

**COMPULSORY LICENSING FOR PHARMACEUTICAL PATENTS: EXAMINING THE
CONSISTENCY OF THE LOCAL WORKING REQUIREMENTS UNDER SECTION 84 OF
THE INDIAN PATENT ACT WITH THE TRIPS AGREEMENT AS A MODEL FOR
GHANA**

By

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II. Abstract

Compulsory licensing would offer Ghana a practical means to mitigate the high costs and shortages of medicines resulting from the failure of patentees to work their patented medicines locally. Article 5(A) of the Paris Convention as incorporated into Article 2 of TRIPS is consistent with Section 84 of the Indian Patents Act allows for the granting of compulsory licences to remedy failure to work. Where national laws permit, Article 31 of TRIPS allows the use of compulsory licences on any grounds subject to certain conditions. Although, the Doha Declaration on TRIPS and Public Health confirmed this position, there are contradictory opinions that the non-discrimination principle under Article 27(1) of TRIPS prohibits the granting of compulsory licences for failure to work. To the extent that Article 2 of TRIPS incorporates Article 5(A) of the Paris Convention provision, which is consistent with Section 84, the question that arises is whether Section 84 is consistent with TRIPS. Therefore, the aim of this thesis is to draw on applicable sources of law in an attempt to examine the consistency of Section 84 with TRIPS. This work is based on the hypothesis that Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is consistent with TRIPS and would therefore provide a suitable model for Ghana. This argument is enhanced by the fact that in 2012 India invoked Section 84 in granting a compulsory licence to Natco and to date the consistency of this decision with TRIPS remains unchallenged within the World Trade Organisation Dispute Settlement system. The overriding implication is that if India got away with this decision, then it is probable that Ghana could implement a model similar to Section 84 to obtain affordable medicines without any legal challenge.

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Chapter 1

Ghana's Essential Medicines Need and the Legal Difficulties in using Compulsory Licensing

1.1. Aim of the Chapter

This chapter seeks to present the background of the study. It highlights Ghana's need for essential medicines and the legal difficulties in using compulsory licensing to obtain an affordable supply for distribution.

1.2. Introduction to the Work

Compulsory licensing, as an instrument of government policy,¹ would offer Ghana, a country that is considerably burdened with diseases,² a practical means to mitigate the high costs and shortages of essential medicines.³ Essential medicines per the definition by the World Health Organisation (WHO) are those that 'satisfy the priority health care needs of the population' and 'are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford'.⁴

However, the country faces legal difficulties in using the compulsory licensing instrument for that purpose. For example, in August 2000, GlaxoSmithKline (GSK) threatened to take an Indian company the Chemical, Industrial and Pharmaceutical Laboratories (CIPLA) to court on the basis the company's exportation of Duovir to a Ghanaian drug distributor (Healthcare

¹ Jerome Reichman and Catherine Hasenzahl, 'Non-Voluntary Licensing of Patented Inventions' (UNCTAD-ICTSD Issue Paper No. 5, 2004) 10, defining the term "Non-voluntary" or "Compulsory licensing" as the practice of governments allowing parties other than the original patentees to exploit patented products and processes.

² Country Statistics and Global Health Estimates (WHO and UN Partners). <<http://www.who.int/countries/gha/en/>> [Accessed Mar. 18, 2018]. Jullien Clare Cohen, Martha Gyansa-Lutterodt, Kwasi Torpey, Esmail Laura, Greg Kurokawa, 'TRIPS, the DOHA Declaration and Increasing Access to Medicines: Policy Options for Ghana' (2005) 1 *Globalization and Health* 17, 5, stating that Ghana's major disease burden includes malaria, TB and HIV/AIDS. Eric Tenkorang and Vincent Kuire, 'Noncommunicable Diseases in Ghana: Does the Theory of Social Gradient in Health Hold?' (2016) 46 *Health Education and Behaviour* 1 (Suppl.), 25-26.

³ Karima Saleh, 'The Health Sector in Ghana: A Comprehensive Assessment' (World Bank, 2013) para. 102, finding that several facilities continued to report stock outs. 'Let's End Frequent Shortage of Medicines' (Graphic Online, Tuesday, Aug. 26, 2014). <<http://www.graphic.com.gh/editorials/29516-let-s-end-frequent-shortage-of-medicines.html>> [Accessed Mar. 25, 2018].

⁴ See the Concept of Essential Medicines by the World Health. Available at: <https://www.who.int/medicines/services/essmedicines_def/en/> [Accessed Mar. 10, 2019].

Limited) violates its patent rights in Combivir.⁵ While it appears that this enterprise was purely a private commercial arrangement as opposed to a compulsory licence or parallel importation,⁶ CIPLA ceased exports to Ghana, which caused shortages of Duovir in the country.⁷

Moreover, in 2005, Ghana granted a compulsory licence for public non-commercial use,⁸ however, this national measure was abandoned.⁹ Ghana's failure to utilise the compulsory licensing instrument to obtain affordable medicines is due to the controversy surrounding the World Trade Organisation (WTO)¹⁰ Members' right to grant compulsory licensing for pharmaceutical products under the TRIPS Agreement.¹¹ Notably, the concept and practice of compulsory licences are not new, even in developed countries.¹² This instrument has a long

⁵ Mark Schoofs, 'Glaxo Attempts to Block Access to Generic AIDS Drugs in Ghana' (*The Wall Street Journal*, Dec. 1, 2000). <<http://online.wsj.com/news/articles/SB975628467266044917>> [Accessed Mar. 13, 2017]. See Dr Yusuf Hamied, 'CEO of CIPLA's Letter to GSK'. <<http://www.thebody.com/content/art1606.html>> [Accessed Mar. 24, 2017].

⁶ Article 6 of the TRIPS Agreement, Apr. 15, 1994. Annex 1 C Legal Instrument-Result of the Uruguay Round. Vol. 31, 13 I.L.M (1994) provides that 'For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.' See Keith Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries* (Final Report to World Intellectual Property Organisation, 2001) 2, defining parallel imports as goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorisation of the local owner of the IP right. note that with respect to the exhaustion of IP rights, Paragraph 5(d) of the World Trade Organisation, Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002), (adopted on Nov. 14, 2001) reads as follows:

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.1.

⁷ Caroline Thomas, 'Trade Policy and the Politics of Access to Drugs' (2002) 23 *Third World Quarterly* 2, 258.

⁸ Notification of Emergency and Issuance of Government Use Licence by Ghana (No. SD-110SF.3 Vol., 26 October 2005). Available at: <<http://www.cptech.org/ip/health/cl/Ghana.png>> [Accessed Mar. 27, 2017]. James Love, 'Recent Examples of Compulsory Licensing of Patents' (Knowledge Ecology International, May 6, 2007). See also Brent Savoie, 'Thailand's Test: Compulsory Licensing in an Era of Epidemiologic Transition' (2007) 48 *Virginia Journal of International Law* 1, 237. Jamie Feldman, 'Compulsory Licenses: The Dangers Behind the Current Practice' (2009) 8 *Journal of International Business and Law* 1, 14.

⁹ Emilie Cloatre, *Pills for the Poorest: An Exploration of TRIPS and Access to Medication in Sub-Saharan Africa* (Basingstoke: Palgrave Macmillan, 2013) 53, finding that Ghana did not directly face significant political opposition at the time, although interestingly, this compulsory licensing was later made redundant by the regulations imposed by the Global Fund that now finances the procurement of AVRs in Ghana.

¹⁰ The Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, the Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 4 (1999), 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994).

¹¹ Richard Epstein and Scott Kieff, 'Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents' (2011) 78 *The University of Chicago Law Review* 2, 92, claiming that efforts to justify compulsory licensing for pharmaceutical patents are simply not tenable because defenders fail, first, to understand the power of the background presumption against it. Cole Fauver, 'Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come' (1987) 8 *Northwestern Journal of International Law & Business* 3, 676, explaining that compulsory licences reduce the inventor's incentive to develop new technology.

¹² *ibid.* Fauver, 672, detailing Canada, Germany, Japan, Sweden, Switzerland and the United Kingdom as countries that have maintained local working requirements.

history and has remained a prominent feature of the general philosophy of patent regimes for over a century.¹³ It has become a common and integrated feature of most patent systems, even though it is not often put into practice.¹⁴ Many patent law regimes provide for the granting of compulsory licences in a variety of situations.¹⁵ Specific situations in which compulsory licences may be issued are set out in the legislation of each patent system.¹⁶

Many justifications have been offered to account for this practice and they vary considerably between countries.¹⁷ Perhaps the most important and widespread use of compulsory licences by Members is as a remedy for patent-holder abuse, such as failure to work patented inventions over an extended period in the territory of the country that granted the patent.¹⁸ Consequently, in several countries, local working requirements are the basis for granting compulsory licences.¹⁹ For example, Section 84 of the Patents Act 1970 authorises the Controller General

¹³ Friedrich-Karl Beier, 'Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law' (1999) 30 *International Review of Industrial Property and Copyright Law* 3, 259-260, finding that most patent laws in developed countries permit compulsory licences, but stressing that actual grants of such licences remain rare.

¹⁴ For example, compulsory licensing provisions were included in the first Commonwealth Patents Legislation of Australia [C1903A00021: No. 21 of 1903]. Part V-Titled: Section 87 - Working of Patents and Compulsory Licences. Belgium Patent Law (of Mar. 28, 1984, as last amended on Jan. 28, 1997) Article 31, 33 and 35 concerns compulsory licences.

¹⁵ Carlos Correa, 'Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries' (Trade-Related Agenda, Development and Equity Working Papers 5: South Centre, October 1999) 10, discussing the grounds for granting compulsory licences including non-working and inadequate supply. Stephen Ladas, *Patents, Trademarks, and Related Rights-National and International Protection* (Harvard University Press, Vol. 1, 1975) 536, claiming that to meet public interests, even if a patent worked locally remains "unreasonably high prices", or if, having licensed the product for local manufacture, the prices of the patented products are too high licensing can be granted.

¹⁶ 'Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement (UNCTAD-ICSTD Capacity Building Project on IPRs and Sustainable Development, 2005) para. 2.135, stating that compulsory licences are generally a matter of national law in confirmation of the Preamble of Article 31 of TRIPS, which in part reads: 'Where the law of a Member allows for other use...'.
¹⁷ Joseph Yosick, 'Compulsory Patent Licensing for Efficient Use of Inventions' (2001) 2001 *University of Illinois Law Review* 5, 1277.

¹⁸ Michael Halewood, 'Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law' (1997) 35 *Osgoode Hall Law Journal* 2, 249. See Section 27 of the English Patents and Designs Act 1919 (9 & 10 Geo 5 c. 80) and Section 27(2)(a) as then revised read:

If [at any time after the expiration of four years from the date of the patent] the patented invention [being one capable of being worked in the United Kingdom], is not being worked within the United Kingdom on a commercial scale, and no satisfactory reason can be given for such non-working.

¹⁹ WIPO: Refusals to Licence IP Rights – A Comparative Note on Possible Approaches (WIPO, August 2013) 9, Box 2 explains that:

The obligation to work the invention has two different meanings: generally, it means that the patent owner has the duty of making the patented product or the product made with the patented process available to potential consumers; specifically, it means that the patent owner is under the duty of supplying the national market with the patented product or the product made with the patented process that has been manufactured in the territory of the granting country. The second meaning is known as "the local working requirement." It follows an industrial policy rationale, according to which patents are granted to promote the

of Patents (Controller) to grant a compulsory licence²⁰ at any time after the expiration of three years from the date of the granting of a patent, upon an application by any person interested, if, amongst other things, he is satisfied that the patented invention is not worked in the territory of India.²¹

The Controller can also grant a compulsory licence if he is satisfied that the reasonable requirements of the public with respect to the patented invention have not been met.²² There is a further independent condition, on which the Controller can grant a compulsory licence, that is, where the patented invention is not available to the public at a reasonably affordable price.²³ Under Section 84(7)(e), one of the criteria for deciding the latter is ‘if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article’.

