Martin Senftleben, *Copyright, Limitations and the Three Step Test – An Analysis of the Three Step Test in International and EC Copyright Law* (Kluwer Law International 2004) 125.

⁸⁶¹ Such uses were among others prior use, private and non-commercial uses, experimental use - Uruguay Round - Group of Negotiations on Goods (GATT) - Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods - Status of Work in the Negotiating Group – ‘Chairman’s Report to the GNG’ (GATT Document MTN.GNG/NG11/W/76, 23 July 1990) 31-32.

⁸⁶² The draft is named after the former Director General of the GATT Arthur Dunkel that attempted to accommodate the divergent positions between the national delegations - Duncan Matthews, *Globalising Intellectual Property Rights – The TRIPs Agreement* (Routledge 2002) 39; Peter Yu, ‘The objectives and principles of the TRIPS Agreement’ in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 149

⁸⁶³ Uruguay Round - Trade Negotiations Committee ‘Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations’ (GATT Document MTN.TNC/W/FA, 20 December 1991) 70.

⁸⁶⁴ Such notion is not provided in the “sister” provision of Article 30 in relation to copyright Article 13 but is mentioned in relation to Trade Marks (Article 17 TRIPS) and Designs (Article 26 (2) TRIPS).

The Panel in the Canada case found that the TRIPS negotiations do not give an explanation of why this notion was added to the text of Article 30 - *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.71].

By noting the differences in wording Kur queries whether the different wording in comparison to Art 13 TRIPS and hereby Article 9(2) of the Berne Convention could stipulate that this would entail “a less rigid interpretation” - Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ [2008-2009] *Richmond Journal of Global Law and Business* 287, 310. Geiger, Gervais and Senftleben mention that the addition of this notion is “a significant change to be sure.” - Christophe Geiger, Daniel J. Gervais and Martin Senftleben, ‘Understanding the “three-step test”’ in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 170.

It has been argued that this provides a broader scope of Article 30 TRIPS.⁸⁶⁵ It could also stipulate that a test of proportionality between the interests of right holders with those of third parties is warranted, where the detriment of the right holders must be put in relation with the benefit of users.⁸⁶⁶ Third parties' interest could "include those of follow-on inventors, competitors, and users, as well as the interests of society at large, for instance, in addressing a public health crisis or in ensuring the advancement of science and technology."⁸⁶⁷ As mentioned above, the public interest always necessarily incorporates third parties interests.⁸⁶⁸ Hence, the notion of third parties interest within Article 30 TRIPS can be regarded as verbatim mention of public interest considerations.

5.4 Interpretation of Article 30 TRIPS

Article 30 TRIPS provides national legislators with a yardstick to enact exceptions TRIPS compliant exceptions. The case law with regards to Article 30 TRIPS could shed some light on its scope. However, the status of Panel Reports for the decision making of other panels is opaque. A panel decision only binds the litigants *inter partes*: It does not directly have an effect on other WTO Members.⁸⁶⁹ The role of the panels and the Appellate Body is to solely clarify the Agreement's provisions with regards to the question in suit. They do not provide for an authoritative interpretation.⁸⁷⁰ The right to provide binding interpretations of provisions of the TRIPS Agreement lies with the WTO Ministerial Conference and the WTO General Council.⁸⁷¹

While Panel- and Appellate Body decisions do not form a *stare decisis* and probably also do not form subsequent practice in the reading of Article 31.3 (b) of the Vienna Convention on

⁸⁶⁵ Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet & Maxwell 2012) [2.396]. Kur asks whether the different wording would allow "a less rigid interpretation." - Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 221.

⁸⁶⁶ Martin Senftleben, *Copyright, Limitations, and the Three-step Test: An Analysis of the Three in International and EC Copyright Law* (Kluwer Law International 2004) 211.

⁸⁶⁷ Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (OUP 2007) 311.

⁸⁶⁸ *supra* 2.4.

⁸⁶⁹ Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreement* (Cambridge University Press 2012) 20.

⁸⁷⁰ Olivier Cattaneo, 'The Interpretation of the TRIPS Agreement - Considerations for the WTO Panels and Appellate Body' [2000] *Journal of World Intellectual Property* 627, 658.

⁸⁷¹ Art. iX (2) Marrakesh Agreement; see - Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreement* (2012 Cambridge University Press) 20.

the Law of Treaties,⁸⁷² they are not irrelevant. Subsequent panels that have followed *Canada – Patent Protection of Pharmaceuticals* referred to the findings of this Panel decision.⁸⁷³ The decision therefore may guide subsequent Panels.⁸⁷⁴ Hence, an analysis of Article 30 TRIPS by this Panel decision serves two important points: First, it will shed light on the Panel’s view on how TRIPS compliant exceptions may be drafted. Furthermore, this establishes whether the current interpretation and application of Article 30 provides sufficient scope for applying public interest considerations in national patent exceptions.

5.4.1 WTO Panel decision (Canada-EC Dispute)

Article 30 TRIPS has been subject of a Dispute Settlement Procedure before the WTO that the panel handed down its decision on the 17th of March 2000.⁸⁷⁵ The case involved the complaint brought forward by the then European Communities against Canada. The complaint was based on whether Articles 55.2 (1) and 55.2 (2) of the Canadian Patent Act are consistent with the TRIPS Agreement. The former provision contained a “regulatory review exception” which enabled competitors to undertake tests and experiments without the consent of the patent owner in order to obtain regulatory approval to market the generic pharmaceutical before the expiry of the patent. By using this exception the generic drugs would have been able to get market access immediately after the patent expires.

The latter provision related to a stockpiling exception which should permit competitors to make the patented product before the expiry of the patent. The competitors had to keep these products within stock and were not able to market these until the patent expired. Again, the rationale behind this provision was to enable the swift marketing of generic drugs which

⁸⁷² Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ [2008-2009] *Richmond Journal of Global Law and Business* 287, 328-329.

⁸⁷³ e.g. *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* - Report of the Panel (15 March 2005) WTO Document WT/DS174/R; *China – Measures affecting the Protection and Enforcement of Intellectual Property Rights* - Report of the Panel (26 January 2009) WTO Document WT/DS362/R..

⁸⁷⁴ Omar Gad states that the Panel- and Appellate bodies’ decisions would surpass mere clarification but can rather “be considered de facto interpretation powers.” - Mohamed Omar Gad, ‘TRIPS Dispute Settlement and Developing Country Interests’ in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, Kluwer Law International 2008) 353, 369. See also - Christophe Geiger, Daniel J. Gervais and Martin Senftleben, ‘Understanding the “three-step test”’ in Daniel J. Gervais (ed) *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 180.

⁸⁷⁵ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R..

otherwise could only be manufactured after the patent expires in order to avoid an infringement of the patented invention. Without such an exception the patent owner would receive an extended term of *de facto* market exclusivity.⁸⁷⁶

Canada conceded that both provisions in dispute would be a violation of Article 28 (1) TRIPS that provides the patent holder to prevent others from “making, using, offering for sale, selling, or importing” the patented invention without his consent if this was not excused by Article 30 TRIPS.⁸⁷⁷ It however, brought forward that such use would be allowed based on Article 30 of TRIPS when interpreted liberally. This would reflect the programmatic provisions of Article 7 and 8 TRIPS.⁸⁷⁸ Therefore, both disputed exceptions would comply with the TRIPS Agreement.⁸⁷⁹ The panel eventually found that the stockpiling exception would not conform with the TRIPS Agreement while it affirmed that the regulatory review exception would be TRIPS compliant.⁸⁸⁰ Canada therefore repealed its stockpiling exception.

5.4.1.1. The Panel’s general approach

Before assessing the contents of Section 30 TRIPS, the Panel made important observations with regards to the general means of interpretation of the provision. The Panel stated that the rules of interpretation of the disputed provisions (Articles 27 (1), 30 and 33 TRIPS) were governed by the Vienna Convention on the Law of Treaties.⁸⁸¹ The panel additionally held that it can take recourse to “international instruments on intellectual property incorporated

⁸⁷⁶ The European Commission undertook a sector inquiry into the pharmaceutical sector. The inquiry established that the average gap between the loss of exclusivity by the originator drug and the first entry of a generic drug was more than 7 months – European Commission, *Pharmaceutical Sector Inquiry – Preliminary Report Fact Sheet "Prices, time to generic entry and consumer savings*, (28 November 2008) 2 <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/1_Prices_time_to_generic_entry_and_consumer_savings.pdf> accessed 23 May 2015.

⁸⁷⁷ This has been clearly stated in the decision in relation to the stockpiling exception - *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.18]. In relation to the regulatory review exception this has not been stated directly but it can be assumed that Canada was of the opinion that the exception met the conditions of Article 30 - *ibid* [7.39]: A statement which would not be necessary if Canada would have considered the provision not a violation of Article 28 (1) TRIPS.

⁸⁷⁸ Martin Senftleben, ‘Towards a Horizontal Standard for Limiting Intellectual Property Rights? - WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law’ [2006] IIC 407, 413.

⁸⁷⁹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [3.2].

⁸⁸⁰ *ibid* [8.1]. The dispute settlement procedure did not involve an assessment of whether a provision regarding a research exception was consistent with the TRIPS Agreement but it discussed it within it.

⁸⁸¹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.13].

into the TRIPS Agreement”.⁸⁸² These could be used as means for interpreting the disputed provisions pursuant to Article 32 of the Vienna Convention which regards “the preparatory work of the treaty and the circumstances of its conclusion”⁸⁸³ as supplementary means of interpretation. Hence, the panel could scrutinise Article 9 (2) of the Berne Convention as Article 30’s “parent provision” when interpreting Article 30 TRIPS.⁸⁸⁴

An issue that was brought forward by both parties was how subsequent practice according to Article 31 (3) (b) of the Vienna Convention was to be applied in the case at hand. This dissent was based on the fact that both parties had differing view as to how such practice in relation to the disputed provisions developed.⁸⁸⁵ The consultations preceding the dispute settlement proceeding were initiated less than two years after legislation in developed WTO Members such as Canada and the European Communities had to be TRIPS compliant according to Article 65 (1) TRIPS.⁸⁸⁶ Canada therefore argued in relation to subsequent practice that “there was a strong presumption that legislation passed by important Members in the immediate aftermath of an agreement and not challenged or protested by other parties was, in fact, accepted or acquiesced in by the other contracting partners.”⁸⁸⁷

Canada argued that WTO Member states have been providing for exceptions to patentee’s rights for generic drug and other regulated product applications for marketing authorizations, albeit implementing TRIPS. This would amount to such subsequent practice.⁸⁸⁸ The Canadian argument was based on court decisions in Germany, Italy and Japan relating to exceptions for experimental use. Canada was of the opinion that if these Member States would have found such decisions as non-compliant with the TRIPS Agreement they would have changed their legislation accordingly.⁸⁸⁹ The Panel however, discarded Canada’s argument. It held that “subsequent acts by individual countries did not constitute ‘practice in the application of the

⁸⁸² *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.14].

⁸⁸³ *ibid* [7.14].

⁸⁸⁴ *ibid* [7.14].

⁸⁸⁵ *ibid* [7.13].

⁸⁸⁶ The provision reads: “Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement”.

⁸⁸⁷ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [4.35].

⁸⁸⁸ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [4.15].

⁸⁸⁹ *ibid* [4.15].

The Panel did not follow Canada’s line of argumentation “because the subsequent acts by individual countries did not constitute "practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation" within the meaning of Article 31.3(b) of the Vienna Convention.” – *ibid* [7.47].

treaty which establishes the agreement of the parties regarding its interpretation' within the meaning of Article 31.3(b) of the Vienna Convention.”⁸⁹⁰

Following its previous finding that Article 9(2) of the Berne Convention can assist in interpreting Article 30, the panel initially acknowledged the difference in wording between the two provisions. It found that the reason for the differing terminology between “limited exceptions” and its Berne Convention counterpart which permits the reproduction of a work in “certain special cases” cannot be extracted from the negotiating history of Article 30.⁸⁹¹ The negotiating records only show that the term was included in an early stage of the negotiations before it was decided to use the template provided by the Berne Convention.⁸⁹²

As another important general point, the panel held that Canada had the burden of proof that Sections 55.2(1) and 55.2(2) of its Patent Act were compliant with Article 30 TRIPS.⁸⁹³ This has important implications for Member States that wish to provide for new exception within their national statutes. As already mentioned, the case law provided by panels does not constitute precedents. But it is likely that future panels would follow the Canada-EC Panel when scrutinising the compliance of a national exception provision with Article 30 TRIPS. The Member State that enacted the questionable exception is therefore bound to provide evidence that the provision in question would comply with Article 30.

The panel’s most critical (and perhaps most widely criticised) statement in the report surrounded the relationship of the individual steps of Article 30 to one another: It found that all of the conditions of the 3 Step Test are independent from one another and are assessed separately.⁸⁹⁴ Importantly however, they apply cumulatively by which failure to comply with one step would disallow the exception provision in question.⁸⁹⁵ While the Agreement does

⁸⁹⁰ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.47].

⁸⁹¹ *ibid* [7.29]; the Report of the Panel provides a chronological display of how the wording of Article 30 developed in the Uruguay Round negotiations in Appendix 6.

⁸⁹² *Ibid* [7.29]; Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 244.

⁸⁹³ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.16].

⁸⁹⁴ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.20].

⁸⁹⁵ *ibid* [7.20]. The fact that all steps need to be met cumulatively has been confirmed by Dispute Settlement panels in the subsequent Dispute Settlement Procedures with regards to Article 30’s sister provision Article 13 TRIPS in the panel in the US Copyright dispute settlement proceeding - *United States – Section 110(5) of the US Copyright Act* – Report of the Panel (15 June 2000) WTO Document WT/DS160/R [6.97].

not mandate such an approach it can be argued that the Panel followed the drafting history of Article 9(2) of the Berne Convention.⁸⁹⁶

5.4.1.2. The first step (“Limited exceptions”)

The panel agreed with the EC by holding that the term “limited exceptions” had a narrower meaning than argued by Canada.⁸⁹⁷ It held that

“[t]he term "limited exception" must [...] be read to connote a narrow exception - one which makes only a small diminution of the rights in question.”⁸⁹⁸

The panel based this finding on the fact that Article 30 specifically uses the term “limited exceptions”. It concluded that “limited” has a separate meaning to the term “exception”.⁸⁹⁹ This would result in a narrower exception as the term “exception” already implicitly suggests a limitation.⁹⁰⁰

The Panel then sought to provide what the term “limited exceptions” would relate to within the first step. While discussing the stockpiling provision of the Canadian Patent Act, it agreed

⁸⁹⁶ World Intellectual Property Organisation, ‘Records of the Intellectual Property Conference of Stockholm June 11 to July 14, 1967’ (World Intellectual Property Organisation 1971) 1145-1146. The section stipulates a sequential assessment of the criteria of the Three Step test - Christophe Geiger, Daniel J. Gervais and Martin Senftleben, ‘Understanding the “three-step test”’ in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 168.

⁸⁹⁷ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.30].

Canada submitted that an interpretation of the term “limited” should follow dictionary meanings such as “confined within definite limits” and “restricted in scope, extent, amount”. The stockpiling exception would fall under this understanding as it would not impair the patent holders exclusive market since the products produced under the exception could only be manufactured and stockpiled but not commercialised during the last 6 months of the patent term by selling it to the ultimate consumer - *ibid* [7.27], [7.44]. The EC contended that “limited” would mean a narrow exception which is “narrow, small, minor or restricted”. This would have to be measured by the impact that the exception would have on the exclusive rights provided to the patent owner by Article 28 TRIPS. Since the stockpiling exception would curtail 3 rights as provided by article 28 (“making”, “using” and “importing”) such an exception could not be regarded as narrow in the understanding of the EC. Therefore, an impairment of 3 out of 5 rights could not be considered as limited. The EC also emphasised that in relation to patents for pharmaceuticals a curtailment of rights within the last 6 months of the patent term could also not be considered as limited given that due to regulatory approval would give effective market exclusivity of eight to twelve years - *ibid* [7.28].

⁸⁹⁸ *ibid* [7.30].

⁸⁹⁹ Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 244.

⁹⁰⁰ *ibid* 244.

with the EC's interpretation that "limited" is to be measured by the extent to which the exclusive rights of the patent owner has been curtailed: "The full text of Article 30 refers to "limited exceptions to the exclusive rights conferred by a patent"."⁹⁰¹ Due to a perceived lack of other indications, the Panel went to apply a literal interpretation of the text.⁹⁰² Therefore, rather than looking at the size or extent of the economic impact, the query would relate to the extent to which the patent holders rights have been curtailed by the exception.⁹⁰³ In order to support this finding, the Panel noted that an assessment of the economic impact of an exception provision would take place within the two following conditions of Article 30.⁹⁰⁴

Additionally, the two following steps would "provide two sets of standards by which such impact may be judged."⁹⁰⁵ The curtailment of the rights *as such* provided to patent holders under Article 28 would only be covered within the first step under the term "limited exceptions".⁹⁰⁶ The panel confirmed this view when it later discussed the regulatory review exception.⁹⁰⁷ With regards to whether the patent holder's rights needed to be impaired as to quantity or quality, the panel discarded the EC's submission that assessed the question whether an exception is limited or not by counting the numbers of the rights that would be impaired by the measure. It held: "A small act could well violate all five rights provided by

⁹⁰¹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.31].

⁹⁰² *ibid* [7.31].

⁹⁰³ Pedro Roffe and Christoph Spennemann, 'Canada-patent protection of pharmaceutical products' in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 245.

⁹⁰⁴ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.31].

⁹⁰⁵ *ibid* [7.31].