This use was provided for in the Paris Convention on Industrial Property 1883 (Paris Convention).²⁴ However, this possibility is subject to conditions, as set out in Article 5(A)(4), which stipulates that:

A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory licence shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

establishment of domestic industries by means of imports of foreign technology, and local invention and innovation. According to this rationale, patents are not simply granted for promoting invention and innovation. Or, in other words, patents are granted to promote national, rather than foreign invention and innovation.

Georg Bodenhausen, ‘Guide to the Application of the Paris Convention for the Protection of Industrial Property, as Revised at Stockholm in 1967’ (WIPO Publication No. 611(E) BIRPI, 1969, WIPO Reprinted, 1991) 71, stating that importation or sale of the patented product, or of the article manufactured by a patented process, will not normally be regarded as “working” the patent. Halewood (n 18) 246.

²⁰ Sections 84(4) and 88: Powers of Controller in granting compulsory licences. [Act 39 of 1970 amended].

²¹ Section 84(c).

²² Section 84(a).

²³ Section 84(b).

²⁴ Article 5(A)(2) of the Paris Convention for the Protection of Industrial Property of 1883, 21 UST 1583, 828 UNTS 305 (as revised). Article 5(A)(2) states that:

Each country of the Union shall have the right to take legislative measures providing for the granting of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

For a detailed review of the relationship between the Paris Convention and the TRIPS Agreement see Ituku Elangi Botoy, ‘From the Paris Convention to the TRIPS Agreement’ (2004) 7 *The Journal of World Intellectual Property* 1, 115-130.

Remarkably, Article 5(A)(4) of the Paris Convention, which in part has a similar text to Section 84, is incorporated into the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under Article 2.²⁵ Added to this, Section 5 of the TRIPS Agreement, *inter alia*, lays out a framework of substantive and procedural provisions that must be respected when a WTO Member intends to grant a compulsory licence. Although TRIPS does not directly refer to failure to work as the basis for granting a compulsory licence and the grounds on which a compulsory licence may be granted are not specified in the Agreement, when read alongside Article 5(A) of the Paris Convention and Article 2 of TRIPS, the allowance of such a compulsory licence is implied.

Related to this is the fact that since the inception of the TRIPS Agreement some WTO Members have used or threatened to grant compulsory licences to obtain affordable medicines for the protection of public health.²⁶ These include, but are not limited to, the United States (US) for Bayer's antibiotic Ciprofloxacin,²⁷ Brazil for Abbot's Kaletra; Merck's Efavirenz; and Roche's Nelfinavir,²⁸ and Thailand for Merck's HIV/AIDS drug Efavirenz.²⁹ The understanding is that when governments issue or threaten to grant compulsory licences, the result is often a sharp decrease in prices,³⁰ a consensus reached by WTO Members during the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) in recognition of concerns about the effects of patents on the prices of essential medicines.³¹

²⁵ "The TRIPS Agreement" (n 6).

²⁶ Love (n 8) 12-18, providing examples of countries that have used or threatened to use compulsory licences.

²⁷ Divya Murthy, 'The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health' (2002) 17 *American University of International Law Review* 6, 1314-1315.

²⁸ Jennifer Bjornberg, 'Note', 'Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?' (2006) 27 *Northwestern Journal of International Law & Business* 1, 211.

²⁹ Thailand Issues Compulsory Licence for Patented AIDS Drug (2006) 10 *Bridges: International Centre for Trade and Sustainable Development* 42. Cynthia Ho, 'Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS' (2009) 34 *North Carolina Journal of International Law and Commercial Regulation* 2, 378.

³⁰ Sara Ford, 'Compulsory Licensing Provisions under the TRIPS Agreement: Balancing Pills and Patents' (1999) 15 *American University International Law Review* 4, 946.

³¹ "Doha Declaration" (n 6) para. 3.

Health is a fundamental human right recognised in numerous international instruments.³² Importantly, the right to health includes access to essential medicines.³³ Countries are individually,³⁴ and through international assistance and cooperation obliged to fulfil the right to health obligations.³⁵ Therefore, in fulfilment of the right to health obligations, the international community including the WTO expects that essential medicines shall be available at all times in adequate amounts and at a price that both individuals and the community can afford.³⁶

As emphasised by Paragraph 5(b) of the Doha Declaration, ‘Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are

³² for example, Article 25(1) the Universal Declaration on Human Rights [G.A. Res. 217A, at 25, U.N. GAOR, 3d Sess., 67th plen. mtg., U.N. Doc. A/810, 1948] states that: “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services”. Also, Article 12(1) of the International Covenant on Economic, Social and Cultural Rights [G.A. Res. 2200A (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316, Dec. 16, 1966] state parties recognise the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.

³³ Note that the implementation of the ICESCR is monitored by the Committee on Economic, Social and Cultural Rights and the Covenant is supplemented, at regular intervals, by authoritative comments. In its General Comment 14, the Committee interprets the right to health, as defined in Article 12(1) of the Covenant, as an inclusive right of appropriate treatment of prevalent diseases, preferably at community level; and the provision of essential drugs. See the General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant). (Committee on Economic, Social and Cultural Rights. Twenty Second Session, E/C.12/2000/4, Aug. 11, 2000) para. 17.

³⁴ *ibid.* paras. 34-37, providing specific legal obligation on states to promote the right to health. See Duncan Matthews, ‘When Framing Meets Law: Using Human Rights as a Practical Instrument to Facilitate Access to Medicines in Developing Countries’ (2011) 3 *The WIPO Journal* 1, 126, citing *Vincent v. Union of India*, AIR [1987] SC 990 and pointing out that the Supreme Court of India had concluded that the right to health, including access to medical treatment, is a fundamental right. See also Hans Hogerzeil, Melanie Samson and Jaume Vidal Casanova, *Ruling for Access Leading Court Cases in Developing Countries on Access to Essential Medicines as Part of the Fulfilment of the Right to Health* (Geneva, World Health Organization Department of Essential Drugs and Medicines Policy, November 2004) 31-32, citing the *Treatment Action Campaign, Dr Haron Sallojee and Children’s Rights Centre vs. RSA Ministry of Health High Court of South Africa, Transvaal Provincial Div.*, Dec. 12, 2001 and *Decision of the Constitutional Court [Case CCT 8/02, Jul. 5, 2002]* in confirmation of access to medicines as a human right to health component.

³⁵ “General Comment No. 14” (33) para. 39, commenting that:

To comply with their international obligations in relation to article 12, States parties have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law.

³⁶ It is important to note that under Paragraph 1 of the Doha Declaration the WTO recognised the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, and stressed under Paragraph 2 that the TRIPS Agreement to be part of the wider national and international action to address these problems. Moreover, at Paragraph 3, the WTO Members recognised the concerns about IPRs’ effects on prices, and further agreed under Paragraph 4 that TRIPS Agreement does not and should not prevent Members from taking measures to protect public health, and, in particular, to promote access to medicines for all. See also *Access to Medication in the Context of Pandemics such as HIV/AIDS* (Commission on Human Rights Resolution 2001/33, UN Doc. E/CN.4/ Res/2001/33, Apr. 20, 2001). See also Millennium Development Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals (UN MDG Gap Task Force Report, 2008) 35.

granted'.³⁷ Furthermore, while reiterating their commitment to the TRIPS Agreement, the WTO Members agreed that it does not and should not prevent members from taking measures to protect public health.³⁸ This means that where the law of a Member allows for any "Other Use Without Authorization of the Right Holder" as captioned in the title of Article 31 of TRIPS, the Agreement does not prevent such a Member from using those grounds.³⁹ To the extent that, a WTO Member satisfies the substantive conditions and also follows the procedural requirements under Article 31 of TRIPS, such a Member can grant compulsory licences on any grounds including, failure to work.

Under Article 31(b) of TRIPS, Members can circumvent the detailed procedural requirements in the case of a national emergency or other circumstance of extreme urgency. Unfortunately, Article 31 also imposes a condition that has rendered the provision essentially useless to many developing countries.⁴⁰ Article 31(f) of TRIPS confines use to circumstances 'predominantly for the supply of the domestic market of the Member authorising such use'.⁴¹ Therefore, under this provision, a Member may grant a compulsory licence only to a domestic manufacturer.⁴² This created a difficult situation, since the WTO Members that need affordable medicines the most were those without adequate pharmaceutical manufacturing capacities.⁴³

Accordingly, several developing countries were not able to use Article 31 of TRIPS to obtain affordable medicines.⁴⁴ Paragraph 6 of the Doha Declaration recognised that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.⁴⁵ The Members instructed the Council for TRIPS to find an expeditious solution to this problem.⁴⁶ Two years later, on 30 August 2003, the WTO General Council announced a

³⁷ "Doha Declaration" (n 6) paras. 3 & 5(b).

³⁸ *ibid.* para. 4.

³⁹ The African Group claimed that: 'Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health'. See WTO Docs. (IP/C/W/312, WT/GC/W/450, Oct. 4, 2001) para. 1. This is one of the main points of contention during the preparatory work for the Doha Ministerial Council Meeting.

⁴⁰ Erin Anderson, 'Unnecessary Deaths and Unnecessary Costs: Getting Patented Drugs to Patients Most in Need' (2009) 29 *Boston College Third World Law Journal* 1, 96.

⁴¹ Article 31(f) of TRIPS.

⁴² *id.*

⁴³ Anderson (n 40) 96.

⁴⁴ *id.*

⁴⁵ "Doha Declaration" (n 6).

⁴⁶ *id.*

solution.⁴⁷ The solution, in the form of an “interim waiver” sets out detailed formal conditions and procedural requirements on which both developed countries and developing countries seeking to use the system must respect.⁴⁸

On 6 December 2005, the TRIPS Agreement was amended taking into consideration the 30 August 2003 “waiver” Decision.⁴⁹ Nevertheless, the procedural requirements for the granting of compulsory licences under Article 31 of TRIPS are too complex and vague, while the formal substantive conditions developed by the Doha Solution that ought to be satisfied before granting compulsory licences are too burdensome, which further compounds the restrictions imposed by TRIPS.⁵⁰

Faced with the high cost and shortages of “sorafenib tosylate” (marketed as Nexavar),⁵¹ in 2012 India followed the example of several WTO Members that have used or threatened to use compulsory licences to promote affordable medicines by invoking Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, and granted a compulsory licence to Natco Pharma Limited (an Indian generic manufacturer).⁵² While it appears on the face of it that the Controller correctly interpreted Section 84, some question the consistency of the decision with TRIPS.⁵³ Central to

⁴⁷ Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health — General Council Decision of 30 August 2003 (WT/L/540 and WT/L/540/Corr.1). See Decision Removes Final Patent Obstacle to Cheap Drug Imports (WTO News: 2003 Press Releases - Press/350/Rev.1, Aug. 30, 2003). Available at: https://www.wto.org/english/news_e/pres03_e/pr350_e.htm [Accessed Jun. 14, 2017].

⁴⁸ Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health - General Council Chairman’s Statement (WTO Doc. JOB(03)/177 (Reproduced in the WTO Doc. WT/GC/M/82, Nov. 13, 2003). See Rojina Thapa, ‘Waiver Solution in Public Health and Pharmaceutical Domain under TRIPS’ (2011) 16 *Journal of Intellectual Property Rights* 6, 473.

⁴⁹ Protocol Amending the TRIPS Agreement (World Trade Organisation, WT/L/641, Dec. 6, 2005).

⁵⁰ Brin Anderson, ‘Better Access to Medicines: Why Countries are Getting —Tripped Up and Not Ratifying Article 31-Bis’ (2010) 1 *Case Western Reserve Journal of Law, Technology & the Internet* 2, 173-174.

⁵¹ “Sorafenib Tosyalte” is a pharmaceutical therapeutic compound patented by Bayer Corporation marketed as Nexavar and is used in the treatment of advanced stages of kidney cancer (Renal Cell Carcinoma) and liver cancer (Hepatocellular carcinoma). It stops the growth of new blood vessels and impacting other cellular growth mechanisms, the drug can extend the life of a patient, the duration being between 6 months and 5 years. See The United States Food and Drugs Agency Approval for Sorafenib Tosylate. Available at: <http://www.cancer.gov/cancertopics/druginfo/fda-sorafenib-tosylate> [Accessed Mar. 28, 2018].

⁵² The Controller General of Patents and the Order: Mumbai-India (CLA No. 1 of 2011, Decision on Mar. 12, 2012) <http://www.gnaipr.com/CaseLaws/Controller%20Order%20-%2012032012.pdf> [Accessed Mar. 19, 2018].

⁵³ Enrico Bonadio, ‘Compulsory Licensing of Patents: The Bayer-Natco Case’ (2012) 34 *European Intellectual Property Review* 10, 720, stating the ruling might be a violation of Article 27(1) of TRIPS, which precludes India, as a Party to the Agreement, from discriminating between patented products that are imported and those that are locally produced.

this disagreement is the interpretation of certain substantive provisions within the TRIPS Agreement, arguably Articles 27 and 28.⁵⁴

Article 27(1) of TRIPS in part provides that patents shall be available for any inventions and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether the product is imported or locally produced.⁵⁵ Moreover, Article 28 of TRIPS lays out the rights conferred on patent holders, namely, the exclusive right to make, use, offer for sale, sell, or import the patented goods or processes.⁵⁶ The patent holder also has the exclusive right to assign, transfer or licence the patent.⁵⁷ At face value, reading the contextual part of Article 27(1) of TRIPS alone would suggest that so long as the patented product or process is available in the local market, the use of the patent cannot be differentiated on the basis of its sourcing – whether it was manufactured within the country or imported.⁵⁸

Put differently, the argument that follows is that the importation of patents can satisfy local working either partially or fully,⁵⁹ and for the sole reason that the domestic market is supplied, wholly or in part, by imports and not exclusively by local manufacturing.⁶⁰ This viewpoint supports the contradictory claim that Article 27(1) of TRIPS subsequently redefined “working” to include the possibility that this can be adequately satisfied by importation,⁶¹ and local working as being made available in the country, including through imports, rather than through direct local manufacture in the territory of protection.⁶² As Halewood puts it, “working”

⁵⁴ Review of TRIPS, International Trade Daily News (BNA) (International Trade Reporter, Jun 9, 1999) D7, highlighting the controversy surrounding the interpretation of compulsory licensing after the inception of TRIPS.

⁵⁵ Part II, Section 5 of TRIPS - Standards concerning the availability, scope and use of Intellectual Property. Dispute Settlement: World Trade Organisation (The UNCTD UNCTAD/EDM/Misc.232/Add.18, 2003) 19, para. 2.6.3, interpreting Article 27(1). Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2nd edn. 2005) 168, para. 27.5.

⁵⁶ *ibid.* Article 28(1) of UNCTAD: Dispute Settlement, para. 2.6.4, explaining that by way of contrast, Article 28 does not expressly confer a right to “export” patented products, though since a product may need to be “made” or “sold” to be exported, it might be difficult to undertake export of a patented product without contravening one of the enumerated rights.

⁵⁷ Article 28(2).

⁵⁸ Paul Champ and Amir Attaran, ‘Patent Right and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S. - Brazil Patent Dispute’ (2002) 27 *Yale Journal of International Law* 2, 367.

⁵⁹ Antony Taubman, *A Practical Guide to Working with TRIPS* (Oxford University Press, 2011) 104.

⁶⁰ *id.*

⁶¹ Kim Jordan, ‘International Application of a Domestic Intellectual Property Protection Strategy: Extending a Predatory Litigation Strategy to the European Community (1995) 11 *Santa Clara Computer & High Technology Law Journal* 2, 400, stating that the lawful import of a product from another member state satisfies the working requirement.

⁶² Thiamanga Kongolo, *Unsettled International Intellectual Property Issues* (Kluwer Law International, 2008) 6, noting that under TRIPS, “working” has an extensive meaning to include the import of patented products. See also Martin Adelman and Sonia Badia, ‘Prospects & Limits of the Patent Protection in the TRIPS Agreement: The Case of India’ (1996) 29 *Vanderbilt Journal of Transnational Law* 3, 507 at 517.

therefore, has been redefined and diminished to the extent that it no longer serves to guarantee the transfer of anything but finished commodities'.⁶³

Under this understanding, a WTO Member must establish a patent system that does not separate the place of invention and whether products are imported or locally produced.⁶⁴ Therefore, any national measures that seek to eventually discriminate against patents in regard to the place of invention, the field of technology and whether the products are imported or locally produced will be inconsistent with TRIPS.⁶⁵ Moreover, the inclusion of two principal principles, national treatment and the most favoured nation clause, particularly Article 3(1) of TRIPS,⁶⁶ in hindsight, may operate to limit or eliminate the varying patent policy approaches whereby national laws can discriminate against foreign nationals and products involved in trade or differentiate between the treatment conferred to products that are locally produced and those that are imported.⁶⁷

In that context, some countries interpret the general non-discrimination principle under Article 27(1) of TRIPS as an "absolute" provision, which is not subject to the compulsory licensing exception in Article 31.⁶⁸ Also, previous WTO Panel jurisprudence seems to have supported the assertion that Article 27(1) is absolute.⁶⁹ Furthermore, Article 5(A)(1) of the Paris Convention clearly specifies that importation by the patentee alone cannot be a sufficient ground to forfeit a patent.⁷⁰ This provision has the same substantive content as Article 27(1) of

⁶³ Halewood (n 18) 247.

⁶⁴ *id.*

⁶⁵ Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (Kluwer Law International, 3rd edn. 2010) 174.

⁶⁶ Article 3(1) of TRIPS provides that: 'Each Member shall accord to the nationals of other Members treatment no less favourable than it accords to its own nationals with regard to the protection of patents'. See Thomas Cottier, Shaheez Lalani and Michelangelo Temmerman, 'Use It or Lose It: Assessing the Compatibility of the Paris Convention and TRIPS Agreement with Respect to Local Working Requirements (2014) 17 *Journal of International Economic Law* 2, 459. Jerome Reichman, 'Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement' (1995) 29 *The International Lawyer* 2, 347-348.

⁶⁷ Gail Evans, 'TRIPS and the Sufficiency of the Free Trade Principles' (1999) 2 *The Journal of World Intellectual Property* 5, 714, mentioning that both national treatment and most favoured nation principles are instrumental in removing private law, such as IP, from its traditional territorial foundation and aligning it with the free trade principles of international trade law to ensure that domestic laws do not discriminate against either member states or their nationals.

⁶⁸ Panel Report in Canada-Patent Protection of Pharmaceutical Products. Complaint by the European Communities (WT/DS1 14/R, Mar. 20, 2000) paras 7.88-7.93 (Argument by Switzerland).

⁶⁹ *ibid.* para. 7.91. The Panel says that it is an "acknowledged fact" that Article 27 is not subject to the Article 30 and 31 exceptions because it is simply 'understood . . . without the need for any textual provision so providing'.

⁷⁰ Article 5A(1) states that 'Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent'. See Carvalho (n 55) 132, para. 2.13.

TRIPS, which recognises that patented products can be imported.⁷¹ Some interpret this to mean that Article 27(1) of TRIPS forbids the granting of a compulsory licence on the grounds of failure to work, and that on this basis Section 84 is inconsistent with TRIPS.⁷² Thus, the inconsistent interpretation of Article 27(1) of TRIPS is responsible for creating unnecessary tension between WTO Members, and has greatly restricted access to affordable medicines, mainly in developing countries.⁷³

Importantly, one of the stated goals of the TRIPS Agreement was ‘to reduce tensions arising from intellectual property protection’, the possible conflict being between such protection and essential public health objectives – in particular, access to affordable medicines.⁷⁴ It is however, worth emphasising that the controversy concerning the legitimacy of Members’ discretion with regard to the granting of compulsory licences under WTO law only became an issue after the conclusion of the TRIPS Agreement.⁷⁵ Before that point, the notion of Members’ right to grant compulsory licences on the condition that the patentees had failed to work their patented inventions locally was rarely questioned or rejected.⁷⁶

Although some scholars have, in the past, argued for the need for the TRIPS Agreement to be reviewed in order to clarify the misunderstanding regarding the right of WTO Members to grant compulsory licences,⁷⁷ a unique aspect of the WTO is that there already exists a Dispute

⁷¹ Halewood (n 18) 257.

⁷² Bonadio (n 53) 720.

⁷³ Michael Blakeney, *Trade Related Aspects of Intellectual Property: A Concise Guide to the TRIPS Agreement* (Sweet & Maxwell, 1996) 3-6, noting disagreements over pharmaceutical patents between the US and Korea, India, Thailand and Brazil from 1987 through 1992. Theresa Beeby Lewis, ‘Comment, Patent Protection for the Pharmaceutical Industry: A Survey of Patent Laws of Various Countries’ (1996) 30 *Journal of International Law* 4, 859, highlighting recent pharmaceutical patent disputes between the US and Singapore, Costa Rica, China, Egypt, Korea and Thailand.

⁷⁴ “Preamble of the TRIPS Agreement”, ‘Emphasising the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures’. Carlos Correa and Duncan Matthews, ‘The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health’ (Discussion Paper, UNDP, Bureau of Development Policy, December 2011) 7.

⁷⁵ Remarkably, the advent of the TRIPS Agreement has not led many countries to amend their local working provisions. In Europe, for example, as recently as 1997 only the Netherlands and Switzerland had changed their laws. See Section 48B(1)(a) of the Patents Act 1977 (C. 37. United Kingdom). Bernd Hansen and Fritjoff Hirsch, *Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law* (Wiley-Vch: Weinheim, 1997) 406-407.

⁷⁶ Brian Mercurio and Mitali Tyagi, ‘Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements’ (2010) 12 *Minnesota Journal of International Law* 2, 283.

⁷⁷ Richard Marschall, Note, ‘Patents, Antitrust, and the WTO/GATT: Using TRIPS as a Vehicle for Antitrust Harmonization’ (1997) 28 *Journal of Law and Policy International Business* 4, 1190, calling for amendments to TRIPS that would limit the broad escape clause permitting developing nations to use compulsory licences.