⁹⁰⁶ *ibid* [7.31]; Pedro Roffe and Christoph Spennemann, 'Canada-patent protection of pharmaceutical products' in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 247. Importantly, the panel reiterated its approach that effect on the economic value of the patent right was not considered in the assessment of the first step. It disagreed with the submission of Canada that an exception is limited as long as the patent owner remains his right to sell to the ultimate consumer during the patent term which would remain under the stockpiling exception. (Pedro Roffe and Christoph Spennemann, 'Canada-patent protection of pharmaceutical products' in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 245). It held that with regards to the stockpiling exception that such a perspective creates a hierarchy among the exclusive rights with the right to sell on top which has no base within the TRIPS Agreement. If the question to what extent the right of "making" and "using" the patent were curtailed would be less relevant than the right to sell then their addition within the rights of Article 28 TRIPS as well within many national patent laws would be redundant in the panel's view - Pedro Roffe and Christoph Spennemann, 'Canada-patent protection of pharmaceutical products' in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 245.

⁹⁰⁷ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.49].

article 28.1 and yet leave each of the patent owner's rights intact for all useful purposes."⁹⁰⁸ Therefore, such measurement must be assessed by looking at the extent by which the right of the patent owner is limited.⁹⁰⁹

Following this formalistic approach, the panel then addressed the question to what extent the right to exclude by 'making' and 'using' the patent were affected by the stockpiling exception. It held that these rights provided an additional layer of protection in comparison to the right to exclude selling the patented product: "The right to exclude 'making' and 'using' provides protection, [...], during the entire term of the patent by cutting off the supply of competing goods at the source and by preventing use of such products however obtained."⁹¹⁰

Since the stockpiling exception did not provide any limitation as to the quantity of products being made during the last 6 months of the patent's term covered by the exception it would abrogate the rights in question totally in this period. As this constituted a substantial curtailment of the right of Article 28 (1) TRIPS, it could not be regarded as being limited and hence not TRIPS compliant.⁹¹¹ This was greatly due to the fact that there was no limitation as to the quantity which could be produced under the exception. Additionally, the exception remained silent as to "exactly what level of curtailment would be disqualifying."⁹¹²

⁹⁰⁸ Pedro Roffe and Christoph Spennemann, 'Canada-patent protection of pharmaceutical products' in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 245.

⁹⁰⁹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.31].

⁹¹⁰ *ibid* [7.34]. The panel also discussed whether a market advantage of the patent owner that derives from the fact that competitors wishing to make and commercialise the lapse of the term of the patented invention will require some time in order to compete with the patent holder is also covered by the patent right. It held that additional market benefits are within the scope of the rights to exclude others from 'making' or 'using' the patent - Pedro Roffe and Christoph Spennemann, 'Canada-patent protection of pharmaceutical products' in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 246. This is based on the rationale that patents wish to eliminate "competitive commercial activity by others. The delay in the commercial reward does not alter the right to prevent manufacturing for commercial sale. In summary the panel found that extended market exclusivity after the patent has expired is the consequence that derives from the right to prevent 'making' and 'using'. Interestingly, the panel added after this finding that since the rights in question have repeatedly been enacted with knowledge of their market effects such effects would thereby have been endorsed and affirmed. What the panel seems to suggest by this statement is that legislators envisaged and purposely endorsed such after market exclusivity by enacting the right to prevent making or using the patented invention during the patent term.

⁹¹¹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.36].

⁹¹² *ibid* [7.36]. The panel discarded Canada's argument that the stockpiling exception would only be applicable for persons that have used the regulatory review exception under Section 55.2(1). While agreeing that a period of 6 months before the expiry of the patent would reduce the impact on the panel concurred with the EC that a period of 6 months remains to be a commercially significant. – *ibid* [7.37].

With regards to the regulatory approval exception, the panel held that such an action would be covered by Article 30.⁹¹³ Here, the rights of patent owners would be impaired only to a limited extent. The Panel held that such use was solely in order to comply with the regulatory approval process and where such use would not be commercial of the products resulting from this action.⁹¹⁴

The panel's interpretation of the first step represents a steep hurdle that national patent legislation needs to surpass in order to incorporate considerations of public interest within exceptions. This is primarily based on the narrow scope of applicability that such exception provisions are allowed to have under the panel's view. Indeed, the panel's interpretation of the term "limited exceptions" has been criticised as being narrower than its dictionary meaning.⁹¹⁵ What may have led the Panel is the historical context of the provision with regards to the difference in wording to the first step within Article 9 (2) Berne Convention (and Article 13 TRIPS). Here it relates to "certain special cases" whereas the reading within the Article 30 (and indeed in relation to Articles 17 and 26 (2) TRIPS) changed into "limited exceptions".

The panel noted that the present terminology was introduced early in the draft text and that there is no explanation within the documents explaining the change of wording. Arguably, the panel's interpretation of "limited exceptions" relied on the *singularia* rule. This rule

⁹¹³ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.45]. Apart from submitting the same line of arguments in relation to the exception to be limited as brought forward along the stockpiling exception, Canada added to points with regard to the regulatory approval exception. First, Canada argued that the United States had enacted a similar provision to its regulatory with its Bolar Exception in 35 U.S.C. Section 271 (e) in 1984 and therefore before the inception of the TRIPS Agreement. Canada hereby relied on statements of US officials stating that the TRIPS Agreement did not conflict with the Bolar exception which would consequently would make Canada's regulatory review exception TRIPS-compliant due to its similarity with its US counterpart - *ibid* [7.41]. Canada also brought the subsequent practice by other WTO Member through new legislation and through interpretation by court decisions forward that enacted or confirmed similar practice then such allowed by Section 55.2(1). An interpretation of such subsequent practices within the meaning of Article 31(3)(b) of the Vienna Convention would confirm that such practices are permitted by Article 30 - *ibid* [7.42].

The EC argued that the regulatory review exception was not limited in the meaning of Article 30 as allowed third parties to conduct all 5 rights of Article 28 which would otherwise not be permitted without consent of the patent owner. Particular emphasis was given to the fact that the exception allowed the commercial sale of the active ingredient of a patented pharmaceutical to a generic company by a fine chemical producer – *ibid* [7.43].

⁹¹⁴ Pedro Roffe and Christoph Spennemann, 'Canada-patent protection of pharmaceutical products' in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 246.

⁹¹⁵ Frederick M. Abbott, 'Bob Hudec as Chair of the Canada - Generic Pharmaceuticals Panel - The WTO Gets Something Right' [2003] *Journal of International Economic Law* 733, 736.

stipulates that exceptions are bound to be interpreted narrowly.⁹¹⁶ However, the approach taken by the Canada panel stands awkwardly within the context of WTO law. The Appellate Body has held in the *Hormones* decision that the application of the *singularia* rule to interpret exceptions is not mandated.⁹¹⁷ While this decision was not within the IP context, it highlights that different approaches to interpreting exception rules are permissible. It rather appears that the narrow interpretation resulted from the fact that TRIPS-compliant exceptions have to be ‘limited’ in the reading of Article 30 TRIPS. The Canada Panel applied its understanding of “limited exceptions” as being a form of tautology which emphasises the narrowness of the exception.

The Panel’s narrow understanding of how TRIPS-compliant exceptions must be legislated curtails the ability of national legislation to incorporate public interest considerations substantially: The fact that exceptions need to be limited means that the proposed exception can only diminish the extent of the right of the patent holder by a small amount.⁹¹⁸ The Panel has held that the stockpiling exception in the Canadian Patent Act was not limited *enough* as it did not provide a quantitative restriction of medicine produced under the exception.⁹¹⁹ Generally, an exception provision will always diminish the right to exclude others from using the invention. But the question remains uncertain to what extent The Panel’s approach might suggest that legislators would have to provide for detailed legislation in order to meet the first step of Article 30.

Beas Rodrigues Jr. argues that the panel should have rather interpreted the first step as meaning “limited” or “confined within certain limits”⁹²⁰ which resembles the interpretation

⁹¹⁶ The panel’s approach demonstrates that the term ‘exception’ is highly problematic as it could lead to the connotation that the exercise of the patent right is the rule while a deviation thereof is “exceptional” and only permissible in such exceptional circumstances - supra 1.1.

⁹¹⁷ The Appellate Body has held in the *Hormones* decision that “an ‘exception’ does not by itself justify a ‘stricter’ or ‘narrower’ interpretation of the provisions than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in light of the treaty’s object and purpose” - *EC Measures Concerning Meat and Meat Products (Hormones)* Report of the Appellate Body, WT/DS26/AB/R, WT/DS48/AFVR, 16 January 1998 [104].

⁹¹⁸ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.30], [7.32].

⁹¹⁹ Section 55.2(2) of the Canadian Patent Act however stated that stockpiling was only permissible in the last 6 months of the patent term which represents a limitation of the permissible use with regards to time frame. It is questionable how a quantitative restriction can be legislated within a provision that generally drafted in an abstract-general way.

⁹²⁰ Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreement* (Cambridge University Press 2012) 98.

that Canada proposed.⁹²¹ This would better reflect the Agreements objectives and would highlight that it only seeks to provide minimum obligations.⁹²² Additionally, such interpretation would highlight that exceptions should be predictable and clear in order to avoid uncertainty among patent holders and third parties. According to Senftleben, the panel “refrained from developing a separate requirement of legal certainty altogether”⁹²³ with its interpretation. The recently published Declaration on Patent Protection of the Max Planck Institute for Innovation and Competition proposes that a limited exception in the understanding of Article 30 should be “reasonably proportionate to its objective and purpose. It must fulfil a legitimate purpose, be adequate to achieve that purpose, and not exceed what is necessary and sufficient to achieve it.”⁹²⁴

Apart from the Panel’s restrictive way of interpreting the first step, it is the panel’s formalistic approach that “limited exceptions” solely relate to the patent holders right as provided in Article 28 which inhibits applying public interest considerations. It ignores the economic impact of the exception in question and rather looks at how the patent right was limited.⁹²⁵ Dinwoodie and Dreyfuss therefore note that the panel was applying “an accountant’s approach to the issues”⁹²⁶ by “counting rights”⁹²⁷ which amounts to be the sort of “objectivity that that trade lawyers and the WTO often seek.”⁹²⁸ The panel’s assessment of discarding to scrutinise if and to what extent would have economic impact would mean that

⁹²¹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.27].

⁹²² Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreement* (Cambridge University Press 2012) 98.

⁹²³ Martin Senftleben, ‘Overprotection and protection overlaps in IP law’ in Annette Kur and Vytautas Mizaras (eds), *The structure of IP law* (Edward Elgar 2011) 159.

⁹²⁴ Max Planck Institute for Innovation and Competition, Declaration on Patent Protection [23] <http://www.ip.mpg.de/fileadmin/user_upload/Patent_Declaration_en.pdf > accessed 23 May 2015.

⁹²⁵ Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ [2008-2009] *Richmond Journal of Global Law and Business* 317.

Similarly, Dinwoodie and Dreyfuss that note:

“But unlike the EC-GI panel, the US-110(5) and Canada-Pharmaceuticals panels did not do justice to that complexity by considering the relative economic value and social importance of each use or the question of the value of a particular form of exploitation to users relative to right holders. Because some of these considerations are more naturally encompassed by the other subparts of the Exceptions tests, the Canada-Pharmaceuticals panel’s decision to isolate each of the parts of the inquiry made it even harder to consider those variables in determining whether a defense is limited.”

Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (OUP 2012) 62.

⁹²⁶ *ibid* 69.

⁹²⁷ *ibid* 69.

⁹²⁸ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (OUP 2012) 62.

an exception would fall afoul of the first step “even if the patent owner is not negatively affected in practice”⁹²⁹ as Correa notes.

This formalistic approach does not leave any consideration of the policy reason that the national legislator sought to achieve. This leads Kur to state that the approach by the panel is “policy-blind”.⁹³⁰ She adds: “Better than that, it ought to be acknowledged that in view of the task that the three-step-test has to fulfil, it is definitely inappropriate that the purely quantitative assessment should become the sole parameter for deciding on the admissibility of an exception.”⁹³¹ The way that the first step is being assessed does not provide for a useful tool to achieve this balance. However, a meaningful balancing exercise would look at the effect that a measure has for all involved parties. This is clearly not achieved by solely discarding normative considerations.

While the panel allegedly discarded that the economic impact of the exception would not be assessed within the first step it does not fully follow its own conclusion as Beas Rodrigues points out.⁹³² While having stated that the first step does not involve an assessment of the economic effect that the exceptions would have on the patent holder it however held that the stockpiling exception did not constitute a limited exception. This is because it, at least partly, is based its assessment on such a rationale.⁹³³ It held “that six months was a *commercially* significant period of time, especially since there were no limits at all on the volume of production allowed, or the market destination of such production.”⁹³⁴ (Emphasis added)

⁹²⁹ Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (OUP 2007) 307.

⁹³⁰ Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ [2008-2009] *Richmond Journal of Global Law and Business* 340.

⁹³¹ *ibid* 317.

The panel’s reasoning however differs from the findings of the copyright decision where “limited exceptions” is based on a qualitative as well as quantitative assessment - *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [6.109]. This would constitute a less rigid approach taken by the panel in the patent decision according to Senfleben which is based on two issues: First, the patent panel did not apply a maximum level of narrowness in relation to the first step as it did in the Copyright decision where the limitation or exception needed to be cumulatively narrow in quality as of quantity. The patent panel left it open whether this assessment was made as of quality or quantity - Martin Senfleben, ‘Towards a Horizontal Standard for Limiting Intellectual Property Rights ? - WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law’ [2006] IIC 407, 418.

⁹³² Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreement* (Cambridge University Press 2012) 92.

⁹³³ *ibid* 92.

⁹³⁴ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.37].

While the lack of any normative assessment within the first step of Article 30 TRIPS⁹³⁵ fails to serve the purpose of Article 30, it has been argued that the panel that had to adjudicate the *EU-GI* dispute provided a better interpretative approach.⁹³⁶ The sister provision to Article 30 within the law of trade marks provides an example⁹³⁷ which would be considered as being “a limited exception”. Hence, Dinwoodie and Dreyfuss state that such examples provide a useful guideline for interpreting the three step test in order to “illuminate the normative component of the analysis, which adjudicators may otherwise miss, ignore, or minimalise.”⁹³⁸ Therefore, the draft version containing an enumerative list of what exceptions could be considered to fall within Article 30 would have provided guidance to the panel when interpreting the provision.

5.4.1.3. The second step (“unreasonably conflicts with normal exploitation”)

Since the panel discarded the stockpiling exception as falling foul of the first step, it considered the second step of Article 30 TRIPS only in relation to the regulatory review exception.⁹³⁹ It stuck to its approach that economical consideration would not be considered within the first step but within the latter two. It therefore held that ‘exploitation’ of the patent would relate to the commercial activity of the patent holder to extract “economic value from their patent.”⁹⁴⁰ It sought to apply a literal interpretation of the term “normal” by analysing its dictionary meaning. According to the panel the term “normal” could have 2 meanings: First, “an empirical conclusion about what is common within a relevant community”.⁹⁴¹ It also could be the reference to “a normative standard of entitlement.”⁹⁴² The panel held that both of these two meanings were being used in Article 30 TRIPS.⁹⁴³ When considering what would

⁹³⁵ Martin Senftleben, ‘Towards a Horizontal Standard for Limiting Intellectual Property Rights? - WTO Panel Reports Shed Light on the Three-Step Test in Copyright Law and Related Tests in Patent and Trademark Law’ [2006] IIC 407, 418.

⁹³⁶ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (OUP 2012) 69.

⁹³⁷ “such as fair use of descriptive terms”.

⁹³⁸ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (OUP 2012) 69.

⁹³⁹ Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 249.

⁹⁴⁰ *ibid* 247.

⁹⁴¹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.54].

⁹⁴² *ibid* [7.54].

⁹⁴³ *ibid* [7.54]; Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 248. According to the patent panel, a certain area of exploitation can be regarded as a part of „a normal exploitation” in the sense of Art. 30 TRIPS if most patent owners use this area to extract value from their patents (empirical connotation), or if it is essential to the achievement of the goals of

constitute a normal exploitation of the patent, it held that this would amount “to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity.”⁹⁴⁴

The panel argued that patent laws have set up a “carefully defined period of market exclusivity”⁹⁴⁵ that is crafted to induce innovation and this cannot be achieved if patent owners cannot utilise the advantages this inducement sets out.⁹⁴⁶ What the panel stated is that the normal exploitation of a patent includes a “more or less brief period of market exclusivity after the patent has expired.”⁹⁴⁷ According to Roffe and Spennemann, this would mean that “the separate right to prevent ‘making’ the patented product during the term of the patent prevents competitors from building an inventory needed to enter the market immediately upon expiration of the patent.”⁹⁴⁸

In holding that the regulatory approval exception would not violate the second step of Article 30, the Panel backed Canada’s view on the issue. It was contended that the extension of the patent term is based on the increased duration of the regulatory process. This extended term “is not a natural or normal consequence of enforcing patent rights. Rather, it is an unintended consequence of the conjunction of the patent laws with product regulatory laws”⁹⁴⁹, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights. It is likewise a form of exploitation that most patent owners do not in fact employ. “For the vast majority of patented products, there is no marketing regulation of the kind covered by Section 55.2(1), and thus there is no possibility to extend patent exclusivity by delaying the marketing approval process for competitors.”⁹⁵⁰

patent policy (normative connotation). The two meanings of the term „normal” were thus applied as a prerequisite for qualifying a certain area of exploitation as a part of „a normal exploitation.””.

⁹⁴⁴ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.55].

⁹⁴⁵ *ibid* [7.55].

⁹⁴⁶ *ibid* [7.55].

⁹⁴⁷ *ibid* [7.56].

⁹⁴⁸ Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 248.

⁹⁴⁹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.57].

⁹⁵⁰ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [757]; Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 248.