Settlement Understanding (DSU) system.⁷⁸ This system mandates the Dispute Settlement Body (DSB) to resolve conflicting legal matters arising from WTO Agreements, including TRIPS.⁷⁹ Since the inception of the WTO, increasing numbers of trade-related disputes have been brought before the DSU system.⁸⁰ However, the DSB has adopted 2 vital reports regarding the implications of the TRIPS Agreement on pharmaceutical patents.⁸¹ Nonetheless, the issue of whether WTO Members' have the right to grant compulsory licences remains unsettled in the DSB system.

The dispute between the US and Brazil⁸² regarding the consistency of Article 68 of Brazil's Law with TRIPS, was settled by the parties.⁸³ This has deprived us of the true interpretation of the consistency of the granting of a compulsory licence provided that the patented invention has not been worked locally.⁸⁴ In view of this, if Ghana - which relies heavily on the importation of essential medicines - were to grant a compulsory licence based on the Section 84 model with a view to mitigating the high costs and shortages resulting from the failure of patentees to work their patented medicines locally, as India did in *Bayer v Natco*, it is inevitable that questions regarding the consistency of such a national action with TRIPS will continue to arise, given that this is still a controversial and unsettled legal matter under the WTO DSU system, as far as the TRIPS Agreement is concerned.

⁷⁸ Dispute Settlement Rules: Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organisation, Annex 2, the Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 354 (1999), 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994). For additional analysis of the WTO Dispute Resolution Rules. Ernst-Ulrich Petersmann, *The GATT/WTO Dispute Settlement System: International Law, International Organizations and Dispute Settlement* (Volume 23, Kluwer International Law-Martinus Nijhoff, 1997) 117, discussing the new Dispute Settlement System of the 1994 WTO Agreement.

⁷⁹ "WTO Agreement" (n 6), proclaiming in Article III, Section 3 that one of the functions of the WTO is to administer the dispute settlement body.

⁸⁰ Since 1995, over 535 disputes have been brought to the WTO, initiated by 50 Members, in relation to 20 WTO Agreements. As of Dec. 31, 2017, a panel had been established in respect of 308 disputes. This led to panel reports in 235 of these disputes (not all cases in which a panel is established result in a panel report as the parties might settle their dispute even after a panel has been established). See WTO Dispute Settlement Activity — some figures. <https://www.wto.org/english/tratop_e/dispu_e/dispustats_e.htm> [Accessed Mar. 29, 2019].

⁸¹ "Canada-Patent Protection of Pharmaceutical Products" (n 68) and India - Patent Protection for Pharmaceutical and Agricultural Chemical Products. Complaint by the US (WT/DS79/6, Apr. 16, 1999).

⁸² Request for Consultations by the United States, Brazil – Measures Affecting Patent Protection, WT/DS199/1, G/L/385, IP/D/23, Jun. 8, 2000.

⁸³ Notification of Mutually Agreed Solution, Brazil – Measures Affecting Patent Protection, WT/DS199/4, G/L/454, IP/D/23/Add.1, Jul. 19, 2001).

⁸⁴ Bradley Condon and Tapen Sinha, *Global Lessons from the AIDS Pandemic: Economic, Financial, Legal and Political Implications* (Springer-Verlag, 2008) 40.

What seems to compound this controversy further is the idea that the granting of compulsory licences by developing countries will threaten the attainment of socio-economic objectives, due to the loss of inward foreign direct investment (FDI) opportunities.⁸⁵ Moreover, it has been asserted that any aggressive use of the compulsory licensing instrument may result in retaliatory action, high litigation costs and their potential frustration owing to the impact of Free Trade Agreements (FTAs), which have discouraged several developing countries from the use of compulsory licences to promote affordable medicines.⁸⁶ This subject is particularly pertinent as Ghana has signed several FTAs that contain potentially restrictive provisions.⁸⁷

1.3. The Context: Ghana's Essential Medicines Need

A lack of essential medicines appears to be a global issue, which means that Ghana and other developing countries are not immune from this problem.⁸⁸ One major barrier to access to medicines in Ghana is affordability.⁸⁹ Consequently, a large portion of the population is denied access to medicines, as treatments are simply unaffordable for the average Ghanaian.⁹⁰ Generally, the average per capita expenditure for medicines in Ghana can be estimated at

⁸⁵ Donald Harris, 'TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing' (2011) 18 *Journal of Intellectual Property Law* 2, 391-392.

⁸⁶ Ho (n 29) 448-449. Alexandra Watson, 'International IP Rights: Do TRIPS' Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries?' (2009) 32 *Boston College International and Comparative Law Review* 1, 151-153, stating that Brazil, South Africa, and Thailand have all at some point been placed on the 301 Watch-List.

⁸⁷ AGOA is contained in the US implementation legislation: Title 1 of The Trade and Development Act of 2000 P.L. 106-200. 114 Stat. 251 (19 USC 3701). The partnership agreement between the members of the ACP states of the one part, and the European Community and its Member States, of the other part: Cotonou Agreement. O. J. L. 317/3. 15.12.2000. <http://ec.europa.eu/europeaid/where/acp/overview/documents/devco-cotonou-consol-europe-aid-2012_en.pdf> [Accessed Feb. 12, 2017]. Ghana-US Trade and Investment Framework Agreement. <https://ustr.gov/sites/default/files/uploads/agreements/tifa/asset_upload_file126_7726.pdf> [Accessed Mar. 8, 2017]. Note that para. 4 recognises the importance of fostering an open and predictable environment for international trade and investment. This is tied up with para. 11, which provides recognition of the importance of providing adequate and effective protection and enforcement of IP rights. Ghana-EU National Indicative Programme. <http://eeas.europa.eu/development-cooperation/docs/national-indicative-programme_2014-2020/2014-2020_national-indicative-programme_ghana_en.pdf> [Accessed Mar. 28, 2017]. Ghana Bilateral Trade Agreements with Switzerland, the Netherlands, Germany, Denmark and the United Kingdom. <<http://investmentpolicyhub.unctad.org/IIA/CountryBits/79>> [Accessed Feb. 26, 2017].

⁸⁸ Andy Gray and Henri Manasse, 'Shortages of Medicines: A Complex Global Challenge' (2012) 90 *Bulletin of the World Health Organisation* 3, 158. See 138th session of the World Health Assembly Executive Board. (Provisional agenda item 10.5. EB138/41, Dec. 18, 2015) para. 1. WHA67.22 Resolution on Access to Essential Medicines (Agenda item 15.4. Ninth plenary meeting, A67/VR/9. May 24, 2014) 2.

⁸⁹ Angella Ofori-Atta and Sammy Ohene (ed), *Changing Trends in Mental Health Care and Research in Ghana* (Sub-Saharan Publishers and University of Ghana, 2014) 30. Kwame Ohene Buabeng, Lloyd Matowe and Jacob Plange-Rhule, 'Unaffordable Drug Prices: The Major Cause of Non-compliance with Hypertension Medication in Ghana' (2004) 4 *Journal of Pharmaceutical Science* 3, 352, mentioning unaffordability of drug prices.

⁹⁰ id.

roughly US\$ 12 per month, suggesting relatively high expenditure on medicines.⁹¹ The average price for branded medicines in Ghana is several times higher than the international reference price, as the country is procuring medicines at 150 per cent of the international drug reference price.⁹² Overall, the percentage difference in prices observed between brands and generics ranges from 21 per cent to 1360 per cent for 17 essential medicines.

Thus, patients have to pay up to 1360 per cent more for a branded medicine than they would have to pay for a generic medicine.⁹³ Indeed, the prices of branded medicines in nearly all cases are much higher than the prices of generic ones.⁹⁴ The country also experiences shortages of essential medicines both in the public and private sectors.⁹⁵ This includes generic ones.⁹⁶ This is compounded by the fact that profit margins are kept relatively high for importers.⁹⁷ There are no multinational pharmaceutical companies currently manufacturing medicines locally.⁹⁸ However, major multinational firms have offices in Ghana where they market and distribute their leading brands.⁹⁹ Consequently, Ghana has relied heavily on the importation of essential medicines, which entails high costs and shortages.¹⁰⁰

1.4. Legal Difficulties of Ghana using Compulsory Licensing

Ghana faces legal difficulties in using the compulsory licensing instrument to promote affordable medicines. For example, in 2005, Ghana granted a compulsory licence for public

⁹¹ Andreas Seiter and Martha Gyansa-Lutterodt, 'Policy Note: The Pharmaceutical Sector in Ghana' (November 2009) 22-23. Available at: <<http://apps.who.int/medicinedocs/documents/s16765e/s16765e.pdf>> [Accessed Mar. 17, 2017].

⁹² Saleh (n 3) 104.

⁹³ *ibid.* 38.

⁹⁴ Medicine Prices in Ghana: A Comparative Study of Public, Private and Mission Sector Medicine Prices (The Ministry of Health through the Ghana National Drugs Programme and in collaboration with the WHO and Health Action International, 2004) 4. See also Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development. Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover (Eleventh session, agenda item 3, Human Rights Council Resolution: A/HRC/11/12, Mar. 31, 2009) 8, para. 19, observing that in regard to medicines, a product patent enables a patentee to set high prices.

⁹⁵ Saleh (n 3) 102, finding that several facilities continued to report stock outs.

⁹⁶ *id.*

⁹⁷ *ibid.* 109.

⁹⁸ Ghana Pharmaceutical Country Profile (Ghana Ministry of Health and the WHO, February 2012) 12. <http://www.who.int/medicines/areas/coordination/Ghana_PSCPNarrativeQuestionnaire_03022012.pdf> [Accessed Mar. 12, 2017].

⁹⁹ Ghana Pharmaceutical Country Profile (Ghana Ministry of Health and the WHO, February 2009) 10. <<http://apps.who.int/medicinedocs/documents/s16765e/s16765e.pdf>> [Accessed Apr. 13, 2017].

¹⁰⁰ *id.*

non-commercial use,¹⁰¹ however, this initiative was later abandoned.¹⁰² As already indicated, Ghana's failure to utilise the compulsory licensing instrument to obtain affordable medicines is due to the controversy surrounding the WTO Members' right to grant compulsory licensing for pharmaceutical products under the TRIPS Agreement.¹⁰³ Nevertheless, until TRIPS, access to affordable medicines had never been a major issue in Ghana.¹⁰⁴ However, the adoption of TRIPS changed this dramatically.¹⁰⁵

Notably, to meet its obligations under TRIPS, the Ghanaian government, despite the availability of a transitional period under TRIPS,¹⁰⁶ modified the Patent Law of 1992 in 2003.¹⁰⁷ The changes introduced in the 2003 Patent Act removed key flexibilities that are pertinent to the promotion of local manufacture of patented medicines.¹⁰⁸ Specifically, the Ghanaian Patent Law of 1992 permitted the granting of compulsory licensing in cases of no or insufficient local working of a patented invention.¹⁰⁹ Local pharmaceutical companies could

¹⁰¹ "Notification of Emergency and Issuance of Government Use Licence by Ghana" (n 8). See Savoie (n 8) 237. See also Feldman (n 8) 14.

¹⁰² Cloatre (n 9) 53.

¹⁰³ Epstein and Kieff (n 11) 92. See Fauver (n 11) 676.

¹⁰⁴ Note that Ghana in 1962 set up a state pharmaceutical manufacturing corporation, the Ghana Industrial Holding Pharmaceuticals Corporation (GIHOC) as part of Ghana's industrialisation drive, with the specific aim of manufacturing essential medicines locally (Ghanaian Enterprises Decree, 1968 (NLCD 207). GIHOC was run by Ghanaian management and technical staff and the company was supported by the United Nations Industrial Development Organisation (UNIDO), which offered technical expertise in production, quality control, plant maintenance and training of technical staff. John Sutton and Bennet Kpentey, *An Enterprise Map of Ghana* (London, published by the International Growth Centre, 2012) 158. Cohen, *et al.* (n 2) 1, citing the only problems were weak or corrupt institutions, contributing to less than effective pharmaceutical purchasing and distribution systems.