Importantly, the Panel did not discuss what constitutes “unreasonably” in this context as it did not find there to be a conflict with the normal exploitation of the patent owner which made a further discussion redundant.⁹⁵¹ Omar Gad perceives this as a flaw in the analysis.⁹⁵² He argues that the fact that exceptions should not unreasonably conflict with such interpretation of normal exploitation would provide more flexibility for policy considerations combined with the Copyright Panel’s approach⁹⁵³ that “normal” exploitation clearly means something less than the full use of an exclusive right.”⁹⁵⁴

In its assessment of the second step, the panel opened a gateway for normative considerations which could give legislators some ambit to apply public interest considerations. The panel discarded the EC’s submissions that normal exploitation would relate to “all gains derived from such rights as flowing from “normal exploitation””.⁹⁵⁵ It rather referred to stipulate that “normal” would have to be considered as “in the sense of being essential to the achievement of the goals of patent policy”.⁹⁵⁶ Roffe and Spennemann regard the panel’s reference to patent policy in relation to what would constitute a normal exploitation an opening to implant policy consideration as mentioned within Article 7 of the TRIPS Agreement: In their view the exercise of a patent would be falling under the scrutiny of whether it would contribute to technological innovation.⁹⁵⁷

The normative approach that the panel took in comparison to the copyright panel in relation to the term normal was pointed out by Senftleben:

⁹⁵¹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.59].

⁹⁵² Mohamed Omar Gad, ‘TRIPS Dispute Settlement and Developing Country Interests’ in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, Kluwer Law International 2008) 371.

⁹⁵³ *United States – Section 110(5) of the US Copyright Act – Report of the Panel* (15 June 2000) WTO Document WT/DS160/R. The Dispute Settlement Panel was established to assess the EC’s complaint of Article 110 (5) (B) of the US Copyright Act and the so-called “homestyle” exemption.

⁹⁵⁴ Mohamed Omar Gad, ‘TRIPS Dispute Settlement and Developing Country Interests’ in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, Kluwer Law International 2008) 371.

⁹⁵⁵ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.58].

⁹⁵⁶ *ibid* [7.58].

⁹⁵⁷ Roffe and Spennemann state that when a patent would be used to block other competitors to develop new products then this would be considered as not promoting innovation and therefore would not be regarded as forming a “normal exploitation” of the right - Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 278.

The normative connotation of „normal,“ however, was interpreted differently. The patent panel rejected the legal positivist argument that all areas of exploitation resulting from exclusionary patent rights were to be regarded as parts of „a normal exploitation.“ It required a justification in the light of underlying patent policies instead. The copyright panel, by contrast, clarified that both actual and potential forms of exploitation resulting from the exercise of exclusive copyrights, in principle, constituted parts of „a normal exploitation.“ It introduced a quantitative confinement to ways of exploiting copyrights that yield significant or tangible commercial gains. Whereas the patent panel adopted a normative policy approach, the copyright panel rather followed a legal positivist approach.⁹⁵⁸

The more policy accommodating approach in the Canada dispute in comparison to the US Copyright decision has also been identified by Geiger. He states that the interpretation in the latter decision may have two important backdrops with regards to policy making: First, such interpretation could cement a status-quo which would prevent extending exceptions which were unforeseen by the text of Article 13 TRIPS.⁹⁵⁹ Second, exceptions in relation to future forms of exploitation may be impaired “every time a technical evolution allows controlling previously uncontrollable uses, thus creating new possibilities for exploitation.”⁹⁶⁰ The decision in the Canada panel however, would provide more leeway.

The second step clearly indicates that considerations in relation to patent policy are adopted within the second step. The interpretation of “normal exploitation” relates to the incentive function that patents aim to establish. The Panel’s emphasis on patent policy highlights a utilitarian approach.⁹⁶¹ This links back to an economic understanding that patents should be provided to the extent that they serve their utilitarian function.⁹⁶² A normal exploitation could be provided where this serves the incentive function. Hence, a limitation that does not affect the incentive function would not harm the normal exploitation of the patent.

The second step additionally offers interpretive gateway in order to ensure that legislators can directly adopt public policy considerations within patent exceptions.⁹⁶³ The second step states that an exception only does not pass muster when it *unreasonably conflict(s) with the normal*

⁹⁵⁸ Martin Senfleben, ‘Towards a Horizontal standard for Limiting Intellectual Property Rights? – WTO Panel Reports shed Light on the Three Step Test in Copyright Law and Related Tests in Patent and Trademark Law’ [2006] IIC 407, 429.

⁹⁵⁹ Christophe Geiger, ‘Implementing an International Instrument for Interpreting Copyright Limitations’ [2009] IIC 627, 634.

⁹⁶⁰ *ibid* 634.

⁹⁶¹ Dan L. Burk and Mark A. Lemley, ‘Policy Levers in Patent Law’ [2003] Virginia Law Review 1575, 1580.

⁹⁶² See again the finding of the German Federal High Court in Clinical Trials I. which said that “unlimited protection by the patent is unjustified where further technical development is impeded.” - BGH, GRUR 1996, 109 (114) - Klinische Versuche I = BGH, RPC 1997, 623 (642) - Clinical Trials I.

⁹⁶³ Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ [2008-2009] Richmond Journal of Global Law and Business 287, 317-318.

exploitation. The panel unfortunately did not discuss the notion of what would be considered to be “unreasonably” conflicting as it considered the regulatory review exception not to be conflicting with the normal exploitation of the patent holder.⁹⁶⁴ The term “unreasonably” needs to be normatively assessed and not just be limited to “strictly economic approach”.⁹⁶⁵ This provides the necessary ambit to apply policy considerations which the TRIPS Agreement itself acknowledges.⁹⁶⁶

The second step specifically acknowledges that the patent holder’s exploitation can be tempered with when conflicting interests mandate this. The particular notion of ‘unreasonably’ which provides a form of test of proportionality then allows legislators or courts to balance the involved interests. Therefore, the wording of the second step and its interpretation provide sufficient leeway to incorporate public interest within patent exceptions. The assessment falls in the prerogative of the legislator.⁹⁶⁷ Courts that apply the 3 Step Test when interpreting national exception will also be able to incorporate public interest within this term.

5.4.1.4. The third step (“legitimate interests”)

Before providing its’ assessment of the final step of Article 30 in relation to the regulatory approval exception, the panel acknowledged Canada’s complicated position of having the burden of proof for showing compliance with the third step.⁹⁶⁸ This was because Canada had to prove that the disputed exception did not “unreasonably prejudice the legitimate interests of the patent owner”, i.e. a negative. First, however, this would require establishing what

⁹⁶⁴ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.59].

⁹⁶⁵ Christophe Geiger, ‘Implementing an International Instrument for Interpreting Copyright Limitations’ [2009] IIC 627, 635. *Geiger* acknowledges the different wording of the Three Step test in relation to patent and copyright law and bases his findings on the fact that Article 30 additionally adds that exceptions must “not *unreasonably* conflict with the normal exploitation of the patent” (emphasis added). Therefore, the normative approach that can be taken in his view is based on the term “unreasonably”.

One could *a fortiori* come to a finding that normative considerations can be taken into account where one finds that there might be a conflict with the normal exploitation of the patent holder as the term of “reasonableness” connotes that interests other than those of the patent holder can be taken into account – *ibid* 636.

⁹⁶⁶ Christie and Wright note that the term “unreasonably” is only mentioned in the patent and design provisions of the TRIPS Agreement which “appears to be significant. In particular, the design and patent provisions will not prohibit an exception that conflicts with a normal exploitation, so long as that conflict is not unreasonable” - Andrew Christie and Robin Wright, ‘A Comparative Analysis of the Three-Step Tests in International Treaties’ [2014] IIC 409, 424 .

⁹⁶⁷ Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (OUP 2007) 311.

⁹⁶⁸ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.60].

these interests are.⁹⁶⁹ The Panel assisted in the analysis and held that the third step would involve a similar discussion as within the second step with regards of the regulatory approval exception.⁹⁷⁰ Hence, the question was whether the extra marketing exclusivity and the economic benefits deriving from extended market exclusivity could be considered as constituting the legitimate interest of the patent owner.⁹⁷¹ Additionally, it would need to be assessed whether the regulatory review exception would then ‘unreasonably prejudice’ such an interest.⁹⁷²

The panel found that the term ‘legitimate’ must be regarded as “a normative claim calling for protection of interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms.”⁹⁷³ The panel rebutted the EC’s interpretation of legitimate interests as legal interests in the full enjoyment of patent rights during the entire term of the patent; a point already brought forward in the context of normal exploitation within the second step.⁹⁷⁴ The panel rejected this argument for several reasons.⁹⁷⁵

⁹⁶⁹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.60].

⁹⁷⁰ *ibid* [7.61].

⁹⁷¹ *ibid* [7.61].

⁹⁷² *ibid* [7.61].

⁹⁷³ Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 249.

⁹⁷⁴ Legitimate interests must be legal interests in the EC’s view which consequently could only be the full enjoyment of the rights as provided under Article 28 for the entirety of the patent term - *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.62]. The crucial issue therefore was whether the full enjoyment of the patent holder’s rights could be seen as unreasonable regarding the “legitimate interests of third parties” - *ibid* [7.62]. The EC also submitted that third parties in the reading of Article 30 could only be the patent owners’ competitors. By this the interests of the general public could not be factored in against the interest of the patent owner to enjoy his patent rights for the entire term. The EC argued that the TRIPS Agreement already incorporates society’s interest and that patent rights granted under the provisions of the Agreement as being part of the balance of rights and obligations have been deemed to be beneficial for society. Hence, based on the benefits that patent rights provide for society in general, and in relation to health policy in particular, these rights could not adversely affect or conflict with “interests represented by general social welfare policy.” – *ibid* [7.62]

⁹⁷⁵ “First, since by that definition every exception under Article 30 will be causing “prejudice” to some legal rights provided by Article 28 of the Agreement, that definition would reduce the first part of the third condition to a simple requirement that the proposed exception must not be “unreasonable”. Such a requirement could certainly have been expressed more directly if that was what was meant. Second, a definition equating “legitimate interests” with legal interests makes no sense at all when applied to the final phrase of Article 30 referring to the “legitimate interests” of third parties. Third parties are by definition parties who have no legal right at all in being able to perform the tasks excluded by Article 28 patent rights. An exceptions clause permitting governments to take account of such third party legal interests would be permitting them to take account of nothing. And third, reading the third condition as a further protection of legal rights would render it essentially redundant in light of the very similar protection of legal rights in the first condition of Article 30 (“limited exception”).” - *ibid* [7.68]. See also - Martin Senftleben, ‘Towards a Horizontal standard for Limiting Intellectual Property Rights? – WTO Panel Reports shed Light on the Three Step Test in Copyright Law and Related Tests in Patent and Trademark Law’ [2006] IIC 407, 430.

Accordingly, the phrase “legitimate interests” appears wider than “legal interest” in the panel’s view. It based its finding by comparing Article 30 to its template that was incorporated within Art. 9 (2) of the Berne Convention. As mentioned, an earlier version of Article 30 had an enumerative list of exceptions that were considered to fall within the scope of Article 30. Examples are private use, scientific use, prior use, an exception for pharmacists.⁹⁷⁶ This list however, was not included in the final version and the more general and abstract provision was chosen for the final text.⁹⁷⁷ Article 30 differs in that respects from Article 9 (2) of the Berne Convention as it adds that the ‘legitimate interests of third parties’ must be taken into account. The Berne Convention template merely refers to the ‘legitimate interests’ of the author. The Panel therefore, held that absent other explanations ‘the legitimate interests’ of third parties within Article 30 TRIPS would only make sense where it is a “concept broader than legal interests.”⁹⁷⁸

The Panel also rejected the EC’s second line of argument. Here, the EC argued that the patent holder is subject to loss of economic benefits where his products are subject to regulatory review.⁹⁷⁹ This would be the time in which the regulatory review is being undertaken and would lead to a reduction of marketing exclusivity. Thus, patent holders “should be entitled to impose the same type of delay in connection with corresponding regulatory requirements upon the market entry of competing products.”⁹⁸⁰ Normatively, this argument was grounded on the claim that all patent holders should be treated equally. Patent holders whose patented products were subject of a regulatory review would be deprived of a substantial part of the 20 year term of market exclusivity that patent laws aim to provide.⁹⁸¹

⁹⁷⁶ Uruguay Round - Group of Negotiations on Goods (GATT) - Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods - Status of Work in the Negotiating Group – ‘Chairman’s Report to the GNG’ (GATT Document MTN.GNG/NG11/W/76, 23 July 1990) 31-32. See also - Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 250.

⁹⁷⁷ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.70].

⁹⁷⁸ Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 250.

⁹⁷⁹ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.74].

⁹⁸⁰ *ibid* [7.74].

⁹⁸¹ *ibid* [7.75].

The Panel acknowledged that the argument brought forward by the EC could fall within its finding of what constitutes legitimate interests.⁹⁸² A normative, policy based rationale could be found as the EC brought forward, in the fact that many WTO Member States had legislated *de jure* extensions of patent terms due to the delay that regulatory review entails for marketing opportunities.⁹⁸³ This has been done in particular in the field of pharmaceutical products where a delay due to regulatory review regularly occurs.

On balance, the Panel decided not follow the EC's line of argument. Therefore, the reduction of *de facto* market exclusivity could not be regarded as legitimate interests of patent holders.⁹⁸⁴ This was not helped by the fact that some WTO member states have legislated positively for an extension of patent terms where patented products are subject to regulatory approval for marketing purposes convince the Panel.⁹⁸⁵ Nor did it find the interests of patent holders whose marketing exclusivity has been reduced due to marketing approval compelling.⁹⁸⁶ The Panel found that there is still no clear line as some countries opt for a term extension for products where marketing approval is required while others do not, even though the issue was already apparent during the negotiation of the TRIPS Agreement.⁹⁸⁷ However, such an unresolved issue should not be subject of adjudication.⁹⁸⁸ Based on these findings, the Panel came to the conclusion that the regulatory review exception in Section 55.2(1) would meet all three conditions of Article 30 and therefore does not fall foul of Canada's obligations in relation to Article 28(1) TRIPS.⁹⁸⁹

While scrutinising the third step and the question as to what meaning could be attributed to the term "legitimate interests", the Panel unfortunately lacked a wider discussion in relation to the meaning of third parties interests. This would again stipulate a primacy of the interest of the right holders according to Gad.⁹⁹⁰ However, the fact, that Article 30 TRIPS adds the

⁹⁸² *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.76].

⁹⁸³ In the EU for instance by the Regulation (EC) No 469/2009 of the European Parliament and the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

⁹⁸⁴ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.82].

⁹⁸⁵ *ibid* [7.82].

⁹⁸⁶ *ibid* [7.82].

⁹⁸⁷ *ibid* [7.82].

⁹⁸⁸ *ibid* [7.82].

⁹⁸⁹ *ibid* [7.84].

⁹⁹⁰ Mohamed Omar Gad, 'TRIPS Dispute Settlement and Developing Country Interests' in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, Kluwer Law International 2008) 372.

phrase “taking the interests of third parties” conversely to its template from the Berne Convention could lead to the conclusion that the scope of this provision is broadened.⁹⁹¹ Canada submitted that this term would provide for an interpretative base to consider public interest considerations.⁹⁹² The panel however, did not give much clarification as to what it considered to be “third parties” for the purposes of Article 30.⁹⁹³

Based on what has been said about public interest, this notion can be regarded as the location where public interest considerations are integrated into the Three Step test.⁹⁹⁴ It is here where the interests of the patent owners and those of third parties are juxtapositioned. These interests will often conflict⁹⁹⁵ which means that a balancing exercise needs to be applied. The wording of the third step mandates that while the exception should not unreasonably prejudice the patent owner’s interest⁹⁹⁶ that this needs to be placed into the context of the interests of third parties. This demands nothing less than a balancing of the interests involved, i.e. the relevant interests of the groups that would be affected by the exception provision.

The conflicting interests that are considered here have various backgrounds. The Declaration on Patent Protection names the following stake holders whose interests could be incorporated within the third step:

“Legitimate interests of third parties include those of

- Follow-on innovation;
- Competitors and other market actors;
- Scientific research;
- Consumers;
- The public at large.”⁹⁹⁷

⁹⁹¹ Daniel Gervais, *The TRIPS Agreement – Drafting History and Analysis* (4th edn, Sweet & Maxwell 2012) [2.396].

⁹⁹² Canada stated that the term would encompass “general societal interests” - *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.67].

⁹⁹³ The EU submitted that only the interests of competitors of the right holder could be considered to “third parties”- *ibid* [7.67].

⁹⁹⁴ The public interest is necessarily based on some form of third party interest as has been established in Chapters 2 and 3 of this work.

⁹⁹⁵ Andrew Christie and Robin Wright, ‘A Comparative Analysis of the Three-Step Tests in International Treaties’ [2014] IIC 409, 430.

⁹⁹⁶ Only such that are legitimate may be taken into consideration which means that not all interests of the right holder are deemed to be relevant in the assessment of Article 30 - *ibid* 428.

⁹⁹⁷ Max Planck Institute for Innovation and Competition, Declaration on Patent Protection [25] <http://www.ip.mpg.de/fileadmin/user_upload/Patent_Declaration_en.pdf > accessed 23 May 2015.

The importance of the third step has been emphasised by legal commentators. Geiger, for instance, holds the third step is the most important one.⁹⁹⁸ In his opinion, the examination of the test in copyright law should commence from the final step and use “the second step afterwards as a corrective measure to eliminate the most abusive conflicts with the exploitation of the work.”⁹⁹⁹ This would allow taking all involved interests into account. He bases his finding by means of a systematic interpretation of all provisions within the TRIPS Agreement that have been modelled on the original Three step test as introduced into the Berne Convention in 1971.¹⁰⁰⁰

Pires de Carvalho emphasises the importance of considering third parties’ legitimate interests. He suggests remodelling the provision by either considering the “legitimate interests of third parties” as a separate fourth condition of Article 30 or as a term that serves to inform all other steps.¹⁰⁰¹ Such an approach would serve to provide a more normative interpretation of the other steps so as “to qualify the exploration of a patent as normal, as well as to help to assess whether a certain exception is limited or not.”¹⁰⁰²

5.4.2 Summary of the panel decision and critique

The Panel’s guideline in interpreting Article 30 can be found in paragraph 7.26 of the report where it acknowledges that exceptions are a necessary tool for patent policy:

In the Panel’s view, Article 30’s very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement. Obviously, the exact scope of Article 30’s authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in

Senftleben states that third party interests could be those of “researchers and the public at large” - Martin Senftleben, ‘Overprotection and protection overlaps in IP law’ in Annette Kur and Vytautas Mizaras (eds), *The structure of IP law* (Edward Elgar 2011) 168.