¹⁰⁵ Correa and Matthews (n 74) 5. Gail Evans, 'Strategic Patent Licensing for Public Research Organisations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries' (2008) 34 *American Journal of Law & Medicine* 2, 179, recounting how India enjoyed the policy "space", which allowed its scientists to develop cost-effective manufacturing processes for molecules already invented and patented in other countries.

¹⁰⁶ Subject to the transitional arrangement under Article 65(2) of TRIPS India, being a developing country, was allowed 10 years from 1995 to make the transition to a full patent regime. Jerome Reichman, 'Securing Compliance with the TRIPS Agreement after *US v India*' (1998) 1 *Journal of International Economic Law* 4, 594. Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2002) 295.

¹⁰⁷ Under Section 7 of the 1992 Patent Law, the Ghanaian government had the authority to temporarily exclude inventions or discoveries, such as pharmaceuticals from patentability "... in the interests of national security, economy, health or any other national concern". The 2003 Patent Act removed this exception. Arguably, the government of Ghana could have excluded specific pharmaceutical products from patentability as a temporary means to address urgent public health concerns. Temporary excludability is particularly useful when procedural requirements to compulsory licensing cannot be met. See Cohen, *et al.* (n 2). However, as Correa explains, a literal interpretation of Article 27.1 does not allow the exclusion of pharmaceuticals. He notes that under TRIPS Article 27.2 *ordre public* and Article 8.1 "...pharmaceuticals might conceivably be excluded from patentability, but neither appear sufficient to justify this exclusion except in limited circumstances", such as to prevent commercial exploitation. In any case, the option of using temporary excludability appears unviable at the present time. See Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre, October 2000) 12.

¹⁰⁸ Cohen, *et al.* (n 2) 4.

¹⁰⁹ PNDC Law 305A of Dec. 30, 1992. Section 45(1).

easily obtain pharmaceutical patents in this environment to manufacture affordable medicines for distribution. Ghana's ability to obtain essential medicines, whether such products were on or off patent, was not a major issue given that several leading developing countries, such as India under its Patent Act, 1970, were technically able to manufacture low-cost generic medicines for export to the country.¹¹⁰

Although Ghana has some essential medicines need, and under Section 13(1) of the Patents Act 2003 the minister can grant compulsory licences to protect public health, still, access to affordable medicines has not been obtained. For example, as highlighted earlier, in 2000, when Ghana tried to import affordable medicines from India, the country was threatened with a legal challenge by GSK, and this initiative was eventually abandoned.¹¹¹ Moreover, due to GSK's intervention in 2005, Ghana continued to face shortages of Duovir.¹¹² Therefore, the country attempted to utilise the compulsory licensing regime under TRIPS to obtain affordable medicines for public non-commercial use.¹¹³ While this national measure to obtain affordable medicines from India was consistent with the Doha Paragraph 6 Programme, it appears that political pressure compelled Ghana to abandon this compulsory licence.

1.5. The Aim of this Work and Research Questions

The aim of this work is to examine the consistency of Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, with TRIPS. The central question in this work is whether, given the textual correlation between Section 84 and Article 5(A) of the Paris Convention, the latter having been incorporated into TRIPS by Article 2, Section 84 is consistent with TRIPS, and if so whether it would provide a suitable model for Ghana. A follow up question is whether the failure of any Member of the WTO to challenge the Indian decision within the DSU system provides ample justification concerning the consistency of Section 84 with TRIPS. Related questions in the background to this work are whether, in practice, Ghana would be able to withstand any potential bilateral pressure, high litigation costs, and the extent to which the implementation of

¹¹⁰ Chapter II (amended) Invention not Patentable. Section 3 lists the subject matter that is deemed non-patentable to include: inventions that are "injurious to public health" as well as: 'any process for the medicinal... curative... or other treatment of human beings . . . to render them free of disease or to increase their economic value or that of their products.'

¹¹¹ Schoofs (n 6).

¹¹² Thomas (n 7) 258.

¹¹³ "Notification of Emergency and Issuance of Government Use Licence by Ghana" (n 8).

the Section 84 model would threaten the attainment of socio-economic objectives resulting from FDI-related economic loss given that Ghana has signed several FTAs that contain potentially conflicting provisions.¹¹⁴

¹¹⁴ See (n 87) on AGOA.

1.6. The Hypothesis of the Work

The work is based on the hypothesis that Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is consistent with TRIPS, and therefore it could provide a suitable model for Ghana.

1.7. Methodology

In proof of hypothesis, a qualitative research approach was used, as a broad range of legal analysis was required.¹¹⁵ The legal analysis constitutes the core of the study, and primarily academic literature was extensively reviewed. The analysis used interpretive methods to examine relevant sources of law. As the hypothesis cuts across different bodies of law (including TRIPS and the Indian Patent law), the spectrum of primary sources used was quite broad and included both primary and secondary sources (legal instruments including, but not limited to, laws and legislation, judicial decisions, legal literature, legislative reports and reports by international institutions).¹¹⁶ This study used an element of comparative legal analysis.¹¹⁷ This was based on national law (Indian Patent Act) and international law (TRIPS Agreement), drawing mainly on relevant provisions in these two bodies of law that have similar substantive structures.

This ensured that the subject was not explored from one legal perspective, but rather through a variety of legal lenses to provide a credible contextual interpretation.¹¹⁸ To this end, the principles of treaty interpretation under the Vienna Convention on the Law of Treaties (VCLT), which also guide the interpretation of WTO law, were engaged.¹¹⁹ The purpose was to gain a deeper understanding of the true interpretation, concerning the consistency of Section 84 with

¹¹⁵ Simeon Yates, *Doing Social Science Research*, (SAGE Publications, 2004) 139, observing that the use of qualitative research methods is often perceived as providing richer data than purely quantitative methods may allow.

¹¹⁶ David Silverman, *Interpreting Qualitative Data: Methods for Analysing Talk, Text and Interaction*, (SAGE Publications, 1993) 89, explaining the importance of documents as a further source of useful data.

¹¹⁷ Norman Denzin and Yvonne Lincoln, Introduction: The Discipline and Practice of Qualitative Research. In: *THE SAGE HANDBOOK OF QUALITATIVE RESEARCH*, Norman Denzin and Yvonne Lincoln (eds.), (SAGE Publications, 2005) 3, noting that comparative analysis method consists of a set of interpretive, material practices that make the phenomenon visible.

¹¹⁸ Pamela Baxter and Susan Jack, 'Qualitative Case Study Methodology: Study Design and Implementation for Novice Researchers' (2008) 13 *The Qualitative Report* 4, 545.

¹¹⁹ The Vienna Convention on the Law of Treaties, 1155 U.N.T.S. 331, 8 I.L.M. 679, entered into force Jan. 27, 1980.

TRIPS. Therefore, decisions of the WTO/DSU Panels and Appellate Bodies were drawn upon in order to examine whether the common view, which emphasises that the granting of a compulsory licence provided that the patented invention has not been worked locally under Section 84 is inconsistent with TRIPS, remains the true interpretation of the general position of the TRIPS Agreement, as opposed to a rather narrow reading of a small part of the Agreement, such as Article 27(1) of TRIPS, without due regard for the text or document as a whole.¹²⁰

As the core research question is whether, given the textual correlation between Section 84 and Article 5(A) of the Paris Convention, the latter having been incorporated into TRIPS by Article 2, Section 84 is consistent with TRIPS, and if so whether it would provide a suitable model for Ghana, this supports the use of the case study method in order to test the validity of the hypothesis.¹²¹ It is argued that the case study method is the most appropriate to study complex socio-legal situations where multiple variables exist.¹²² Accordingly, the decision by the Controller and the Intellectual Property Appellate Board (IPAB)¹²³ in the Bayer v Natco case was reviewed to further aid a deeper interpretative understanding of the contextual and operational relationship between Article 5(A) of the Paris Convention, the TRIPS Agreement and Section 84, concerning the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India.

The case review helped to strengthen, or specifically provide an interpretation that is supportive of the argument that the overriding implication of Section 84, and the Bayer v Natco decision, if followed, would enable Ghana, and other developing countries, to grant compulsory licences for any patent protecting a product solely because that product is not being worked locally. What sustains this argument further is the view that the failure of any Member of the WTO to challenge the Indian decision within the DSU system provides ample justification concerning the consistency of Section 84 with TRIPS. Moreover, while the comparative legal analysis

¹²⁰ Bonadio (n 53) 724, stating that was contrary to Article 27 of the Vienna Convention, which states that: ‘a party may not invoke the provisions of its internal law as justification for its failure to perform a treaty’.

¹²¹ Robert Yin, *Case Study Research: Design and Methods* (SAGE Publications, 1984) 23, mentioning that case study research method is important to investigate a contemporary phenomenon within its real-life context when the boundaries between phenomenon and context are not clearly evident, and in which multiple sources of evidence are used.

¹²² David de Vaus, *Research Design in Social Research* (ed), (SAGE, 2001) 231.

¹²³ ‘The Indian Intellectual Property Appeals Board’ (Order No. 45 of 2013) (M.P. Nos. 74 to 76 of 2012 & 108 of 2012 in OA/35/2012/PT/MUM, Sept. 14, 2012. <<http://www.ipabindia.in/Pdfs/Order-45-2013.pdf>> [Accessed Mar. 12, 2017].

constitutes the core of this study, it is accompanied by a complementary socio-legal approach. The purpose of the socio-legal constituents is that they complement the legal analysis with an understanding of the extent to which, and how, legal norms are implemented in line with domestic public policy.

As Taubman puts it, ‘the concept of “trade-related aspects” of IP did not mean ignoring the wider public policy questions of social welfare and economic development’.¹²⁴ The socio-legal components draw mainly on Section 83 principles, the TRIPS Agreement, its Preamble, context, object and purpose, *travaux préparatoires* and patent law history. Reference to the patent law history was necessary to evaluate the policy aspect of patent law and the critical role that compulsory licences may play in the promotion of the reasonable requirements of the public. In effect, there is considerable opportunity for TRIPS implementation to include the attainment of public policy goals through sound policy-making, and not simply to involve the passing of legislation to achieve passive, formal compliance with the letter of the law of TRIPS.¹²⁵ This supplemented the legal analysis in a way that better reflects the position, or consistency of Section 84 with TRIPS.

This approach provided confirmation that the TRIPS Agreement does not completely forbid members from granting compulsory licences on any grounds, or specifically, if the right is abused with reference to failure to work patented products or if the process is not applied within the territory of protection, as is clearly provided under Article 5(A) of the Paris Convention, and also inclusively referenced in TRIPS by virtue of Article 2. This understanding helped to address the study’s core research question, and enabled an understanding that is more supportive of the interpretation that nothing, in the light of TRIPS, would, in fact, preclude the possibility of Ghana, which relies heavily on the importation of essential medicines, from implementing a model similar to Section 84, as a practical means to mitigate the high costs and shortages resulting from the failure of patentees to work patented medicines locally.

¹²⁴ Antony Taubman, Thematic Review: Negotiating Trade-Related Aspects of Intellectual Property Rights. In: THE MAKING OF THE TRIPS AGREEMENT PERSONAL INSIGHTS FROM THE URUGUAY ROUND NEGOTIATIONS, Jayashree Watal and Antony Taubman (eds.), (WTO Secretariat, 2015) 23.

¹²⁵ *ibid.* 24.

1.8. Research Scope

1.8.1. Why Ghana?

The thesis focuses on patent law and specifically on compulsory licensing for pharmaceutical patents. The main country of study is Ghana but, to a substantial degree, the findings will be applicable to transitional and developing countries that compare with Ghana.¹²⁶ My decision to select Ghana as the case for this study was influenced by various factors. First, Ghana hosts many generic manufacturers.¹²⁷ Second, since the amendment of its 1992 patent regime in 2003, Ghana has experienced strong protection and enforcement in regard to pharmaceutical patents. This has taken away its ability to obtain pharmaceutical patents to produce affordable medicines locally, and, even though the country has pharmaceutical industrial capacity, the lack of patents to embark on the local manufacture of essential medicines means that Ghana relies excessively on the importation of essential medicines. These elements make Ghana a suitable context to investigate with regard to the impact of stronger patent rights, as required under TRIPS, and their relationship with the high costs of essential medicines resulting from importation, as Ghana imports approximately 70 per cent of its essential medicines and only 30 per cent are produced locally.¹²⁸

1.8.2. Why India?

Empirical accounts suggest that the Indian Patents Act 1970 has had a profound influence on the development of the country's local pharmaceutical industry.¹²⁹ As of now, India has achieved an eminent global position in the pharmaceutical sector and the country is touted as the pharmacy of the developing world – supplying affordable medicines for the protection of public health around the globe.¹³⁰ However, evidence suggests that India's compliance with

¹²⁶ World Bank classification of countries. <<https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>> [Accessed Mar. 14, 2017].

¹²⁷ Jonathan Harper and Martha Gyansa-Lutterodt, *The Viability of Pharmaceutical Manufacturing in Ghana to Address Priority Endemic Diseases in the West Africa Sub-region* (Federal Ministry for Economic and Corporation and Development of Germany, Trade and Investment Promotion Sectoral Policy, 2007) 42.

¹²⁸ *ibid.* 41.

¹²⁹ Evans (n 105) 179, mentioning that a major contributor to the development of a pharmaceutical industry in India was the speed with which its scientists were able to develop cost-effective manufacturing processes for molecules already invented and patented in other countries - a practice supported by the Indian Patents Act 1970.

¹³⁰ Aman Goyal, "Letter to the Editor", 'Pharmacy of the World is Ill?' (2015) 15 *Developing World Bioethics* 1, ii. Suresh Koshy, Note, 'The Effect of TRIPs on Indian Patent Law: A Pharmaceutical Industry Perspective' (1995) 1 *The Boston University Journal of Science & Technology Law* 4, 12.

TRIPS took away key flexibilities that existed with its Patents Act 1970,¹³¹ and ultimately made some essential medicines reasonably expensive.¹³² Similar to Ghana, India's attempts to utilise the TRIPS flexibilities to promote affordable medicines have met legal challenges by some pharmaceutical companies.¹³³ Some pharmaceutical companies have attempted to use multiple strategies to block or delay the entry of affordable generic medicines into India.¹³⁴ In addition to this, the home governments of major multinational pharmaceutical companies, particularly the US, have persistently engaged in efforts to put pressure on India to change its patent law and to introduce further barriers to affordable generic medicines.¹³⁵

Consequently, India, a country that can easily produce generic copies of patented medicines, has had to rely on the importation of essential medicines, such as Nexavar.¹³⁶ In an unprecedented response to the lack of affordable Nexavar due to Bayer's failure to work the patented invention on a commercial scale in the country, and the tenacious resistance to its usage of the TRIPS flexibilities to promote affordable medicines, the Controller, on 12 March 2012, invoked Section 84 as the basis for granting a compulsory licence to Natco.¹³⁷ The Controller, together with the IPAB decision in *Bayer v Natco*, provided an interpretative understanding in confirmation of the consistency of Section 84 with TRIPS. Until now, no Member of the WTO has attempted to challenge the Indian decision within the DSU system. This provides ample justification concerning the consistency of Section 84 with TRIPS, and therefore it could provide a suitable model for Ghana.

¹³¹ Janice Mueller, 'The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation' (2007) 68 *University of Pittsburgh Law Review* 3, 518-519.

¹³² Rishi Gupta, 'TRIPS Compliance: Dealing with the Consequences of Drug Patents in India' (2004) 26 *Houston Journal of International Law* 3, 606.

¹³³ *Novartis AG and another v. Union of India and others*, W.P. Nos. 24759 and 24760 of 2006, High Court of Madras. Vijay Yalamanchili, 'State of India's TRIPS-compliant Patent Regime' (2007) 26 *Biotechnology Law Report* 3, 223.

¹³⁴ Gopakumar Nair and Andrey Fernandes, 'Patent Policies and Provisions Relating to Pharmaceuticals in India' (2014) 19 *Journal of Intellectual Property Rights* 1, 14.

¹³⁵ See "India - Patent Protection for Pharmaceutical and Agricultural Chemical Products" (n 68). See also India Needs to Resist Pressure from Big Drug Firms and their Backers to Change Patent Laws. Scroll In Online. 12 April 2016. <<http://scroll.in/article/741820/india-needs-to-resist-pressure-from-big-drug-firms-and-their-backers-to-change-patent-laws>> [Accessed Apr. 20, 2016], observing that India's intellectual property model is under attack not because it has failed, but because it has succeeded – in balancing private profits with public health.

¹³⁶ 'Report of the National Commission on Macro Economics and Health' (Ministry of Health and Family Welfare, Government of India, 2005) 28-34. 'The World Medicines Situation' (WHO/EDM/PAR/2004.5, World Health Organisation, 2004) 62, Table 7.2. See also Kunnathully Madhavan Gopakumar, 'Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime' (2010) 3 *The Law and Development Review* 2, 330. Shubham Chaudhuri, Pinelopi Goldberg and Panle Jia, 'Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India' (2004) 95 *American Economic Review* 5, 1483, estimating that patented products would rise between 100 and 400 per cent.

¹³⁷ "Controller's Order" (n 52).

1.9. Limitations

The primary limitation of this study relates to the use of the case study research approach. Critics of this method argue that case studies, although providing a profound understanding of a single case, lack external validity.¹³⁸ In the case of this thesis, this means that the arguments are not necessarily applicable to other developing countries, since they may exhibit contextual factors that are different from India, in particular a lack of political strength to withstand any economic implications if compulsory licences were to be granted. Nevertheless, it should be emphasised that this study does not strive to make empirical generalisations; rather it aims to examine the consistency of Section 84 with TRIPS, and question whether, given the textual correlation between Section 84 and Article 5(A) of the Paris Convention, the latter having been incorporated into TRIPS under Article 2, TRIPS truly prohibits the granting of compulsory licensing provided that the patented invention has not been worked in the territory of India, and if so whether Section 84 would provide a suitable model for Ghana.

1.10. Structure of the Thesis

Chapter 1 has sought to present the background of the study and has highlighted Ghana's need for essential medicines and the legal difficulties in using compulsory licensing to obtain an affordable supply for distribution. Chapter 2 examines the legal context of the requirement in regard to the working of patented inventions and the granting of compulsory licences in India pursuant to the Section 84 decision in *Bayer v Natco*, which attempted to establish the consistency of Section 84 with TRIPS.

Chapter 3 draws on applicable sources of law with a view to offering an interpretation regarding whether Section 84 is consistent with TRIPS. Chapter 4 aims to examine whether Article 27(1) of the TRIPS Agreement would prohibit WTO Members from adopting local working requirements. The chapter argues that Article 27(1) of the TRIPS Agreement would not prohibit WTO Members from adopting and implementing any local working requirements that follow the Indian model in Section 84.

¹³⁸ De Vaus (n 122) 237. Robert Stake, 'The Case Study Method in Social Inquiry (1978) 7 *Educational Researcher* 2, 7, stating that case study is seen to be a poor basis for generalisation.

Chapter 5 assesses the complex conditions and procedural requirements for the granting of compulsory licences under Article 31 of TRIPS and the Doha Solution. The chapter argues that the conditions under Article 31 of TRIPS are complex while the formal procedural requirements developed by the Doha Solution are too burdensome, which further compounds the restrictions imposed by TRIPS; therefore, a Section 84 model remains a feasible option that can promote affordable medicines.

Chapter 6 evaluates the feasibility of Ghana implementing the Section 84 model as India did given concerns and evidence concerning the potential FDI-retributive effects, bilateral pressure, high litigation costs and their potential impact on the country attaining its socio-economic objectives. It will be argued that although there would be no legal obstacle under TRIPS, without political support, due to FTAs and high litigation costs the implementation of the Section 84 model in Ghana would not be feasible. Chapter 7 draws all of the other chapters together in an attempt to affirm the hypothesis regarding the consistency of Section 84 with TRIPS and its adoption by Ghana.

Chapter 2

Section 84: Working of Patents and the Granting of Compulsory Licences

2.1. Aim of the Chapter

This chapter examines the legal context of the requirement regarding the working of patented inventions and the granting of compulsory licences in India pursuant to the Section 84 decision in *Bayer v Natco*, which attempted to establish the consistency of Section 84 with TRIPS.

2.2. Introduction to the Chapter

Section 84 lays down three specific instances upon which an interested party may apply for the granting of a compulsory licence at any time after the expiration of three years from the date of the granting of a patent. The first is where the reasonable requirements of the public with respect to the patented invention have not been satisfied.¹³⁹ The second is where the patented invention is not available to the public at a reasonably affordable price,¹⁴⁰ and the third is where the patented invention is not worked in the territory of India.¹⁴¹ Before granting a compulsory licence, the Controller must consider certain major conditions set out in Section 84(7), for example, if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being worked to the fullest extent that is reasonably practicable;¹⁴² or if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article.¹⁴³

On 9 March 2012, the Controller granted a compulsory licence to Natco based on Section 84. In this light, the Controller considered the relevant provisions of the Paris Convention, the TRIPS Agreement and the Indian Patents Act, and decided that the combination of Article 27(1) of TRIPS and Article 5(A) of the Paris Convention reinforced an interpretation that failure to

¹³⁹ Section 84(1)(a).

¹⁴⁰ Section 84(1)(b).

¹⁴¹ Section 84(1)(c).

¹⁴² Section 84(7)(d).

¹⁴³ Section 84(1)(e).

manufacture Nexavar in India supported the granting of a compulsory licence to Natco.¹⁴⁴ He stated that:

While importation of a patented invention shall not result in the forfeiture of a patent, it however follows that a reasonable fetter on the patent rights in the form of compulsory licence is very well within the purview of the Paris Convention and the TRIPS Agreement, when there is an abuse of patent right.¹⁴⁵

Demonstrating the consistency of Section 84 with TRIPS, the Controller found ample justification for the compulsory licence in Section 83(b) of the Patent Act, which states that ‘patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article’,¹⁴⁶ and Section 83(c), which states that ‘the grant of a patent right must contribute to the promotion of technological innovation and to the transfer and dissemination of technology’.¹⁴⁷ Furthermore, Section 83(f) states that patents should not be abused, and that patentees should not resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.¹⁴⁸ In confirming the compulsory licence, the Controller construed that work in the territory of India implies manufacture in India to a reasonable extent such that the Indian patent law principles enumerated in Section 83 can be brought into effect.¹⁴⁹ ‘In the absence of manufacturing in India, Section 83 will be a dead letter’.¹⁵⁰

2.3. Section 84: A Legal Obligation to Work Patents in the Territory of India

Section 84 remains the validating section referenced by a legal obligation on the part of patentees to work their patented inventions within the territory of India. Section 84(1)(a), when read with Sections 84(4) and 84(7), enumerates the various circumstances where the reasonable requirements of the public with respect to a patented medicine shall be deemed not to have been satisfied.¹⁵¹ Under Section 84(4), the Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or that the patented invention is not worked in the territory of India, or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he deems fit.