⁹⁹⁸ Christophe Geiger, ‘Implementing an International Instrument for Interpreting Copyright Limitations’ [2009] IIC 627, 638.

⁹⁹⁹ *ibid* 637.

¹⁰⁰⁰ *ibid* 637-638. Geiger bases his findings primarily on Article 17, the provision within Trade Mark law, only contains one main criteria, namely to “take account of the legitimate interests of the owner of the trademark and of third parties.”

¹⁰⁰¹ Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (4th edn, Wolters Kluwer 2014) [30.11].

¹⁰⁰² *ibid* [30.11].

mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.¹⁰⁰³

This statement may induce the Panel's willingness to adopt an approach that would seek to provide a balance between the interests. Its approach to interpreting Article 30 however, has been widely criticised in not providing any leeway for national legislators to apply public policy considerations.¹⁰⁰⁴ Dinwoodie and Dreyfuss pinpoint this when they state:

The Panels ignored the domestic rationales for the challenged legislation, they considered the various parts of the tests cumulatively (which meant that the interests of thirds parties were not reached) and they largely refused to interpret terms like 'normal', 'legitimate', 'prejudice' and 'unreasonable' normatively.¹⁰⁰⁵

While the panel has acknowledged that both Articles 7 and 8 of TRIPS do play a role in assessing Article 30, it did not abide by this statement in its assessment.¹⁰⁰⁶ These provisions labelled as "Principles" and "Objectives" do contain public interest considerations. While the panel has acknowledged that the Vienna Convention on the Interpretation of Treaties would be applicable it was argued that it incorrectly applied the interpretive rules: The criticism relates in particular about the fact that the panel did not give Article 31 of the Vienna Convention enough weight to the fact that treaties are supposed to be interpreted "in the light of its object and purpose."¹⁰⁰⁷

What ultimately makes the application of the Panel's approach problematic in relation to how public interest considerations can be applied are two connected factors: First, the first step does not by any means take any public interest considerations (i.e. the reason why legislators

¹⁰⁰³ Canada – Patent Protection of Pharmaceutical Products- Report of the panel (17 March 2000) WT/DS114/R [7.26].

¹⁰⁰⁴ Its approach has been criticised as having focussed solely on commercial aspects - Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreement* (Cambridge University Press 2012) 96.

¹⁰⁰⁵ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, 'Enhancing global innovation policy: the role of WIPO and its Conventions in interpreting the TRIPS Agreement' in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 124-125.

¹⁰⁰⁶ Mohamed Omar Gad, 'TRIPS Dispute Settlement and Developing Country Interests' in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, Kluwer Law International 2008) 370-371.

¹⁰⁰⁷ Susy Frankel, 'The WTO's Application of 'The Customary Rules of Interpretation of Public International Law' to Intellectual Property', [2005-2006] *Virginia Journal of International Law* 365, 397; Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreement* (Cambridge University Press 2012) 97; Christophe Geiger, 'Exploring the flexibilities of the TRIPS agreement's provisions on limitations and exceptions' in Annette Kur and Vytautas Mizaras (eds), *The structure of Intellectual Property Law* (Edward Elgar 2011) 287.

wish to provide for an exception) into account.¹⁰⁰⁸ It solely assesses the first factor from the curtailment of the patent owner's right. As Professor Howse stated, "the Panel was only interested in how much the rights holder might lose, not in how much society might gain, from a given exception. It never asked what scope the exception might require to achieve the social purposes at issue."¹⁰⁰⁹ Second and connected to the first point raised, is the fact that the test is applied cumulatively. This means that once an exception provision does not surpass the first step, it will fail Article 30 altogether¹⁰¹⁰ and the underlying societal interest of the exception provision will never be taken into account.¹⁰¹¹ Thirdly, the question also arises why the interests of third parties have been added to all other "3 Step Test" in the TRIPS Agreement when an assessment of the underlying public interest, i.e. policy reasoning, is not always taken into equation when assessing the compatibility of an exception provision with the TRIPS Agreement. Aside from Article 13 of TRIPS, a reference to the interests of third parties has been included in all provisions other provisions in relation to exception.¹⁰¹² While the Panel acknowledged that the reason for adding this to the trade marks, designs and patent sections is not clear, it needs to be asked why such an addition was made in the first place. Their addition rather stipulates that the drafters of the Agreement emphasised that the legitimate interests of third parties and through this the public interest, mandatorily needed to be taken into consideration.¹⁰¹³

This restrictive approach by the Panel might be explained by the fact that the Panel's task was just to assess the compatibility of the Canadian provisions with WTO law. It is generally not

¹⁰⁰⁸ See also - Robert Howse, 'The Canadian Generic Medicines Panel – A dangerous precedent in dangerous times' (2000) *The Journal of World Intellectual Property* 493, 496.

¹⁰⁰⁹ *ibid* 496. Kur says with this regard that "the dice may have been thrown before one gets there." - Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 228.

¹⁰¹⁰ Such an approach is not mandatory for the interpretation of the 3 Step Test provisions outside of the Berne Convention as Geiger, Gervais and Senftleben argue – Christophe Geiger, Daniel J. Gervais and Martin Senftleben, 'Understanding the "three-step test"' in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 168 within footnote 3.

¹⁰¹¹ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, 'An international *acquis*: Integrating regimes and restoring balances' in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 154; Henning Grosse Ruse-Khan, 'Assessing the need for a general public interest exception in the TRIPS Agreement' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 183.

¹⁰¹² Christie and Wright provide a comparison of the individual the steps of the "Three Step Tests", and in particular the third step - Andrew Christie and Robin Wright, 'A Comparative Analysis of the Three-Step Tests in International Treaties' [2014] *IIC* 409, 415.

¹⁰¹³ The omission of the notion of third parties interest within Article 13 TRIPS can probably be linked to a thoughtless copy and paste of Article 9(2) of the Berne Convention which there only relates to the right of reproduction.

the task of the adjudicating bodies of the WTO to assess regulation or considerations outside of its ambit. This may be a general problem for highly specialised international bodies that have to adjudicate issues that transcends its own rationality. The WTO is largely focused on the trade-related issues of intellectual property which doctrinally presents a problem at acknowledging other societal aspects.¹⁰¹⁴ It might also be that the composition of the Panel was problematic. In comparison to national judges, the Panel members do not have to adhere to a constitutional order which generally encompasses the society at large and not one particular field of it.¹⁰¹⁵ This might explain the focus on economic issues of the right holder and the lack of consideration of other aspects such as third party interest surrounding the exception provision.

5.5 Conclusion

Part 1 demonstrated that legislators acknowledge a trade-off that needs to be struck between the interest of the right holder and the public interest. The way exceptions are applied is thoroughly influenced by the balancing exercise that legislators have done.¹⁰¹⁶ Courts take this into consideration when interpreting exception provisions. As seen, legislators curtail the right to the amount necessary to fulfil the public interest. They do so in a proportionate way, meaning that the right should not be curtailed further than is necessary to address the public interest. In other words, legislators start providing the scope for an unauthorised use within an exception in the public interest. They then analyse whether the patent right is not disproportionately curtailed.

The way the Panel in *Canada – Patent Protection of Pharmaceuticals* assessed conversely does not leave any room to consider the reason why the exception provision had been legislated if it fails on the first step of Article 30 TRIPS. Hence, the approach that the Panel took does not reflect or consider how national legislator devise exceptions and hence jeopardise legislative freedom.¹⁰¹⁷ Any third party interest is not being taken into

¹⁰¹⁴ supra 5.2.2.1.

¹⁰¹⁵ supra 5.1.2.2.

¹⁰¹⁶ supra 3.6.

¹⁰¹⁷ Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 239.

considerations with this approach and therefore shows a stark incongruence with approaches taken by the domestic legislator.

Additionally, the Panel's approach does not provide any room to apply fundamental right considerations on which an exception provision may be based on. This is problematic since these considerations need to be applied mandatorily in Germany.¹⁰¹⁸ This may also present an issue for the UK legislator with the requirements of the Human Rights Act 1998.¹⁰¹⁹ Legislators may face the problem in having to abide to two conflicting legal regimes. Additionally, the fact that the exception may be based on a fundamental right rejects the *singularia* rule that exceptions should be interpreted narrowly.¹⁰²⁰ This stands in stark contrast with the panel's view that a limited exception may only denote a "small diminution" of the patent right.¹⁰²¹

The comparison between the approaches towards applying public interest considerations to exceptions has shown that there exist areas of incompatibility between the WTO with that of nation states.¹⁰²² While the interpretation of Article 30 of the TRIPS Agreement in Canada provides nation states with difficulties in applying public interest considerations, it can, if correctly interpreted, provide for enough scope for national legislators to formulate exceptions to patent infringement in the public interest. The obstacles that occur with its application which the interpretation of the Panel creates is not mandatory and do not reflect the underlying principles that the Agreement mandates. Additionally, it needs to be borne in mind that the Agreement only seeks to provide a minimum level of protection, i.e. conformity among WTO Member States and does not mandate how national or regional legislation is to be worded.¹⁰²³ Once this minimum level has been achieved, the national legislator has free choice on how to tailor its patent system.

¹⁰¹⁸ supra 3.4.4.6.

¹⁰¹⁹ supra 4.7.3.

¹⁰²⁰ supra 3.4.4.6 for the situation in Germany.

¹⁰²¹ supra 5.4.1.2.

¹⁰²² Grosse Ruse-Khan states that there is a "potential impact on domestic regulation of (non-trade and non-economic) societal interests for the sake of a harmonized global economy." - Henning Grosse Ruse-Khan, 'Proportionality and Balancing within the Objectives for Intellectual Property Protection' in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 164.

¹⁰²³ Susy Frankel, 'The WTO's Application of 'The Customary Rules of Interpretation of Public International Law' to Intellectual Property', [2005-2006] *Virginia Journal of International Law* 375.

But the approach taken by the *Canada – Patent Protection of Pharmaceuticals* Panel still presents a steep obstacle for applying public interest considerations to exceptions to patentee's rights. And it is not clear whether future panels would not follow the *Canada – Patent Protection of Pharmaceuticals* Panel decision. Kur argues while there might not be an automatic binding effect there "might indeed become binding in the sense that it reflects a common understanding as to what is the correct interpretation of a given provision."¹⁰²⁴ Hence, the question remains how public interest considerations can be applied by national legislators without violating its obligations towards to TRIPS Agreement.

¹⁰²⁴ Annette Kur, 'Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?' [2008-2009] *Richmond Journal of Global Law and Business* 287, 329.

Chapter 6: Analysis of issues and policy recommendations

6.1 Introduction

This chapter is divided into two main parts: it first discusses legislative alternatives with regard to policy making in the public interest within patent law. These span from applying other legislative tools rather than exceptions to allow an unauthorised use of the patented item. Alternatively, the public interest can be inserted verbatim into an exception provisions as well as applying a fair use clause which is already available under US copyright law.¹⁰²⁵ It will be held that these do not present more advantageous tools or might be unsuitable in comparison to an exception provision.

Based on these advantages that exceptions provide, the second part of this chapter will address the issue of compatibility with international laws that national legislators may need to tackle when applying public interest considerations. The current interpretation of Article 30 of the TRIPS Agreement presents a hurdle to surpass for public interest considerations. What will be sought is to provide for an interpretation of Article 30 that would allow such a balancing. This should be possible according to Vaver and Basheer.¹⁰²⁶ The chapter will conclude with policy recommendations based on the findings of the chapters. The aim will be how to provide for exceptions based on public interest that are in line with national, i.e. fundamental rights and international obligations.

¹⁰²⁵ 17 U.S. Code § 107.

¹⁰²⁶ “Nothing in TRIPs eliminates the basic idea that patents involve a balance of rights between patent holders and the public. Nor does TRIPs affirm the out-dated idea that patents are natural rights. Most nations accept that patents are there to encourage innovation and disseminate practical knowledge. Rewarding inventors, while preserving a lively public domain for the public--non-inventors--to browse and think (and perhaps even also become inventors), is a means to that end.” - David Vaver and Shammed Basheer, ‘Popping patented pills: Europe and a decade's dose of TRIPs’ [2006] EIPR 282, 290.

6.2 Alternatives to provide for public interest

The purpose that exceptions to patent law are built upon reflects a third party interest to use the patented invention. This use does not necessarily need to be reflected within a concrete purpose in an exception provision. Legislators have other means to allow third party use with an invention. The alternatives will be discussed and their viability assessed. Importantly, it has to be noted that the legislator rather than courts are called upon to apply third party interest.

6.2.1 Public interest interpretation

This alternative is not really an alternative *in strictu sensu*. What the public interest interpretation means is to apply a teleological interpretation when interpreting exceptions to patent rights.¹⁰²⁷ According to Häberle, the teleological interpretation of a statutory provision inevitably would apply public interest considerations because he understands the purpose of a law as being a public one. This would make the query of the provision's purpose leading to its underlying public interest. The courts apply such considerations surrounding the law as "silent companions".¹⁰²⁸ Courts eventually utilise and concretise considerations of public interest through interpretation of exceptions¹⁰²⁹ while orientating themselves to such legislatively outlined concepts.¹⁰³⁰

Indeed, the courts play a crucial role in applying public interest considerations: Häberle states that legislators nowadays adopt various aspects of public interests as being considered which stipulates turning away from a monistic view on public interest. The various aspects of public interests that legislation stipulates then requires the administration and courts to apply these considerations and serve as vehicles of norm setting of public interests.¹⁰³¹ This approach is particularly relevant for British patent law. The German courts have already

¹⁰²⁷ It has been said that the CJEU would apply such an approach when interpreting exception provisions within the Information Society Directive - Christophe Geiger, Jonathan Griffiths, Martin Senftleben, Lionel Bently and Raquel Xalabarder, 'Limitations and Exceptions as Key Elements of the Legal Framework for Copyright in the European Union – Opinion of the European Copyright Society on the Judgment of the CJEU in Case C-201/13 Deckmyn' [2015] 93, 97.

¹⁰²⁸ Peter Häberle, *Öffentliches Interesse als juristisches Problem* (Athenäum Verlag 1970) 241.

¹⁰²⁹ *ibid* 241.

¹⁰³⁰ *ibid* 207.

¹⁰³¹ *ibid* 57-58.

applied this method of interpretation.¹⁰³² But it has been said that the Human Rights Act 1998 would gradually introduce a more purposive approach in the United Kingdom.¹⁰³³

6.2.2 Referencing the “Public interest” verbatim in exception provision

The public interest could most notably be applied within an exception provision as a verbatim condition within the statutory text. This would be a broadly phrased general clause¹⁰³⁴ and such an exception provision could be phrased like:

“The right of the patent holder does not extend to unauthorised uses which are in the public interest.”

Patent acts do allow the limitation of the right within the public interest or welfare: In Germany § 13 (1)1 of the German Patent Act, for instance, allows the unauthorised use of the patented invention in the public welfare. It has been said that the notion “public welfare” is narrower than the term public interest.¹⁰³⁵ The problem with such an approach lies at hand: The term “public interest” needs to be interpreted and the particular public interest identified. This leads to a certain degree of legal uncertainty for both users and patent holders. The text of such a provision requires a public body, such as the comptroller of patents, the Federal government or finally courts would need to establish what uses may be in the public interest. This stipulates that such use of the term “public interest” could only be viable for a case-by-case application. For instance, in such circumstances where a user wishes to use the invention and is not able to reach a licensing agreement, a compulsory license can be issued while the patent holder receives compensation.

¹⁰³² supra 3.5.3.

¹⁰³³ supra 4.7.3.2.

¹⁰³⁴ According to Teubner, general clauses are very suitable for collision norms due to their high degree of indeterminacy in order to accommodate conflicts between societal subsystems - Gunther Teubner, *Das Recht als autopoietisches System* (Suhrkamp 1989) 140.

¹⁰³⁵ See - Peter Mes, Patentgesetz (3rd edn, C.H. Beck 2011) § 13 [3]; Christof Lenz and Timo Kieser, ‘Schutz vor Milzbrandangriffen durch Angriffe auf den Patentschutz?’ [2002] *Neue Juristische Wochenschrift* 401, 402.

6.2.3 Fair use

The suggestion that a fair use clause should be adopted within patent law follows similar considerations like exception provisions that verbatim reference to the public interest.¹⁰³⁶ For example, the fair use exception legislated within 17 U.S.C. § 107 provides for an exception for an unauthorised use of a copyrighted work. It also applies criteria for the assessment whether a use can be considered to be fair and hence exempted from infringement.

The advantage in relation to the alternative to include a verbatim public interest exception is the fact that the criteria that are used within the fair use exception are more concrete and hence operable for courts. Here however, lies the dilemma of such a version within European law. It has been said that public interest considerations are applied in Europe would solely be applied by the legislator. European IP legislation does not provide for apical norms like the Innovation clause within the US Constitution that would functionalise IP rights in fostering the public interest which courts could rely on.¹⁰³⁷ Courts in Europe rather interpret the norms generally by following the legislators wording.¹⁰³⁸

The idea of providing a fair use within patent law in Europe remains to be an interesting idea. This would enable to respond swiftly to changes in technology,¹⁰³⁹ which would ultimately serve public interest when one bears in mind that this is a concept that is constantly being updated and warrants swift response by the legal system. What would assist courts with such a fair use clause would be a non-exhaustive list of case groups that would be considered to be fair. This would serve as interpretative assistance when trying to come to a finding if whether a use is fair or not.