¹⁴⁴ “Controller’s Order” (n 52).

¹⁴⁵ *ibid.* 41-42.

¹⁴⁶ *ibid.* 43.

¹⁴⁷ *id.*

¹⁴⁸ *id.*

¹⁴⁹ *ibid.* 43-44.

¹⁵⁰ *ibid.* 44.

¹⁵¹ Section 84(7)(a)-(e).

For instance, ‘the reasonable requirements of the public shall be deemed not to have been satisfied’ if, on account of the refusal to grant a compulsory licence, an existing trade or industry or the development or establishment of any new trade or industry in India is prejudiced’,¹⁵² or ‘the demand for the patented article has not been met to an adequate extent or on reasonable terms’,¹⁵³ or ‘a market for export of the patented article manufactured in India is not being supplied or developed’,¹⁵⁴ or ‘the establishment or development of commercial activities in India is prejudiced’.¹⁵⁵ The reasonable requirements of the public shall further be deemed not to have been satisfied ‘if, by reason of conditions imposed by the patentee upon the grant of licences under the patent... or the establishment or development of any trade or industry in India, is prejudiced’,¹⁵⁶ or ‘if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of the patent or coercive package licensing’.¹⁵⁷

Furthermore, the reasonable requirements of the public shall be deemed not to have been satisfied if a patented article is not being worked in India on a commercial scale to an adequate extent or to the fullest extent that is reasonably practicable,¹⁵⁸ or if the working of the patented medicine on a commercial scale in India is being hindered by the importation of the patented article from abroad by the patentee or his agents, or by persons directly or indirectly purchasing from the patentee, or by third parties against whom the patentee has not enforced the patent.¹⁵⁹ According to Section 84(1)(b), a compulsory licence can also be obtained to prevent the abuse of a patented medicine if the medicine is not available to the public at a reasonably affordable price.¹⁶⁰

¹⁵² Section 84(7)(a)(i).

¹⁵³ Section 84(7)(a)(ii).

¹⁵⁴ Section 84 (7)(a)(iii).

¹⁵⁵ Section 84 (7)(a)(iv).

¹⁵⁶ Section 84 (7)(b).

¹⁵⁷ Section 84 (7)(c).

¹⁵⁸ Section 84 (7)(d). For the meaning of the expression “work a patent.” See *infra* (n 166) and the accompanying text.

¹⁵⁹ Section 84(7)(e)(i)-(iii). *Infra* (n 166) and the accompanying text, highlighting the prevalent judicial trend that considers a patented article imported from abroad to have been worked in India, provided that the patentee can reasonably justify the circumstances which prevented him from manufacturing the patented article locally within India.

¹⁶⁰ Section 84 (1)(b).

Section 84 does not state specifically the possible factors that the Controller must take into consideration when determining whether or not a patented drug is reasonably priced.¹⁶¹ Be that as it may, a generic manufacturer seeking a compulsory licence under Section 84(1)(b) has the burden to *prima facie* establish that the patented medicine is not reasonably priced,¹⁶² for instance, by providing evidence of the prices charged by the patentee in India and then comparing those prices with the prices charged by the patentee for the same medicine outside of India,¹⁶³ or by comparing those prices with the prices of the medicine's non-patented substitutes available in India.¹⁶⁴ Section 84(1)(c) does not define or explain what it means to “work a patent”. The courts in India have broadly interpreted the “working of a patent in India” to mean that the patented invention is locally manufactured within the territory of India.¹⁶⁵

It is noteworthy that while considering whether or not a patent has been worked in India, the importation of such a patent is also permissible, provided that the patentee can reasonably explain and justify the circumstances that prevented him from manufacturing it locally within the country.¹⁶⁶ As part of the admissibility requirements, an application for a compulsory licence under Section 84 can be filed at any time after the expiration of three years from the

¹⁶¹ Madhavi Chopra, ‘Of the Big Daddy, the Underdog, the Mother Hen, and the Scapegoats: Balancing Pharmaceutical Innovation and Access to Healthcare in the Enforcement of Compulsory Patent Licensing in India, its Compliance with TRIPS, and Bayer v. Natco’ (2015) 13 *Santa Clara Journal of International Law* 2, 349.

¹⁶² Section 87 (1).

¹⁶³ Mueller (n 131) 593.

¹⁶⁴ *id.*

¹⁶⁵ Bayer Corp. v. Union of India, Writ Petition No. 1323 of 2013, Jul. 15, 2014 (Bombay High Court). <https://www.jetro.go.jp/ext_images/world/asia/in/ip/pdf/bombay_high_court_judicature_20140812.pdf> [Accessed Sept. 12, 2015] 48, stating that ‘When a patent holder is faced with an application for compulsory license, it is for the patent holder to show that the patented invention / drug is worked in the territory of India by manufacture or otherwise’.

¹⁶⁶ *ibid.* 48-49 ‘Manufacturing of a patent . . . may not always be necessary to establish the working of a patent in India . . . Where a patent holder satisfies the authorities, the reason why the patented invention could not be manufactured in India then the patented invention can be considered as having been worked in the territory in India even by import’. Notably, the importation of a patent, as opposed to its local manufacturing in India, may not necessarily be a viable option for “working the patent” from both business and public health standpoint. See G.B. Reddy and Harunrashid Kadri, ‘Local Working of Patents: Law and Implementation in India’ (2013) 18 *Journal of Intellectual Property Rights* 1, 22, stating that ‘local production of a patent ensures price reduction, increases supply and competition and . . . increases domestic expertise in the production of medicines for key local diseases, increases transfer of technology and knowledge, increases employment, opens a new export market and improves foreign exchange flows’. Nonetheless, the local manufacturing of a patent is also not always feasible, especially when its importation may be a better option towards “working the patent” in India. *ibid.* 23, ‘In particular cases, the bulk production of patented goods from an existing plant and importing the goods to the country of patent grant may be more convenient for the patentee, rather than to establish a new industrial unit. It saves the start-up costs, manpower, maintenance cost, administrative expenses and other infrastructural expenses, including electricity, water, etc.’ Therefore, while deciding whether a patentee should be permitted to work his patent in India through its importation, a “case-to-case” basis approach is appropriate with each case being decided on its own merits. *ibid.* Bayer Corp. v. Union of India (n 165) 48.

date of the granting of the patent,¹⁶⁷ after the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions, where such efforts have not been successful within a reasonable period, not ordinarily exceeding six months.¹⁶⁸

However, the requirement for a compulsory licence applicant to make initial efforts towards obtaining a voluntary licence from a patentee is dispensed with ‘in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anticompetitive practices adopted by the patentee’.¹⁶⁹ The obligation to work patented inventions locally is a principle that forms a significant foundation of the Indian patent regime.¹⁷⁰ Under the general principles applicable to the working of patented inventions locally in India, patents are granted to encourage inventions and to ensure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay.¹⁷¹

Paragraph (b) of Section 83 maintains that patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. Furthermore, Paragraph (c) states that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.¹⁷² Importantly, Paragraph (d) of Section 83 stipulates that patents granted should not impede the protection of public health and nutrition and should act as instruments to promote the public interest, especially in sectors of vital importance for the socio-economic and technological development of India.

An important consideration is that patents granted should not in any way prohibit Central Government from taking measures to protect public health.¹⁷³ Moreover, Paragraph (f) provides that the patent right shall not be abused by the patentee or person deriving title or

¹⁶⁷ Section 84(1).

¹⁶⁸ Section 84(6)(iv) read with “Explanation Clause” to Section 84(6)(iv) providing that, “reasonable period” in Section 84(6)(iv) ‘shall be construed as a period not ordinarily exceeding a period of six months’.

¹⁶⁹ *id.*

¹⁷⁰ Shamnad Basheer and Mrinalini Kochupillai, *The ‘Compulsory License’ Regime in India: Past, Present and Future* (Report for the Japanese Patent Office, 2005) 36.

¹⁷¹ Section 83(a).

¹⁷² Section 83(c).

¹⁷³ Section 83(e).

interest on patent from the patentee, and that the patentee or person deriving title or interest on patent from the patentee shall not resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology. Added to this is the general principle applicable to the working of patented inventions locally in the territory of India, which is that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.¹⁷⁴

2.4. Utilisation of Section 84: The Compulsory Licensing Decision in Bayer v Natco

Bayer developed Nexavar, and it obtained a patent from the US Patent Office on 13 January 1999. Bayer subsequently filed a Patent Cooperation Treaty¹⁷⁵ application on 12 January 2001.¹⁷⁶ It was granted a patent (No. 215758) as well as regulatory approval for importing and marketing Nexavar in India in 2008.¹⁷⁷ Finding Nexavar to be exorbitantly priced for the average Indian consumer but therapeutically indispensable as a life-extending medicine, Natco approached Bayer on 6 December 2010 for a voluntary licence to manufacture and sell the medicine in India.¹⁷⁸ This move was in compliance with the statutory requirements under Section 84(6)(iv), in regard to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period, as deemed fit by the Controller.

This prior consultation was in accordance with the procedural requirements established in Article 31(b) of TRIPS - that authorisation from the patent right holder should be obtained on reasonable commercial terms and conditions.¹⁷⁹ However, this attempt by Natco to secure a

¹⁷⁴ Section 83(g).

¹⁷⁵ Article 3 of the Patent Cooperation Treaty”, TIAS 8733; 28 UST 7645; 9 I.L.M. 978 (1970).

¹⁷⁶ “Controller’s Order” (n 52) para. 3. Note that Bayer filed its patent application for Nexavar in the US on Jan. 13, 1999, and followed it by filing its PCT International Application, bearing PCT/US00/000648, on Jan. 12, 2000. On Jul. 5, 2001, Bayer’s PCT application entered the national phase of registration in India. Bayer received all requisite regulatory approvals for importing and marketing Nexavar in India by January 2008, and finally a patent no. 215758 was granted to it on Mar. 3, 2008. For a chronological overview of when and how Bayer obtained the patent on Nexavar, first in the United States and thereafter in India. *ibid.* paras. 4-5.

¹⁷⁷ “IPAB’s Decision” (n 123) para 3.

¹⁷⁸ “Controller’s Order” (n 52) 6, documenting that Natco had proposed to sell the drug at a price of Rs. 8800/- for one-month therapy as compared to Bayer’s price of about Rs. 2,80,428/-).

¹⁷⁹ Article 31(b) reads as follows:

Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time....’