What however, remains difficult with such a measure is the fact that courts are generally restricted in “making the law” in the analysed jurisdictions. This becomes particularly noticeable when applies the fundamental/human rights framework. Any interference with the right to property which, as established, is applicable to patent rights needs to be based on “a

¹⁰³⁶ See for instance - Maureen A. O'Rourke, 'Toward a Doctrine of Fair Use in Patent Law' [2000] Columbia Law Review pp 1177; Katherine J. Strandburg, 'Patent Fair Use 2.0' [2011] UC Irvine Law Review pp 265; Ruth Okediji, 'Toward an International Fair Use Doctrine' [2000] Columbia Journal of Transnational Law 75, 111.

¹⁰³⁷ Andrea Ottolia, *The Public Interest and Intellectual Property Models* (G. Giappichellie Editore 2010) 125.

¹⁰³⁸ This is done in a more literal way in the UK and more teleological way in Germany as discussed above.

¹⁰³⁹ This in particular when bearing in mind the time it took to legislate for research exceptions - supra chapters 2 and 3.

foreseeable basis in the law.”¹⁰⁴⁰ This requires the legislators to *ex ante* provide for an exception rather than the courts creating one - they are rather left “to apply this IP framework, not to rewrite it.”¹⁰⁴¹

6.2.4 User Rights

A more radical way to ensure that the interests of third parties are adopted is to culminate these in enforceable user rights.¹⁰⁴² Similar to this approach, Dan Wielsch has argued that exceptions can serve as “access rules” (*Zugangsregeln*)¹⁰⁴³ that allow the use of information that is also crucial for other systems of society, apart from economic rationality of patent rights.¹⁰⁴⁴ This approach would then allow public interests to “be treated on an equal footing with owners’ rights: systems would no longer be inclined to interpret proprietary rights broadly while construing user interests narrowly.”¹⁰⁴⁵ It would mandate the legislator and

¹⁰⁴⁰ Alexander Peukert, ‘The fundamental right to (intellectual) property and the discretion of the legislature’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 142.

¹⁰⁴¹ *ibid* 142.

¹⁰⁴² See for instance in relation to copyright – Jane C. Ginsburg, ‘From Having Copies to Experiencing Works: the Development of an Access Right in U.S. Copyright Law’ [2003] *Journal of the Copyright Society of the USA* pp 113; P. Bernt Hugenholtz and Ruth L. Okediji, ‘Conceiving an International Instrument on Limitations and Exceptions To Copyright’ (Open Society Institute, 2008)

< http://www.opensocietyfoundations.org/sites/default/files/copyright_20080506.pdf > accessed 23 May 2015.

¹⁰⁴³ He however argues that the commonly used term ‘exceptions’ (“Schranken”) is too narrow as it limits the conflict that the exception is addressed to accommodate is that of individual interests and public interests and would not have social systems as reference - Dan Wielsch, ‘Iustitia mediatrix: Zur Methode einer soziologischen Jurisprudenz’ in Graf-Peter Calliess, Andreas Fischer-Lescano, Dan Wielsch, Peer Zumbansen (eds), *Soziologische Jurisprudenz: Festschrift für Gunther Teubner zum 65* (De Gruyter 2009) 410.

Hence, he introduces the term “access rights” (“Zugangsregeln”) - Dan Wielsch, *Zugangsregeln* (Mohr Siebeck 2008).

¹⁰⁴⁴ Wielsch argues from a systems theoretical perspectives and explains that “[t]he task of assure the integrity of societal knowledge sharing is done by access rules. They limit the exclusive right of the right holder by considering the discourse of the knowledge sharing institutions. By this they create possibilities of using the IP right without authorisation – however not automatically without remuneration. Access right hereby complement the exclusive rights in a legal order and inhibit that the use of subjective-individual rights distorts the basis for the production of such goods. Instead of limitations that are built on the differentiation between individual and public interest, they operate with reference to social systems. They are to be targeted at maintaining the conditions of knowledge sharing in the particular social system in which the IP protected good (work, invention) represents a communication. By adapting exclusive rights and freedom of use system-specific, access rights create the systemic connectivity of the IP right in question.” - Dan Wielsch, ‘Iustitia mediatrix: Zur Methode einer soziologischen Jurisprudenz’ in Graf-Peter Calliess, Andreas Fischer-Lescano, Dan Wielsch, Peer Zumbansen (eds), *Soziologische Jurisprudenz: Festschrift für Gunther Teubner zum 65* (De Gruyter 2009) 410-411.

¹⁰⁴⁵ Rochelle C. Dreyfuss and Susy Frankel, "From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property" (2014). New York University Public Law and Legal Theory Working Papers. Paper 478. University Public Law and Legal Theory Working Papers. Paper 478, 32.

courts to balance the involved interests of patent owner and users alike¹⁰⁴⁶ and “ask the questions at the heart of incentive-based systems: how much incentive is needed to inspire creativity and whether the challenged measure interferes substantially with that incentive.”¹⁰⁴⁷

Such user rights would present certain difficulties for the current patent system.¹⁰⁴⁸ The question would be how such user rights would work in practice and who would be able to bring forward such rights.¹⁰⁴⁹ Implementing user rights might therefore go beyond of what is required to fulfil the public interest. Additionally, such approach already needs to be undertaken when the purpose of an exception can be subsumed under a fundamental right.¹⁰⁵⁰ Then the court is compelled to address the collision of fundamental rights.¹⁰⁵¹ Additionally, the shift of paradigms that has been started with the *Ashby* decision might trigger a generally more balanced view of IP legislation without the need to generate user rights as such.¹⁰⁵²

6.2.5 Other means of incorporating public interest considerations apart from exceptions

Finally, public interest as of third party interest could be adopted outside the realm of exceptions but could be included within other legislative tools of patent law such as exclusions, the patentability criteria and the patent term. While patents are nowadays available for any invention, patent legislation provides conditions on their grant. The patentability criteria, such as novelty, inventive step and industrial applicability that are

¹⁰⁴⁶ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, 'An international *acquis*: Integrating regimes and restoring balances' in in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 162.

¹⁰⁴⁷ Rochelle C. Dreyfuss and Susy Frankel, "From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property" (2014). New York University Public Law and Legal Theory Working Papers. Paper 478. University Public Law and Legal Theory Working Papers. Paper 478, 32-33.

¹⁰⁴⁸ Hoeren posits that the term can be misleading – Thomas Hoeren, 'Access Right as a postmodern symbol of Copyright Deconstruction?' in APDI - Associação Portuguesa de Direito Intelectual, *Direito da Sociedade da Informação - Volume VI* (2006) 465.

¹⁰⁴⁹ In relation to how such user rights would be enforceable internationally - Graeme B. Dinwoodie and Rochelle C. Dreyfuss, 'An international *acquis*: Integrating regimes and restoring balances' in in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 162.

¹⁰⁵⁰ supra 3.4.4.6.

¹⁰⁵¹ This seems to be the case when the CJEU refers to exceptions and limitations of copyright protection as “user rights” that appears to be “recent tendency” - Christophe Geiger, Jonathan Griffiths, Martin Senftleben, Lionel Bently and Raquel Xalabarder, 'Limitations and Exceptions as Key Elements of the Legal Framework for Copyright in the European Union – Opinion of the European Copyright Society on the Judgment of the CJEU in Case C-201/13 Deckmyn' [2015] 93, 97-98.

¹⁰⁵² supra 4.6.

mentioned within Article 27 (1) TRIPs can be regarded as conditions on the grant of the patent right. Additionally, certain subject matter can be excluded from patent protection which presents itself as an “exception” to the general rule of any invention being considered to be patentable.

All these criteria that restrict the grant of a patent can be regarded as *ex-ante* measures or conditions. They already need to be taken into account before the patent is granted as they set conditions on the grant of the patent. They are also examined and assessed by patent offices. Their provision can also be generally based on some form of public interest. The legislator however, needs to assess providing such *ex-ante* measures. If a certain subject matter is excluded from patent protection *ex-ante*, then this might lead to the problem that research on this subject matter may not be adequately incentivised as patent protection would be missing. This could make inventors resort to protecting their inventions through trade secrets. Bently therefore describes exclusions as “on-off” switches.¹⁰⁵³

6.2.5.1. The patentability criteria

The patentability criteria present an important condition on the grant of a patent. Article 52(1) EPC on which most corresponding provisions in the national patent acts in Europe are modelled upon, states that “European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application” and therefore mirrors Article 27(1) TRIPs substantially. Importantly, the German and British Patents Acts have mirroring provisions.¹⁰⁵⁴ The potentially far reaching scope that patent protection may have is restrained substantially through these provisions.

The novelty requirement requires the invention in suit to consist of subject matter that is not already available in the public domain; in patent terms not part of the state of art.¹⁰⁵⁵ The provision prevents patent monopolies on items which have already been made available to the public. This literally means that one cannot “reinvent and patent the wheel.” The public would be deprived if a patent holder could exercise exclusive rights over already available

¹⁰⁵³ Lionel Bently et al, ‘Exclusions from Patentability and Exceptions and Limitations to Patentees’ Rights’ (WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I, World Intellectual Property Organisation 2010) 65.

¹⁰⁵⁴ Section 1(1) UK Patents Act 1977; § 1(1) PatG.

¹⁰⁵⁵ Article 54(1) EPC; Section 2(1) UK Patents Act 1977; § 3(1) PatG.

items. One can refer again to the example of the wheel and imagine what effects exclusive rights over it would have. Additionally, it requires the development of new inventions and therefore serves the public interest in technological advance.

Another important requirement is that the invention needs to involve an inventive step in order to be granted. The patent acts in Europe hold an invention to involve an inventive step when it is not obvious to the person skilled in the art.¹⁰⁵⁶ In comparison to the novelty requirement that makes a quantitative evaluation by requiring that the claimed invention is not part of the state of the art, the requirement of inventive step is a qualitative requirement.¹⁰⁵⁷ It requires an invention to surpass a certain threshold of inventiveness. It seeks to bar the patenting of work bench extensions of items already available to the public while a patent right should only be granted to meritorious inventions. The requirement can also be traced back to the public interest in technological advance.

The industrial application criterion which is the last of the three patentability criteria spent much of its existence in the shadow of the other two criteria. It was considered to be a provision to delineate items that were considered to be falling within the technological field which was considered to be covered by patent rights rather than other intellectual property rights and to avoid overlaps. The importance of the provision however, increased in European Patent law with the inception of the Biotech Directive. It stipulated that patent applicants were now required to disclose the particular function of a gene.¹⁰⁵⁸ This is meant to serve to prohibit all potential uses of such a patent to be monopolised without the patent holder actually referring to the purpose of his invention.

6.2.5.2. Exclusions

While Article 27(1) TRIPs sets out Member States have to provide patent protection for any invention, products or processes, given that they fulfil the patentability criteria, Member States are allowed to exclude certain subject matter from being patented. The subject matter that falls under the exclusions is diverse and is only barred from patent protection if the invention relates to the excluded subject matter as such. It is difficult to deduce a common reason for their provision. Hence, it is not possible to pinpoint one particular public interest behind these provisions.

¹⁰⁵⁶ Article 56 EPC; Section 3 UK Patents Act 1977; § 4 PatG.

¹⁰⁵⁷ Lionel Bently and Brad Sherman, *Intellectual Property Law* (4th edn, OUP 2014) 555.

¹⁰⁵⁸ Article 5(3) Biotech Directive.

Many patent acts worldwide exclude discoveries, scientific theories or mathematical methods from receiving patent protection.¹⁰⁵⁹ From an economic stand point, this ultimately can be based on a pro-competition rationale. If these items were patentable, then the dependency of third parties to use that item would significantly be more dependent on the agreement of the patent holder.¹⁰⁶⁰ This can then be firmly based on the public interest in technological advance and freedom of research.

Other exclusions, such as those in relation to computer programmes¹⁰⁶¹ or literary and dramatic works¹⁰⁶² are provided in order to avoid overlaps of protection between different fields of intellectual property. This serves to protect a certain subject matter under its dedicated intellectual property right. This functional approach can also be correlated to technological advance. Subject matter should be kept in its destined intellectual property framework that arguably provides for the adequate framework of providing incentives while allowing sufficient dissemination of the good. This is not achieved where the subject matter is placed under a different IP right where the term, scope of protection and allowed uses differ.¹⁰⁶³ The fact that methods of medical and veterinary treatment are barred from being protected by patents¹⁰⁶⁴ can be correlated directly to the public interest in ensuring public health care.¹⁰⁶⁵ Finally, subject matter can be excluded from patentability where its exploitation is against the *ordre public* or against morality.¹⁰⁶⁶

6.5.2.3. Patent term

The minimum term of patent protection is clearly a compromise in order to strike a balance between providing sufficient incentive while allowing the invention to be freely disseminated and used after the lapse of the term. The law as it stands now will not permit a term of protection for patents lower than 20 years.¹⁰⁶⁷ Like other intellectual property rights, the

¹⁰⁵⁹ e.g. Article 52(2)(a) EPC, Section 1(2)(a) UK Patents Act 1977; § 1(3) Nr. 1 PatG.

¹⁰⁶⁰ Dan Wielsch, *Zugangsregeln* (Mohr Siebeck 2008) 25.

¹⁰⁶¹ e.g. Article 52(2)(c) EPC; Sec. 1(2)(c) UK Patents Act 1977; § 1(3) Nr. 3 PatG.

¹⁰⁶² e.g. Sec. 1(2)(a) UK Patents Act 1977; § 1(3) Nr. 1 PatG.

¹⁰⁶³ It can then however be argued whether patents rights with its fixed term serve this purpose. (See above).

¹⁰⁶⁴ Sec. 4a UK Patents Act 1977; § 2a (1) Nr. 2 PatG.

¹⁰⁶⁵ So for instance the Enlarged Board of Appeal of the EPO - *Diagnostic Methods* G 01/04(2006)OJ EPO 334, 348.

¹⁰⁶⁶ Sec. 1(3) UK Patents Act 1977; § 2(1) PatG.

¹⁰⁶⁷ Art. 33 TRIPS.

protected invention falls into the public domain after the expiry of the patent term.¹⁰⁶⁸ This can be based on the public interest of technological advance since other parties are then free to use the invention in any way. The wide availability of using the information underlying the patent is deemed to serve as a springboard for further innovation. Additionally, the interest in having more and cheaper products after the exclusive right seizes serves consumer interest. Within the term of protection the patent holder however enjoys exclusivity. The approach of having a fixed patent term can be traced back to a cost-benefit analysis of the law.

The 20 year term has to be read in line with the alleged rationale of patent rights to provide incentives and the fact that patent protection is now eligible for all invention through Article 27(1) TRIPS. This implies that all inventions would require such a term in order to provide incentives. However, different fields of technology require a different term of protection or indeed no protection at all. The patent term in combination with the non-discrimination requirement is yet another example for the monolithical approach that patent protection provides for sectors of industry that are very diverse.¹⁰⁶⁹ This rigidity of the fixed term has led Professor Blakeney to call patent protection as “a clumsy instrument”.¹⁰⁷⁰

6.2.6 Summary

All the discussed alternatives to apply public interest considerations have their virtues and some clearly fulfil a public interest such as the *ex-ante* measures. They however, lack the flexibility that exceptions have.¹⁰⁷¹ This is because of their nature not to discard the right as a whole but to rather limit its exercise. This is why from a policy point of view, exceptions are deemed to have a great potential to insert such considerations into patent law. While Bently found exclusions to be comparable to “on/off”- switches,¹⁰⁷² he describes the advantage of

¹⁰⁶⁸ Most notably works protected by copyright generally will fall into the public domain after a given term of protection. Trade Marks however can exist theoretically exist perpetually which can be based on the function of the trade mark to serve to identify the source of goods or services.

¹⁰⁶⁹ Mark A. Lemley and Dan L. Burk, 'Policy Levers in Patent Law' [2003] Virginia Law Review 1575, 1577.

¹⁰⁷⁰ European Patent Office, *Interviews for the Future* (European Patent Office 2006) 33.

[http://documents.epo.org/projects/babylon/eponet.nsf/0/811B5B74A1E21290C12572D80037A6DE/\\$File/Interview_Blakeney.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/811B5B74A1E21290C12572D80037A6DE/$File/Interview_Blakeney.pdf)> accessed 23 May 2015.

¹⁰⁷¹ Kur identifies exceptions “as tools for fine-tuning the effects of intellectual property rights *par excellence*.” - Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 238.

¹⁰⁷² *supra* 6.2.5.

exceptions as a policy instrument in relation to exclusions from patentability with an eluding metaphor: “[E]xceptions are more like “dimmer switches”, than can be turned down (to reduce costs), without necessarily turning off the light.”¹⁰⁷³ This means that exception could provide for a tool to accommodate a potential conflict of interests in a more balanced way than could be achieved with the rather “blunt all-or-nothing” approach that exclusions provide.

Other means, such as the verbatim referencing of public interest are not applicable for blanket exceptions as they lack clarity. User rights, while presenting an interesting approach, do not seem practical *de lege lata* but might be an issue in future. Implementing a fair use clause could be mechanism, to improve the insertion of public interest considerations. This leaves responsive legislation and public interest interpretation, i.e. a purposive or teleological interpretation of exception provisions, by the courts as most viable methods of applying public interest considerations for the moment. Such an interpretation generally also ensures that “certain fundamental freedoms” are ensured.¹⁰⁷⁴ This however, leaves the problem with international frameworks, i.e. such as the TRIPS Agreement, as an issue which could curtail such an approach.

6.3 Incorporating public interest considerations within Article 30 TRIPS- *de lege lata*

Based on the approach and findings of the Panel in the *EC-Canada* dispute, Gervais sets out types of exceptions common within many patent jurisdictions that would fall within Article 30, such as “experimental use, private use, early working of the patent by a “generics” pharmaceutical company to obtain regulatory approval (sometimes referred to as the “Bolar” exception).”¹⁰⁷⁵ Correa adds that the importation of patented products where they have been put on the market within another jurisdiction with the patent holders consent (i.e. the right has been exhausted), use of the invention for teaching purposes and “use of the invention by a

¹⁰⁷³ Lionel Bently et al, ‘Exclusions from Patentability and Exceptions and Limitations to Patentees’ Rights’ (WIPO Standing Committee on the Law of Patents, SCP/15/3 Annex I, World Intellectual Property Organisation 2010) 65.

¹⁰⁷⁴ Alexander Peukert, ‘The fundamental right to (intellectual) property and the discretion of the legislature’ in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 145.

¹⁰⁷⁵ Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet & Maxwell 2008) [2.397].

third party who started –or undertook bona fide preparatory acts–before the application for the patent (or of its publication.)” could also be covered by Article 30.¹⁰⁷⁶ The EC itself submitted in the dispute proceedings that a research exception would be compliant with Article 30 noting that this was because such research was non-commercial¹⁰⁷⁷ which contrasts the decided case law in the UK and Germany.¹⁰⁷⁸ Hence, some already available exceptions would have to be considered as not complying with Article 30 TRIPS.¹⁰⁷⁹

In relation to developing new exceptions or to amend the shape of exceptions of present provisions, the most problematic issue in complying with the Three Step Test is the fact that it is applied in a rigorous way by which all steps need to be met in order for an exception to be compliant with Article 30 TRIPS.¹⁰⁸⁰ With regards to how public interest considerations are considered and incorporated in the assessment of Article 30, the problem lies in the fact that the economic considerations of the right holder prevail in the first parts of the test while interests of other 3rd parties are not considered until the first two steps have been successfully passed. The third step which could allow to internalise considerations and interests of other parties or the public as such¹⁰⁸¹ are disregarded when economic rationalities prevail under first two steps and constitute an insurmountable threshold to surpass.¹⁰⁸²

¹⁰⁷⁶ Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (Oxford University Press 2007) 303. Straus however stresses that the importation of the right would not conform Article 30 when the product has been put onto the market anywhere in the world and then imported (i.e. international exhaustion) but only where it was put onto markets with comparable market conditions - Josef Straus, ‘Implications of the TRIPS Agreement in the Field of Patent Law’ in Friedrich-Karl Beier and Gerhard Schrickler (eds), *From GATT to TRIPs – The Agreement on Trade-Related Aspects of Intellectual Property Rights* (1996 VCH Verlagsgesellschaft) 203.

¹⁰⁷⁷ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) ‘WTO Document WT/DS114/R’ 74-76.

¹⁰⁷⁸ The finding that the research exception would be limited according to the first step of Article 30 because it was non-commercial does of course not follow the case law of the UK (supra 3.3.2.) and even more Germany (supra 3.4.2.).

¹⁰⁷⁹ See Roffe and Spennemann’s reference to Garrison and Pires de Carvalho - Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 274.

¹⁰⁸⁰ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) ‘WTO Document WT/DS114/R’ [7.20].

¹⁰⁸¹ supra 5.4.1.4.

¹⁰⁸² It could be argued that the application of economic considerations to interpret Article 30 TRIPS as applied by the *EC-Canada* Panel could mean that the WTO follows to a great extent economic considerations and demonstrates a bias towards an economic rationality - Dan Wielsch, ‘Iustitia mediatrix: Zur Methode einer soziologischen Jurisprudenz’ in Galf-Peter Calliess, Andreas Fischer-Lescano, Dan Wielsch, Peer Zumbansen (eds), *Soziologische Jurisprudenz: Festschrift für Gunther Teubner zum 65. Geburtstag am 30. April 2009* (Walter de Gruyter 2009) 396.

However, the rigorous approach by the panel of applying a test where all steps had to cumulatively have to be assessed step-by-step is not a necessary way of interpreting Article 30 TRIPS or generally other provisions that are modelled on the Three Step Test of the Berne Convention.¹⁰⁸³ Since the decisions of the panels are not universally binding but only have effect *inter partes*, (i.e. the parties of the dispute)¹⁰⁸⁴ this would mean that Member States are generally free to legislate for exceptions. But the risk of attracting a Dispute Settlement procedure remains to be a sword of Damocles to national legislators.¹⁰⁸⁵ This is because the Panel's approach to interpretation Article 30 does remain relevant and cannot be totally discarded¹⁰⁸⁶ and a more permissive amendment of Article 30 does not appear to be imminent.¹⁰⁸⁷

6.3.1. Preliminary considerations

The problem with applying Article 30 TRIPS in order to assess whether an exception is TRIPS-compliant is the fact the Panel's assessment of Article 30 TRIPS does not acknowledge the way national legislators devise exceptions within their patent laws. It has to be said that the adjudicating bodies of the WTO are not mandated to do so. They are only bound to apply WTO law in general, not rules or constitutional considerations that national legislators have to abide to.¹⁰⁸⁸ This discrepancy in approaches may curtail the application of public interest considerations in exceptions to patent rights. As discussed, national legislators

¹⁰⁸³ *supra* 5.2.1.

¹⁰⁸⁴ Annette Kur, 'Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?' [2008-2009] *Richmond Journal of Global Law and Business* 287, 328; Susy Frankel, 'The WTO's Application of 'The Customary Rules of Interpretation of Public International Law' to Intellectual Property', [2005-2006] *Virginia Journal of International Law* 265, 385.

¹⁰⁸⁵ *supra* 5.5.

¹⁰⁸⁶ While neither panel decisions nor reports by the Appellate Body do technically bind future panels (Susy Frankel, 'The WTO's Application of 'The Customary Rules of Interpretation of Public International Law' to Intellectual Property', [2005-2006] *Virginia Journal of International Law* 385) - they may still choose to follow them and Panels have followed the decisions of previous Panels – *supra* 5.4 in fn 873. Geiger, Gervais and Senftleben also note that the fact there exists a "WTO jurisprudence" could mean that panels wish to achieve consistency and by this follow previous panel decisions - Christophe Geiger, Daniel J. Gervais and Martin Senftleben, 'Understanding the "three-step test"' in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 179-180. Kur states with this regard that by following previous reports panels would create a self-endorsing dynamism - Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 240.

¹⁰⁸⁷ A group of researchers have published "Proposals for Amendment of TRIPS" which entail an amendment of Article 30 TRIPS. The new provision provides for a radical change of the wording and would cover case groups that were considered to be exempted from patent infringement Proposals for Amendment of TRIPS – 'Proposals for Amendment of TRIPS' in Annette Kur & Marianne Levin (eds), *Intellectual Property in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 493-494.

¹⁰⁸⁸ As an international instrument seeking to provide minimum common standards this could not be possible.

have provided for exceptions where they deemed them to be necessary, in other words when their purpose served the public interest. The approach that the Panel took in the *EC-Canada* dispute does not mandatorily require an assessment of the purpose of the exception provision when it already fails to surpass the first step of Article 30 TRIPS.¹⁰⁸⁹ This appears awkward if exceptions generally have the task to provide a balance between the interests of the patent holder with that of the public.¹⁰⁹⁰

Additionally, the assessment of Article 30 TRIPS by the Panel does also not allow applying considerations of fundamental rights within its ambit. This assessment is mandated now both in the United Kingdom and Germany.¹⁰⁹¹ British and German Legislators are deemed to consider the fundamental right positions of individuals affected by a piece of legislation. The current application of Article 30 TRIPS may therefore jeopardise the constitutionally mandated procedure as it does not require an assessment to look at the fundamental rights positions of the beneficiaries of an exception.¹⁰⁹² Again, the WTO Panels do not have to take these considerations into account but there is also no rule that they are not able to do so.¹⁰⁹³

Such an approach could be promoted by the fact that the three step test within Article 30 TRIPS and elsewhere should be seen as enabling¹⁰⁹⁴ and guiding legislators in providing for

¹⁰⁸⁹ This makes the Panel's assessment basically redundant as it does not mandatorily assess the purpose of the exception provision. But as Jhering has said: "purpose is the creator of all law [and] there is no norm that does not owe its existence to a purpose" – Rudolf von Jhering, *Der Zweck im Recht* (Breitkopf und Härtel 1877) VI
¹⁰⁹⁰ supra 3.6. The "Proposals for Amendment of TRIPS" (supra fn 1087) would entail such a balancing approach within a new Article 8A of the Agreement - 'Proposals for Amendment of TRIPS' in Annette Kur & Marianne Levin (eds), *Intellectual Property in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 465 - 467.

¹⁰⁹¹ supra 3.4.4 and 4.7 respectively.

¹⁰⁹² The omission of fundamental rights positions itself serve a biased approach towards Article 30 TRIPS. Teubner argues that constitutional civil rights by which he means fundamental rights can function as "collision rules ... in which the particularistic universality of politics or economics is changed by the incorporation of polycontextural elements" – Gunther Teubner, 'Altera Pars Audiatur: Law in the Collision of Discourses' in Richard Rawlings (ed), *Law, Society, and Economics - Centenary Essays for the London School of Economics and Political Science 1895-1995* (OUP 1997) 173.

Transposed to the scenario analysed his approach means that the position of other parties - Teubner would argue other societal discourses - are considered and do not succumb to the "particularistic universality of economics".

¹⁰⁹³ While the WTO adjudicating bodies (i.e. DSU Panels and the Appellate Body) do not have to take other legislative measures into considerations, Marceau argues that they should assume "that WTO Members must comply with their human rights obligations and therefore they should interpret and apply WTO law accordingly." - Gabrielle Marceau, 'WTO Dispute Settlement and Human Rights' [2002] *European Journal of International Law* 753, 763.

¹⁰⁹⁴ Christophe Geiger, Daniel J. Gervais and Martin Senftleben, 'Understanding the "three-step test"' in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) pp 183.

exceptions and not to make this endeavour a difficult task.¹⁰⁹⁵ The structure of the test does provide for enough leeway to follow considerations taken by the legislator when devising an exception and can also acknowledge the public interest considerations that the legislator took. What is required is that all involved interests are considered and find application in a proportionate way.

6.3.2 Preliminary difficulties with applying public policy considerations within Article 30 TRIPS

The first step with its narrow scope leaves little room for legislators to manoeuvre. It appears that the *EC-Canada* Panel was led to be convinced that the juxtapositioning of “limited” and “exceptions” emphasised a narrow interpretation and followed this tautology. This narrow approach is enhanced by the panel’s strict approach of Article 30 as a “one after the other” step.¹⁰⁹⁶ While Article 30 can be read to take public policy considerations into account in a balancing exercise, the greatest threshold that needs to be passed is the rigorous approach to assessing the provision in its “three step test” notion.¹⁰⁹⁷ The primary focus on commercial interests within the first two steps will make it difficult for WTO Members to promote their own public interest as predominantly assess the effect on the exclusive rights of the patent holder¹⁰⁹⁸ - with the caveat of the notion of “unreasonableness” with the second step. This assessment arguably demonstrates a certain bias towards the proprietary interests of the right holders.¹⁰⁹⁹

Such an approach to the three steps is however not necessary. A group of experts from the Max Planck Institute on Innovation and Competition in Munich and Queen Mary University

¹⁰⁹⁵ The Proposals for Amendment of TRIPS” (supra n 1087) would render Article 30 TRIPS to such an enabling provision - ‘Proposals for Amendment of TRIPS’ in Annette Kur & Marianne Levin (eds), *Intellectual Property in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 493 – 494.

¹⁰⁹⁶ supra 5.4.2.

¹⁰⁹⁷ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *A Neofederalist Vision of TRIPS – Resilience of the International Intellectual Property Regime* (OUP 2012) 70; Ruth Okediji, ‘Toward an International Fair Use Doctrine’ [2000] *Columbia Journal of Transnational Law* 75, 111 (in relation to copyright).

¹⁰⁹⁸ Henning Grosse Ruse-Khan, ‘Assessing the need for a general public interest exception in the TRIPS Agreement’ in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 182.

¹⁰⁹⁹ Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ (2008) Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No. 08-04, 26 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1317707> accessed 23 May 2015.

of London have prepared a declaration in relation to the Three Step test in copyright law.¹¹⁰⁰ While analogies from the situation within copyright law need to be applied with caution, Roffe and Spennemann argue that this approach would also be applicable in relation to Article 30 and exceptions to patent infringement.¹¹⁰¹ They argue that the purpose of both copyright and patent and the competing interests surrounding both sets of law resemble as to permit such an analogy.¹¹⁰² The declaration states within its first point that “[t]he three steps are to be considered together and as a whole in a comprehensive overall assessment.”¹¹⁰³ The Patent Declaration that was published in 2014 follows this approach.¹¹⁰⁴

The rigorous approach that the panel takes is also in contradiction with the objectives that the TRIPS Agreement stipulates. Therefore, rather than regarding it as a Three Step Test, it should be reversed¹¹⁰⁵ or perceived as a “Three Factor test”¹¹⁰⁶ in order to assess all conflicting interests adequately and ensure a balanced system of patent protection. In other words as stipulated by the preamble of TRIPS: “*Recognizing* the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.” The German Federal High Court has held in its *Polyferon* decision that Article 30 would mandate that a balancing of interests needs to take place when providing for an exception.¹¹⁰⁷ While this decision was decided before the *EC-Canada* Panel, the court’s statement underlines that a different interpretation is possible. A less stringent approach to the Three Step Test could open Article 30 for a more holistic approach that may accommodate a balance between the interest of right holders and third parties. These considerations have been emphasised by the Doha Declaration which could serve future panels as a guideline on how to approach Article 30. Moreover, it seems that

¹¹⁰⁰ Christophe Geiger, Jonathan Griffiths and Reto M. Hilty, ‘Declaration on an balanced Interpretation of the “Three-Step-Test” in Copyright Law’ [2008] IIC 707.

¹¹⁰¹ Pedro Roffe and Christoph Spennemann, ‘Canada-patent protection of pharmaceutical products’ in Carlos M. Correa (ed), *Research Handbook on the Interpretation and Enforcement of Intellectual Property under WTO Rules* (Edward Elgar 2010) 281-282.

¹¹⁰² *ibid* 282.

¹¹⁰³ Christophe Geiger, Jonathan Griffiths and Reto M. Hilty, ‘Declaration on a balanced Interpretation of the “Three-Step-Test” in Copyright Law’ [2008] IIC 707, 711.

¹¹⁰⁴ Max Planck Institute for Innovation and Competition, Declaration on Patent Protection [22] <http://www.ip.mpg.de/fileadmin/user_upload/Patent_Declaration_en.pdf> accessed 23 May 2015

¹¹⁰⁵ Daniel J. Gervais, ‘Towards A New Core International Copyright Norm: The Reverse Three-Step Test’ [2005] *Marquette Intellectual Property Law Review* 1, pp 27.

¹¹⁰⁶ See in relation to copyright - Christophe Geiger, ‘Implementing an International Instrument for Interpreting Copyright Limitations and Exceptions’ [2009] IIC 627, 638.

¹¹⁰⁷ „Das Übereinkommen macht damit zur Pflicht, bei Eingriffen in das Patentrecht eine Abwägung der Interessen vorzunehmen.“ – BGH, GRUR 1996, 190 (192) - Polyferon. (While an English translation of the decision is available in IIC 1997, 240 this particular sentence was unfortunately not translated.).

Article 7 and 8 of TRIPs serve as “constitutional” parameters that must be acknowledged in the entire interpretation of the Three Step Test.

6.3.3. A teleological re-interpretation of Article 30 TRIPS - Article 30 as a proportionality test

While the panel’s interpretation of Article 30 has generally been regarded as being restrictive, it does leave leeway for considering public interest consideration.¹¹⁰⁸ This is based on the fact that the provision does provide terminology that would permit a more normative interpretation by which such considerations could be internalised. Additionally, the way the panel interpreted the provision is not mandatorily the correct way but could be done differently while still being consistent with the Agreement.¹¹⁰⁹ Rather than restricting legislators it could guide and assist them when providing exception provisions. What then must be established is the fact that the purpose of the exception provision needs to be mandatorily considered in Article 30 TRIPS.

The necessary balance between the public interest and that of the patent holder - the balance that exceptions always aim to provide - could be provided by reinterpreting Article 30 TRIPS as a proportionality test.^{1110 1111} In order to reformulate the test to do so it becomes important to see how much scope Article 30 TRIPS would be provide. This requires considering whether the Agreement does provide for sufficient interpretive base to apply such a reinterpretation. With this regards, Grosse Ruse-Khan comes to the finding that this is possible by placing more emphasis on Articles 7 and 8 TRIPS as well as to recognise the

¹¹⁰⁸ *supra* 5.4.1.

¹¹⁰⁹ Dinwoodie and Dreyfuss state that the most obvious way to apply their IP *acquis* (see fn 464) would be to introduce it through interpreting the TRIPS Agreement in line with the *acquis* - Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘An international *acquis*: Integrating regimes and restoring balances’ in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 153.

¹¹¹⁰ The proportionality test can be employed to balance interests and also between private and public interests- Henning Grosse Ruse-Khan, ‘Proportionality and Balancing within the Objectives for Intellectual Property Protection’ in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 161 -162; Orit Fischman Afori, ‘Proportionality – A New Mega Standard in European Copyright Law’ [2014] IIC 889.

¹¹¹¹ Kur proposes such an approach for all three step tests and bases it on the fact that the larger WTO framework would stipulate such a balancing exercise within Article XX GATT - Annette Kur, ‘Limitations and exceptions under the three-step test – how much room to walk the middle ground?’ in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 247.

Doha Declaration as subsequent practice to interpret the Agreement.¹¹¹² In relation to exceptions to patent rights, these considerations could promote a more teleological interpretation of Article 30 TRIPS which entails public interest considerations.

6.3.3.1. Articles 7 and 8 of the TRIPS Agreement

Commentators have argued that Articles 7 and 8 must be taken into consideration when applying a teleological interpretation of provisions of the Agreement.¹¹¹³ They are of particular relevance in the framework of this work as they can be applied in relation to public interests considerations.¹¹¹⁴ The provisions that are considered to be a compromise between the agendas of developed and developing countries¹¹¹⁵ are of particular interpretive importance in relation to exceptions and their underlying rationales of allowing certain uses to be excused from patent infringement.

Article 7 of the Agreement provides for “Objectives” and reads as follows:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of that producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

The provision does not verbatim integrate public interests considerations as an objective of the TRIPs Agreement. However, it does stipulate the necessity to consider the special social dimension of intellectual property¹¹¹⁶ when transfer and dissemination of it is being promoted. Therefore, “intellectual property rights are not an end to themselves”¹¹¹⁷ but are provided for the objectives that Article 7 refers to. These objectives can be interpreted in introducing concepts that into a normative assessment of the terms of Article 30.

¹¹¹² Henning Grosse Ruse-Khan, ‘Proportionality and Balancing within the Objectives for Intellectual Property Protection’ in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 173.

¹¹¹³ Christoph Herrmann, Wolfgang Weiß and Christoph Ohler, *Welthandelsrecht* (2nd edn, C.H. Beck 2007) [914] 432.

¹¹¹⁴ Graham Dutfield and Uma Suthersanen, *Global Intellectual Property Law* (Edward Elgar 2008) 223.

¹¹¹⁵ Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (OUP 2007) 91.

¹¹¹⁶ Christoph Herrmann, Wolfgang Weiß and Christoph Ohler, *Welthandelsrecht* (2nd edn, C.H. Beck 2007) [914].

¹¹¹⁷ Graham Dutfield and Uma Suthersanen, *Global Intellectual Property Law* (Edward Elgar 2008) 223.

In relation to exceptions to patentee's rights, the third objective of Article 7 that the protection and enforcement should contribute "to the mutual advantage of that producers and users of technological knowledge" is of critical importance as it specifically mentions the users of technology. This notion can be interpreted as emphasising the relevance of exceptions in national patent legislation and could pave "the way for the development of future exceptions..."¹¹¹⁸ In relation to public interest consideration, it is especially the last half-sentence that refers to balancing rights and obligations which stipulates a proportionality assessment between the private interests of the right holder with those of the general public. It could encourage WTO Member States to "[p]roviding an incentive for the creation of new innovations through rewards (...) - But equally securing the transfer and diffusion of innovations to the public (via disclosure mechanisms, the idea expression dichotomy in copyright and exceptions to exclusive rights)."¹¹¹⁹

Article 8 then refers to "Principles" and states:

"1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. "

The principles that Article 8 lay out can be regarded as amplifying the objectives of the Agreement that are provided within the preamble.¹¹²⁰ What makes the provision particularly interesting is the fact that it provides a gateway for public interest considerations within national IP legislation as the notion of "public interest" is specifically mentioned.¹¹²¹ Article

¹¹¹⁸ Peter Yu, 'The objectives and principles of the TRIPS Agreement', in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 161.

¹¹¹⁹ Henning Grosse Ruse-Khan, 'Proportionality and Balancing within the Objectives for Intellectual Property Protection' in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 174.

¹¹²⁰ Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet and Maxwell 1996) 3.09.

¹¹²¹ Indeed the legislative history of the TRIPs Agreement indicates the affirmation of public interest considerations within the Agreement when India submitted the following:

14. Primacy of public interest:

"A principle which is closely related to the balance of rights and obligations is the primacy of public interest. The State has the inherent right to take measures in public interest abridging the rights, of the

8 however, stipulates that while Member States may apply these principles, they would have to “be consistent with the provisions of this agreement.” Yusuf stipulates that while the original text did not refer to the consistency test this was apparently added through “the insistence of developed countries.”¹¹²² Since the public interest formulated within Article 8.1 is drafted very broadly, it would appear necessary to clarify its scope in order to make it a yardstick on how far such public interest considerations may still be consistent with the TRIPS Agreement.

With regards to the application of Articles 7 and 8 TRIPS, Canada has argued that Article 7 provides a programmatic point within the TRIPS agreement that serves to balance intellectual property rights with other socio-economic issues that the right of the patent holder.¹¹²³ While not disputing that the provision sets out the TRIPS Agreements’ goal to provide for a balance between intellectual property rights and other socio-economic interests, the European Communities however were of the opinion that such a balance had already been achieved with the final text of the TRIPs Agreement.¹¹²⁴ The Panel took a position between both points of views: While the sheer presence of Article 30 would stipulate that patent rights as provided in Article 28 would require to be adjusted, the wording of the limiting conditions of Article 30 do not stipulate that a “renegotiation of the basic balance of the Agreement” was intended by its negotiators.¹¹²⁵

However, the Panel held that “(b)oth the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.”¹¹²⁶ While referring to Article 7 and 8 of the Agreement, the panel decision lacks consideration when it discusses the

holders of intellectual property rights. One such measure is the grant of compulsory licence on the ground of failure to work or insufficient working. But other measures may also be taken, particularly in respect of patents, in pursuance of such vital concerns as security, public health, nutrition, agricultural development, poverty alleviation and the like.”

Uruguay Round - Group of Negotiations on Goods (GATT) - Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods - Applicability of the Basic Principles of the GATT and of Relevant International Intellectual Property Agreements or Conventions - Communication from India (GATT Document MTN.GNG/NG11/W/39, 05 September 1989) 8.

¹¹²² Abdulqawi A. Yusuf, ‘TRIPS: Background, Principles and General Provisions’ in Carlos M. Correa and Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd edn, Kluwer Law International 2008) 14.

¹¹²³ *Canada – Patent Protection of Pharmaceutical Products*- Report of the panel (17 March 2000) WT/DS114/R [7.24].

¹¹²⁴ *ibid* [7.25].

¹¹²⁵ *ibid* [7.26].

¹¹²⁶ *ibid* [7.26].

individual steps of the Three Step as it held that the basic balance of the agreement ought not to be renegotiated. Based on the findings of the panel, the level of influence that Article 7 has on interpreting Article 30 therefore does not appear to be clear.

But considering Article 7 and 8 when interpreting the three individual steps does not amount to renegotiating the Agreement as Susy Frankel notes.¹¹²⁷ She submits that the panel rather ignored Articles 7 and 8 of the Agreement. She adds that the Panel rather regarded that the basic balance has already been achieved by the provisions of the Agreement. Such an approach that side-lines Articles 7 and 8 would make these provisions redundant.¹¹²⁸ Since the Panel did not give a decisive statement with regards to application and interpretation of Articles 7 and 8,¹¹²⁹ the potential effect of these provisions with regards to Article 30 TRIPS for policy making within national patent legislation remains opaque.

What could strengthen the application of Articles 7 and 8 is their positioning within the Agreement. Based on a systematic interpretation of the position of both provisions within the Agreement, Gervais states in relation to Article 7 that “[t]he fact that a provision of this nature is contained in the body of the agreement, and not in the preamble, would seem to heighten its status,...”.¹¹³⁰ Additionally, Articles 7 and 8 could be regarded as reiterating long-standing intellectual property commitments which need to be borne in mind when interpreting the Agreement.¹¹³¹

¹¹²⁷ Susy Frankel, ‘The WTO’s Application of ‘The Customary Rules of Interpretation of Public International Law’ to Intellectual Property’, [2005-2006] *Virginia Journal of International Law* 364, 397.

¹¹²⁸ *ibid* 397.

¹¹²⁹ Peter Yu, ‘The objectives and principles of the TRIPS Agreement’, in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 155.

¹¹³⁰ Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet and Maxwell 2012) 2.111. Correa adds that while some commentators perceive the fact that Article 7 is termed as a ‘shall’ norm and would therefore would not amount to a “mere hortatory provision” the positioning within the text under the heading ‘General provisions and basic principles’ emphasises their importance for the interpretation of the entire treaty - Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights – A Commentary on the TRIPS Agreement* (OUP 2007) 93.

¹¹³¹ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, ‘An international *acquis*: Integrating regimes and restoring balances’ in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) 155.

6.3.3.2. “The Doha Declarations”

The relevance of Articles 7 and 8 of the TRIPS Agreement for its interpretation could be emphasised by two declarations by the WTO Ministerial meeting in Doha in 2001¹¹³²: the Doha Ministerial Declaration and the Declaration on the TRIPS Agreement and Public Health.¹¹³³ The former instructed the TRIPS Council within its paragraph 19 to examine “the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1.”¹¹³⁴ It additionally adds that “[i]n undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.”¹¹³⁵ While Articles 7 and 8 are specifically mentioned, it remains unclear as to whether the Council’s declaration solely relates to the interpretation of TRIPS with regards to its relationship with the Convention on Biological Diversity or whether a more expansive interpretation that permits their general application throughout the Agreement may be applied.

The Doha Declaration on the TRIPS Agreement and Public Health specifically addresses the difficulties that developing and least developing countries encountered with public health problems. While this declaration highlights the issues surrounding the relationship between patent protection and the public health crisis, it specifically mentions the Member States’ abilities to apply the flexibilities within the Agreement.¹¹³⁶ In particular, it states that “[i]n

¹¹³² Henning Grosse Ruse-Khan, ‘Proportionality and Balancing within the Objectives for Intellectual Property Protection’ in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 181.

¹¹³³ The HIV crisis in developing countries put the practice of patent holders under scrutiny. Additionally, the inflexibility that Article 31 TRIPS provided for developing countries without domestic pharmaceutical capacities to provide for compulsory licenses was widely criticised by NGOs and the media. It could therefore be argued that the developments that culminated in the Doha Declarations can be regarded as an “evolution of law” - Niklas Luhmann, *Das Recht der Gesellschaft* (Suhrkamp 1993) pp. 239. Abegg states that the law evolves where unexpected and scandalous incidents happened such as the HIV crisis and where this attracts public and media attention - Andreas Abegg, ‘Evolutorische Rechtstheorie’ in Sonja Buckel, Ralph Christensen, Andreas Fischer-Lescano (eds), *Neue Theorien des Rechts* (2nd edn, Lucius & Lucius) 418.

¹¹³⁴ <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm> accessed 23 May 2015.

¹¹³⁵ *ibid.*

¹¹³⁶ Paragraph 5 Declaration on the TRIPS Agreement and Public Health:

“We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”¹¹³⁷

The effect of these declarations on future interpretation of the TRIPS Agreement in general, and in relation to Article 30 in particular, however remain blurred.¹¹³⁸ What could raise their importance in future developments is the fact that the Council for TRIPS specifically emphasised to consider the principles and objectives in *each* provision of the TRIPS Agreement. It could therefore be argued that since not every provision of the Agreement necessarily relates directly to the interplay of the Agreement with public health issues, the Council had envisaged a more expansive application of Articles 7 and 8 TRIPS.

Another point in favour of this approach could be the fact that both declarations can be considered to be subsequent practice in the meaning of Article 31 (3) of the Vienna Convention which states that “[t]here shall be taken into account, together with the context ... any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions.” Whether the two mentioned declarations can be considered as such subsequent agreement is arguable. Peter Yu, however, states that “WTO Panels and the Appellate Body are likely to take the documents into account as subsequent developments.”¹¹³⁹ Gervais states that the panels adjudicating the TRIPS provisions after the Doha Ministerial Declaration will give Articles 7 and 8 TRIPS “a higher legal status for interpreting the Agreement...”¹¹⁴⁰ Grosse Ruse-Khan holds that the public interest principle as displayed in Article 8(1) TRIPS will guide the interpretation of the Agreement especially where there is ambiguity due to the broad and open language of the Agreement.¹¹⁴¹ In relation to Article 30, it needs to be mentioned that the Panel Report in the *EC-Canada* dispute

<http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 23 May 2015.

¹¹³⁷ *ibid.*

¹¹³⁸ Henning Grosse Ruse-Khan, ‘Proportionality and Balancing within the Objectives for Intellectual Property Protection’ in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 184.

¹¹³⁹ Peter Yu, ‘The objectives and principles of the TRIPS Agreement’ in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules – Intellectual Property in the WTO Volume 1* (Edward Elgar 2010) 155.

¹¹⁴⁰ Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet and Maxwell 2012) 2.125.

¹¹⁴¹ Henning Grosse Ruse-Khan, ‘Assessing the need for a general public interest exception in the TRIPS Agreement’ in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 180.

predates the declarations provided by the Council of TRIPS in Doha. It remains to be seen as to how a panel would take Articles 7 and 8 into consideration in a post-Doha era.¹¹⁴²

6.3.3.3. Article 30 TRIPS as a proportionality test

One approach to provide for ensuring that public interest considerations are applied in the context of Article 30 TRIPS is by re-interpretating it as a proportionality test.¹¹⁴³ The classical proportionality test that derives from German law has found its way into the legal regimes of the EU and the ECHR.¹¹⁴⁴ The test that is applied within the fundamental/human rights frameworks¹¹⁴⁵ is set out to inquire whether an interference with a right or interest is based on a legitimate purpose, whether the interference is suitable and necessary as well as whether it is proportionate.¹¹⁴⁶ This test therefore requires the assessment of whether all interests have been acknowledged.¹¹⁴⁷ The application of Articles 7¹¹⁴⁸ and 8 TRIPS can provide for interpretive basis to assess the normative language that Article 30 TRIPS uses¹¹⁴⁹

¹¹⁴² Kur holds that the Doha Declaration might initiate a renewed assessment of Article 30 TRIPS - Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 240 - 241.

¹¹⁴³ Such an approach has been urged by Kur - *ibid* 248-249.

The 'Proposals for Amendment of TRIPS' (supra fn 1087) place a proportionality test within a new Article 8a (1) and (2)(c) that aims to ensure that the conflicting interests involving IP rights are put into a proportionate balance. This is a laudable approach for the insertion of public interest considerations into the assessment of compatibility with the TRIPS Agreement *de lege ferenda* - 'Proposals for Amendment of TRIPS' in Annette Kur & Marianne Levin (eds), *Intellectual Property in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 465-467, pp. 538, 548-549.

¹¹⁴⁴ Jeffrey Jowell and Anthony Lester, 'Proportionality: Neither novel nor dangerous' in Jeffrey L. Jowell and Dawn Oliver (eds), *New Directions in Judicial Review* (Stevens 1988) pp 51.

¹¹⁴⁵ supra 3.4.4.4, 3.4.4.5, 4.4.3, 4.5 and 4.6.

¹¹⁴⁶ Jeffrey Jowell and Anthony Lester, 'Proportionality: Neither novel nor dangerous' in Jeffrey L. Jowell and Dawn Oliver (eds), *New Directions in Judicial Review* (Stevens 1988) 52, who refer to three conditions (suitability, necessity and the principle of proportionality in the narrow sense) while Fischman Afori refers to four factors: "[p]roper purpose, rational connection, necessary means, and a proper relation between the benefit gained by realizing the proper purpose and the harm caused to the constitutional right" - Orit Fischman Afori, 'Proportionality – A New Mega Standard in European Copyright Law' [2014] IIC 889, 895.

¹¹⁴⁷ "WTO law does not explicitly operate on the basis of proportionality, but contains several indirect references, generally expressed in terms like 'necessary to' or 'least trade restrictive', or 'appropriate' measures. Such terms illustrate the inherent presence of some kind of proportionality in WTO law by reference to balancing and weighing of measures or interests." - Thomas Cottier, Roberto Echandi, Rafael Leal-Arcas, Rachel Liechti, Tetyana Payosova, and Charlotte Sieber-Gasser, 'The Principle of Proportionality in International Law' [2012] NCCR Trade Regulation Working Paper No 2012/38 <<http://srn.com/abstract=2598410>> accessed 28.05.2015

¹¹⁴⁸ Henning Grosse Ruse-Khan, 'Proportionality and Balancing within the Objectives for Intellectual Property Protection' in Paul Torremans (ed), *Intellectual Property and Human Rights – Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer 2008) 191.

¹¹⁴⁹ Wording such as "unreasonable" and "legitimate" can serve as gateways to insert policy considerations - Annette Kur, 'Limitations and exceptions under the three-step test – how much room to walk the middle ground?' in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 247.

a way to infuse it with public interest considerations¹¹⁵⁰ by which the affected interests are balanced against one another.

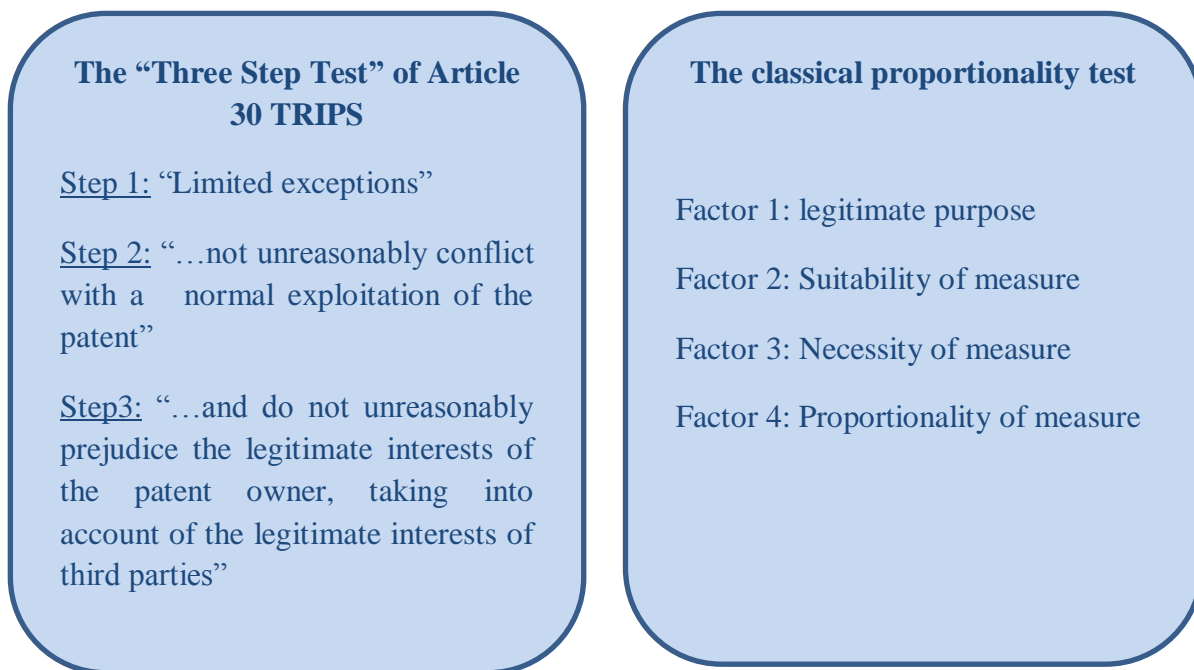


Fig.1

The first step of article 30 TRIPS stipulates that an exception from the exclusive rights of a patent must be limited in the sense that it only represents a small diminution of the patent right as the *EC-Canada* Panel held.¹¹⁵¹ Such an approach does not entail any normative considerations.¹¹⁵² This is however, not a necessary interpretation. Kur states that “[r]ather than determining whether a rule is “limited” (or “special”) in an absolute sense, it should be inquired how it is limited, i.e. what its limitations are. The decisive question to be asked in the light of further elements to be investigated on the following steps would then be whether the exception is limited enough in view of its purpose and potential impact.”¹¹⁵³

¹¹⁵⁰ It is being said that Article 30 TRIPS with its language could work to alleviate conflicting interests - Andreas Abegg, ‘Evolutorische Rechtslehre’ in Sonja Buckel, Ralph Christensen, Andreas Fischer-Lescano (eds), *Neue Theorien des Rechts* (2nd edn, Lucius & Lucius) 417 in fn 65.

¹¹⁵¹ Supra 5.4.1.2.

¹¹⁵² Martin Senftleben, ‘Towards a Horizontal standard for Limiting Intellectual Property Rights? – WTO Panel Reports shed Light on the Three Step Test in Copyright Law and Related Tests in Patent and Trademark Law’ [2006] IIC 407, 421.

¹¹⁵³ Annette Kur, ‘Of Oceans, Islands, and Inland Water – How Much Room for Exceptions and Limitations under the Three Step-Test?’ [2008-2009] *Richmond Journal of Global Law and Business* 287, 317.

The first step may be subsumed under the notion that the interference must be based on a legal provision as it is stipulated within human/fundamental rights frameworks with regards to an interference. In other words, the exception/interference cannot be arbitrary and is limited through the legitimate purpose it wishes to achieve. This would highlight the reason or purpose for curtailing the patent right which would have to be in the public interest. The determination of what is the public interest must be decided on the domestic jurisdiction and WTO adjudicating bodies should provide Member States with a wide margin of appreciation, similar to the situation before the ECtHR. Such margin could be derived from Paragraph 5 (c) of the Doha Declaration on the TRIPS Agreement and Public Health. Here, Member States have the right to determine what would constitute a national emergency or health crisis. Such understanding could be applied more generally that Member States should have the right to determine what would constitute a legitimate purpose to curtail the exclusive right of a patent while still be consistent with TRIPS.

The second step can also be made compatible to work as a proportionality test. This means that an exception does not unreasonably affect the normal exploitation of the right. First, this means that the purpose of an exception is important and can be based on public interest.¹¹⁵⁴ Then it is likely not to unreasonably affect the right as the purpose of the exception would be in the public interest and follow a legitimate purpose. Additionally, the term “normal exploitation” can be assessed by the deciding body as not to bestow any possible and thinkable way of exploitation to the right holder but only such which is necessary to overcome the public goods dilemma. This, of course, needs to be done with caution since one should not risk a disproportionate decrease of incentives to innovate which would be counterproductive. This links to factors 2 and 3 of the proportionality by which a measure must be necessary and suitable to achieve the legitimate purpose.

The third step finally juxtaposes the affected interests which lead to the proportionality test in a narrow sense¹¹⁵⁵ to be applied.¹¹⁵⁶ It can serve as a gateway to directly internalise public interest considerations. This exercise can be nurtured through the fundamental rights

¹¹⁵⁴ This on the other hand ensures that the patent right is again not arbitrarily being curtailed.

¹¹⁵⁵ Jeffrey Jowell and Anthony Lester, ‘Proportionality: Neither novel nor dangerous’ in Jeffrey L. Jowell and Dawn Oliver (eds), *New Directions in Judicial Review* (Stevens 1988) 53.

¹¹⁵⁶ Annette Kur, ‘Limitations and exceptions under the three-step test – how much room to walk the middle ground?’ in Annette Kur with Marianne Levin (eds), *Intellectual Property Rights in a Fair World Trade System – Proposals for Reform of TRIPS* (Edward Elgar 2011) 250.

discourse which has been providing for such a framework to balance colliding fundamental rights. The third step is also the place where the fundamental right considerations of third parties can be internalised and placed against the fundamental rights and interests of the patent holder.¹¹⁵⁷ The colliding rights and interests ultimately need to be accommodated through a balancing operation, which in German legal scholarship is referred to as *praktische Konkordanz*.¹¹⁵⁸

The balanced approach that exceptions generally can provide can also be based on the fact that exceptions can have a twofold nature as they can be remunerated and unremunerated. Where it is found that an unremunerated exception would disproportionately affect the patent holder's right, the legislator could contemplate a remunerated exception. Then, a third party that wishes to use the patented invention must pay the patent holder. Such remunerated exceptions are referred to as non-voluntary or compulsory licenses. While the patent holder loses his exclusivity, he or she still receives remuneration for the use of the third party and does not go empty-handed. In many cases, the royalty paid to the patent holder using the invention under such a compulsory license is quite competitive in market terms. This for instance, can be seen within the already mentioned compulsory license for biotechnological research tools within Swiss patent law.¹¹⁵⁹

Article 30 TRIPS finally should not be perceived as a step-by-step test. Rather, it should enable all conflicting interests into be taken into account – an approach which the proportionality test promotes. Additionally, such approach would allow taking fundamental right positions into account. While the proportionality test has found its way into intellectual property decisions by the CJEU,¹¹⁶⁰ it has to be noted that the test has been criticised as being futile and not able to provide more than a rhetorical tool.¹¹⁶¹ But as Fischman Afori holds, the advantage of the test is that it incorporates the fundamental rights perspective and also

¹¹⁵⁷ Hestermayer argues that such human rights considerations could be internalised into WTO law through WTO jurisprudence by the DSU Panels. He argues that the ECJ has applied human rights considerations even before the Charter on Fundamental Rights was devised by “drawing inspiration from member states’ constitutions and international treaties” which could be done by the WTO Panels - Holger Hestermayer, *Human Rights and the WTO – The Case of Patents and Access to Medicines* (OUP 2007) 288.

¹¹⁵⁸ The principle of practical concordance was established by the German scholar Konrad Hesse - Andreas Fischer Lescano, *Kritik der praktischen Konkordanz* (2008) *Kritische Justiz* 166, 167; Thomas Hoeren, ‘Was bleibt vom Urheberrecht im Zeitalter von Filesharing und Facebook?’ [2012] *EuZ* 8.

¹¹⁵⁹ *Supra* 3.5.2.

¹¹⁶⁰ Case C-275/06 *Productores de Música de España (Promusicae) v Telefónica de España SAU* (ECJ 29 January 2008) [68] - *supra* 4.5.

¹¹⁶¹ Orit Fischman Afori, ‘Proportionality – A New Mega Standard in European Copyright Law’ [2014] *IIC* 909 with further references.

provides that all affected interests are being taken into account.¹¹⁶² With regards to public interest considerations surrounding exceptions, this approach does not just appear viable to ensure that sufficient scope is provided to public interest considerations. It safeguards that such considerations are considered at all.

6.4 Conclusion

The chapter has shown that exception provisions have their advantages with regards to other legislative tools when it comes to addressing limiting the patent right in the public interest. They can serve as a tool to fine tune domestic patent policy. Any incompatibility with the current application of Article 30 TRIPS can be remedied through a purposive interpretation and applying the proportionality test that weighs all interests against one another. This has the benefit that the test would remain responsive to occurrences and developments outside the law that may need to be addressed as seen with the example of the research exception.¹¹⁶³ Additionally, it is the accommodation of conflicting interest which ultimately is in the public interest.¹¹⁶⁴

The usefulness of exceptions with regards to serving the public interest is because they demonstrate which third party interest surrounds the provision. This can then be utilised to provide for a flexible approach because the affected third party interests are being made visible. Eventually, what might occur is that the notion of the third party interest evolves into a notion of user rights.¹¹⁶⁵ This has advantages as Dinwoodie and Dreyfuss highlight.¹¹⁶⁶ Of importance would be the rhetorical balance between the right of the owner and those of users. What assisted this development is the application of fundamental rights within the interpretation of exception provisions.¹¹⁶⁷ Such notion would perhaps render the exception provisions that are currently provided as an intermediate step towards such user rights: When one looks back at how exceptions developed – from judge made rules, over statutory tools

¹¹⁶² Orit Fischman Afori, 'Proportionality – A New Mega Standard in European Copyright Law' [2014] IIC 909 910.

¹¹⁶³ supra 2.4.

¹¹⁶⁴ Robert Uerpmann, *Das öffentliche Interesse: seine Bedeutung als Tatbestandsmerkmal und als dogmatischer Begriff* (Mohr Siebeck 1999) 36.

¹¹⁶⁵ supra 6.2.4.

¹¹⁶⁶ Graeme B. Dinwoodie and Rochelle C. Dreyfuss, 'An international *acquis*: Integrating regimes and restoring balances' in Daniel J. Gervais (ed), *International Intellectual Property – A Handbook of Contemporary Research* (Edward Elgar 2015) pp 159.

¹¹⁶⁷ supra 6.2.4.

exempting certain used from infringement, to being considered as containing user rights where they are based fundamental rights, then such development does not appear unthinkable.

Chapter 7: Conclusion

The thesis aimed to test the hypothesis that exceptions to patentee's rights are provided to serve the public interest. In concluding the work, the main findings of the thesis will be displayed in short points while providing commentary as to how these findings relate to testing the hypothesis, providing answers to the initial research questions and showcasing what practical impact they have:

- 1. Public interest with regards to exceptions to patentee's rights necessarily involves third party interest. Hence, such third party interest needs to be identified by legislators when legislating exceptions.**

Part 1 has established that exceptions to patent rights in the public interest necessarily need to warrant the interests of the parties that would benefit from such a provision. This is because exception provisions permit third parties a use that is otherwise infringing. Part 1 demonstrated this in relation to the research exception. The increasing shift of research being conducted by commercially orientated entities made the old law obsolete because the "users" of the exception provision changed. The introduction of the statutory provisions to exempt experimental uses by commercially orientated undertakings can be seen as a response to the changing needs and interests of those third parties.

Therefore the legislator ought to analyse the necessities of potential third parties that wish to access the patented invention. This could base the analysis of whether and how exceptions ought to be drafted on more concrete footing rather than on informed guess work.¹¹⁶⁸ It can be said that the legislator generally apply such an approach if one bears in mind the legislation that has been brought forward with regards to allowing uses to gain regulatory approval for pharmaceuticals.

¹¹⁶⁸ Gangjee and Burrell mention something true when they argue that "(l)egal intervention in the field of intellectual property is often a matter of informed guesswork" - Robert Burrell and Dev Gangjee, 'Trade Marks and Freedom of Expression – A Call for Caution' [2010] IIC 552

2. Public interest is a concept that requires that the law need to be constantly assessed as to whether they serve the public interest. It therefore is a concept that is constantly adjusted.

A second important point that can be deduced from Part 1, which is related to the first point, is the fact that exception provisions need to reflect current necessities to be considered to be in the public interest. The example with the research exception stipulated that the old law with regards to experimenting was not accommodating how contemporary research was being conducted. Due to the fact that experimenting would serve the public interest in technological advance, the means (i.e. the law) had to be adapted to serve the end, the public interest. This has been done through providing a statutory tool that would permit such uses.

Legislators in the United Kingdom and Germany are therefore mandated to be responsive towards recent developments that could affect the assessment of public interest considerations in exceptions to patent rights. As mentioned under the first point, this generally can be said to be the case in both analysed jurisdictions.

3. In the United Kingdom and Germany it is the legislator that is primarily responsible for applying public interest considerations to exceptions. The purposes for which these exception provisions have been provided for serve the public interest.

An important issue with regards to competence in providing public interest considerations through exceptions to patent rights has been established within Part 1. In the analysed jurisdictions it is the legislator that is primarily mandated to provide for exceptions to patent rights in the public interest. The legislator defines which unauthorised third party use can be deemed to be in the public interest. They then use their prerogative to legislate such exceptions which they deem to be in the public interest. Albeit its infancy in European law this was clearly the case with regards to the research exception.

Another observation in Part 1 is that all exception provisions legislated by the UK and German legislator only exempt a use when it is conducted with a particular purpose. It is then this particular purpose that encases the public interest. Consequently, this means that when a

third party use does not reflect such purpose then it is not a privileged use exempted from infringement. In other words, such use is then not in the public interest.

This leads to another important finding: Legislators have used public interest considerations, i.e. the underlying purpose of an exception, to delineate the spheres that are attributed exclusively to the right holder from such which are in the public interest. While maintaining the exclusive right of the patent holder, public interest considerations in using the invention are assessed and considered. By this a balance between the public interest and the interests of the right holder is generated. The research exception in the UK and Germany are perfect examples for this balancing exercise: While use for experimental purposes is generally allowed, they are only permitted when conducted on the subject matter of the invention. Through this the commercialisation of the patent right is not affected significantly while allowing experimenting.

4. The public interest is however applied through a teleological or purposive interpretation of the law by the courts. This encompasses public interest considerations since the purpose of an exception is to serve the public interest.

The courts play a less prominent role with regards to public interest considerations within exceptions to a patent right than legislators in Germany and the United Kingdom. As such they cannot devise new exception provision. What they are able to do however is to enunciate the public interest considerations underlying an exception. This is done by a teleological or purposive interpretation of the statutory exception provisions.

A teleological interpretation has an important role in assessing the scope of the exception provision. This was demonstrated in chapter 3 in comparing the scope of the research exception in Germany and the United Kingdom. The courts in Germany have applied a thorough teleological approach of the exception provision. This enabled them to emphasise the purpose of the provision. Since the purpose of a provision is in the public interest, a teleological interpretation highlights the public interest on which the exception is built on. In other words, a teleological interpretation is a public interest interpretation.

5. Public interest considerations are applied when a fundamental or human rights discourse is applied to interpret provisions of the ordinary law. Additionally, a proportionate balance between the fundamental rights of the patent holder and those of users serves the public interest.

Fundamental rights have a critical role to play when assessing public interest considerations. This is twofold: On the one hand, the use exempted by an exception can be based on a fundamental right of the user. This notion assists the identification of the third party interest. The fundamental right position of the user informs the legislator and courts which interests need to be considered in the above mentioned balancing exercise between interests of the right holder with those of the public. Acknowledging the fundamental rights position of users also reduces the risk to ignore the interests of third parties in using the patented invention.

On the other hand, due to its compulsory nature, the conflicting fundamental rights of the patent owner and users need to be balanced proportionately. Furthermore, it can be said that achieving such balance is in itself in the public interest. The conflict between the fundamental rights positions of owners and users need to be balanced proportionately. This balancing exercised on the fundamental rights level needs to be reflected in the ordinary law. This has for instance been accomplished by the exceptions provisions of the German Patent Act according to the German Constitutional court.

6. Human Rights considerations will influence exceptions to patent rights in the United Kingdom through the conduit of the Human Rights Act 1998 (HRA). This may lead to a more purposive interpretation of exception provisions.

The fundamental rights discourse that is discussed above will influence the legislation and interpretation of exception provisions in the United Kingdom. It has already been applied since the legislator is mandated to consider ECHR positions under the HRA 1998. This will affect the discourse on intellectual property rights as the human rights positions of both owners and users of a patented invention should be taken into account when legislating an exception provision.

More importantly, the human rights discourse will influence the interpretation of the courts. Courts in the United Kingdom generally apply a rather literal interpretation of statutory law

in order to maintain supremacy of Parliament. With the inception of the HRA 1998 the interpretation will shift away from the literal approach to a more purposive approach which acknowledges the fundamental right position underlying an exception provision. Such an interpretation would also serve to further express public interest considerations.

- 7. Article 30 TRIPS can be reinterpreted into a proportionality test that would allow future WTO DSU Panels to assess whether an exception is conforming TRIPS but allows the legislator to apply domestic and often mandatory public interest considerations. It also encompasses the consideration of relevant fundamental rights positions.**

The current interpretation of Article 30 of the TRIPS Agreement presents a real hurdle to apply public interest considerations. First, this is because the approach presented in the EC-Canada case does safeguard that the purpose of an exception provision is being acknowledged with the 3 Step Test that Article 30 TRIPS represents. This stands in stark contrast to domestic approaches. Furthermore, the current interpretation of Article 30 does additionally not safeguard that third party interests are mandatorily considered. This again, impairs the domestic legislator's ability in assessing which exception would serve the public interest.

Article 30 TRIPS should therefore be reinterpreted into a proportionality test. This would alleviate the currently conflicting approaches in modelling exception provisions while still remaining compatible with the TRIPS Agreement. Such an approach would more reflect how exceptions are legislated domestically while also allowing full compatibility with WTO law as well as human/fundamental rights frameworks that the domestic legislator has to abide to. Such an approach becomes increasingly relevant generally in assessing how transnational frameworks affect domestic legislation.

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