For further analysis of Article 31(b) of TRIPS provision, see Carlos Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford University Press, 2007) 311, discussing the terms and conditions for the grant of compulsory licensing.

voluntary licence from Bayer was not successful, as Bayer refused to grant a voluntary licence to Natco. Although its negotiations with Bayer were not fruitful, Natco was successful in obtaining regulatory approval in April 2011 from the Controller for marketing the generic version of Nexavar in the country.¹⁸⁰ In order to thwart the launch of the generic version of Nexavar in India, Bayer arraigned Natco in a suit for patent infringement, which it filed in the High Court of Delhi on 5 June 2011.¹⁸¹

As a counter-attack, Natco not only decided to defend the patent infringement suit,¹⁸² but also went a step further and filed an application before the Controller on 28 July 2011, seeking a compulsory licence to manufacture and market the generic version of Nexavar in India under Section 84(1), after the expiration of three years from the date of the granting of the patent (Nexavar) to Bayer.¹⁸³ This application was in accordance with Rule 96 of the Indian Patent Rules 2003,¹⁸⁴ premised on the grounds that the patentee (Bayer) had failed to satisfy the reasonable requirements of the public as provided under Section 84. Bayer opposed this application on various grounds. Both parties filed evidence before the Controller for a determination of the case. Natco argued that the compulsory licence for Nexavar would have a dramatic effect on the price of the medicine by bringing the price that Indian patients paid down to approximately ₹108 for a month's dose.¹⁸⁵ According to Natco, this would represent a fraction of Bayer's price of approximately ₹3100 for the same dose.¹⁸⁶ Under the terms of the compulsory licence, Bayer was offered a six per cent royalty from Natco for the total sale of Nexavar.¹⁸⁷

As stated above, in a ruling delivered on 9 March 2012, the Controller granted Natco a licence for the manufacture of affordable generic versions of Nexavar.¹⁸⁸ Against this background, Bayer filed a petition with the IPAB in the interim to order a stay on the compulsory licence

¹⁸⁰ "The Controller's Order" (n 52) 5.

¹⁸¹ Bayer Corp. v. Natco Pharma Ltd., C.S. (O.S.) No. 1090/2011 (Delhi High Court).

¹⁸² The various interlocutory orders passed so far in Bayer Corp. v. Natco Pharma Ltd. indicate that Natco has been defending the patent infringement suit filed by Bayer since June 2011.

¹⁸³ Official draft of Natco's compulsory licence application filed before the Controller in Mumbai. *Official Journal of the Patent Office* (Publication of the Patent Office, Issue No. 32/2011, Aug. 12, 2011) 13344-63.

¹⁸⁴ Under Compulsory Licence and Revocation of Patent. Chapter XIII.

¹⁸⁵ "Controller's Order" (n 52) 55.

¹⁸⁶ *ibid.* 11.

¹⁸⁷ *ibid.* paras. 14 and 15(f) analysing the UNDP's royalty practice and guidelines, adopted globally as a framework for determining the royalty for the grant of compulsory licensing.

¹⁸⁸ *ibid.* 60-62.

granted by the Controller to Natco.¹⁸⁹ The IPAB upheld the decision of the Controller. In summary, the IPAB reasoned that Bayer had failed to manufacture Nexavar locally but rather it was importing the patented product into India. As such, the patentee (Bayer) had failed to satisfy Section 84(1) of the Indian Patent Act pursuant to the reasonable requirements of the public. Likewise, the price of the product was so high that it was not reasonably affordable to the public.

Although the IPAB's decision was not different from that of the Controller, it differed marginally in some key aspects. The only important divergence was the one per cent increase in the royalty rate from six to seven per cent to be paid by Natco to Bayer as a means of ending the dispute. In so doing, the IPAB acknowledged that while the UNDP recommended the award of a maximum possible royalty of six per cent, it took note of the disparate profit margins of Bayer, which were about fourteen per cent, and those of the distributors of Nexavar (about thirty per cent). Therefore, placing reliance on Section 90(2) of the Indian Patent Act, the IPAB increased the royalty rate in order to allow Bayer to obtain reasonable benefit from its patent - Nexavar.¹⁹⁰ In an attempt to overturn the Controller's decision, Bayer unsuccessfully took its case both to the High Court and the Supreme Court of India.¹⁹¹

2.5. IPAB's Interpretation of Section 84: Reasonable Requirements of the Public for Patents to be Worked Locally in the Territory of India

As discussed previously, Section 84(1)((a) and (c) maintain that the reasonable requirements of the public with respect to a patented invention have not been satisfied if the patented invention is not worked in the territory of India. Therefore, the IPAB had to determine whether Bayer had met this requirement. To begin with, Bayer argued that working in India did not mean direct local manufacture in the territory of India. It stated that it was not realistic for it to manufacture the patented invention in India, and that importation was the only option.¹⁹² Bayer

¹⁸⁹ "IPAB's Decision" (n 123).

¹⁹⁰ *ibid.* para. 54.

¹⁹¹ In the High Court of Judicature at Bombay, *Bayer Corporation v. Union of India & Ors.*, Writ Petition No. 1323 of 2013. ASN. 1/52. WP-1323-Jud. [Ordinary Original Civil Jurisdiction] Available at: <<http://indiankanon.org/doc/28519340/>> [Accessed Mar. 23, 2017]. In the Supreme Court of India: *Bayer Corporation (Petitioner(s)) v Union of India & ORS. (Respondent(s)) (With Interim Relief and Office Report). Petition(s) for Special Leave to Appeal (C) No(S). 30145/2014 (Arising out of Impugned Final Judgment and Order dated 15/07/2014. In WP No. 1323/2013 passed by the High Court of Bombay. Item No. 23, Section IX, (Court No. 9). <<http://courtnic.nic.in/supremecourt/temp/sc%203014514p.txt>> [Accessed Mar. 23, 2017].*

¹⁹² "IPAB's Decision" (n 123) para. 50.

relied on the fact that Section 90 of the Indian Patent Act, 2002 (now Section 84(7)) did not include the phrase “manufacture in India”.¹⁹³

Bayer claimed that: ‘It would be economically unfeasible for the appellant to set up a local manufacturing facility to commercially manufacture Sorafenib Tosylate in every country where it has a patent’.¹⁹⁴ The IPAB held that the issue of working in India should be judged on a case-by-case basis to reflect the procedural requirements set forth in Article 31 of TRIPS. It noted that: ‘TRIPS says that the authorisation and other uses must be dealt with on a case-to-case basis.’ The IPAB understood that the word “worked” could have a flexible meaning based on specific facts. Accordingly, it did not rule either way in regard to whether “working in India” necessarily meant “local manufacturing” but agreed that in some cases it may be that inventions cannot be manufactured in India.

It also concurred that there could be inventions for which the reasonable requirements of the public itself were so small in number that setting up a factory for the said purpose was not practicable.¹⁹⁵ Although the IPAB could not decide whether the notion of working totally excluded import or whether “working” was synonymous with “import”, it nevertheless concluded that if there were no manufacturing in India, it could be assumed that there would be no working because evidence of local working was required to satisfy the legal working requirement in the territory of India.¹⁹⁶ The IPAB referred to the guiding principles regarding the working of patented inventions’ as set out in Section 83.

Among other things, it confirmed that patents are granted to encourage invention and to ensure that inventions are worked in India on a commercial scale as early as is reasonably practicable, and that they are not a vehicle to give patentees a monopoly in importing patented articles.¹⁹⁷ Moreover, the IPAB maintained that the protection of patent rights must lead to better technological innovation, technology transfer and dissemination, and that users and producers should benefit from the technology.¹⁹⁸ Furthermore, it reiterated that IP protection should promote social and economic welfare, and balance of rights and obligations, maintaining that

¹⁹³ *id.*

¹⁹⁴ *ibid.* para. 34.

¹⁹⁵ *ibid.* para 51.

¹⁹⁶ *ibid.* para. 52.

¹⁹⁷ *ibid.* para. 17.

¹⁹⁸ *id.*

the granting of patents should not be detrimental to public health; rather they should act as an instrument for the promotion/protection of public health.¹⁹⁹

Importantly, the IPAB argued that the granting of a patent should not counter the Central Government's health measures. More importantly, it reasoned that the IP right should not be abused by the patentee or anyone claiming under him; nor can the patentee act in such a manner that trade or the international transfer of technology is undermined, as patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.²⁰⁰ Moreover, the IPAB referred to Section 83(c), concerning the transfer and dissemination of technological knowledge, and Section 84(7)(a)(iv), regarding the establishment or development of commercial activities in India, referencing the question, 'to what extent can import of goods be considered actual commercial working of the inventions'?²⁰¹

It maintained that Section 84(7) creates a legal narrative regarding when the reasonable requirements of the public shall be deemed not to be satisfied, that is, the grounds under Section 84(1)(a), specifically Section 84(7)(d): 'if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable'.²⁰² In addition, the IPAB agreed that the textual understanding of Section 84(7)(e), which refers to the working of an invention in the territory of India and importation from abroad of the patented articles, obviously refers to dissimilar activities. As a result, any contention concerning the non-viability of local "working" had to be proven, not simply stated.

Notably, the IPAB admitted that while the argument that local working requirements could be met through importation appeared to be true to an appreciable degree, it questioned why Bayer had not met the local working requirements via importation if it had reasonably believed that this was a realistic proposition. This followed Natco's claim that Bayer had a manufacturing facility in India, and therefore it could have manufactured the invention there.²⁰³ In this case,

¹⁹⁹ id. referring to Section 83.

²⁰⁰ id.

²⁰¹ *ibid.* para. 18.

²⁰² *ibid.* para. 31.

²⁰³ id.

the IPAB agreed that Bayer had failed to show why it could not “work” Nexavar locally in India. Therefore, it was held that Bayer had failed the test of Section 84(1) in this regard.²⁰⁴

In dismissing this claim, the IPAB clarified that there was no evidence to substantiate the argument that Bayer had met the local working requirements through importation. It further asserted that in order to be able to satisfy the requirements of Section 83(a) of the Indian Patent Act, such importation must be on a commercial scale to an adequate extent and sold at a reasonably affordable price. This, however, was not the case. Furthermore, the IPAB stated that, in Section 83(b), the requirement that patents were not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article still defeated Bayer’s argument about relying on importation to meet local working requirements, since the foregoing provision still states that the patentee must work the patented invention in the territory of India to an adequate extent.²⁰⁵

Notably, the IPAB reasoned that, in its language, this ground suggested that where the patented invention was not capable of being worked in India, the exercise of compulsory licensing was justified.²⁰⁶ In addition, the IPAB noted, as per Section 84(7), specifically Paragraph (a), that: ‘the reasonable requirements of the public shall be deemed not to have been satisfied; if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms’.²⁰⁷ Significantly, Bayer could not sustain this argument given that it had refused to grant a licence to Natco, and the patentee was still contesting CIPLA’s patent infringement in a separate proceeding.²⁰⁸

Similarly, in addressing the issue of non-discrimination in the import rules under TRIPS Article 27(1), the IPAB correctly noted that the provisions address non-discrimination in the granting

²⁰⁴ *ibid.* para. 53.

²⁰⁵ Christopher May and Susan Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner, 2006) 170, explaining that rather than facilitating the importation of new technologies for production, patents have historically been used to maintain import monopolies.

²⁰⁶ Section 37(2) (b) of the UK Patent Act 1949 (12, 13 & 14 Geo 6 c 87) reads: ‘That a demand for the patented article in the United Kingdom is not being met on reasonable terms, or is being met to a substantial extent by importation’.

²⁰⁷ Section 84(7)(d) states that:

The reasonable requirements of the public shall be deemed not to have been satisfied; if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable.

²⁰⁸ Bayer Corp. v CIPLA Pharm. Case No. CS (OS) 523/2010 and I.A. Nos. 3714/2010, 6065/2010 and 12765/2010^[1] and CC 19/2011 in the High Court of Delhi at New Delhi-India.

of patents based on import, not the issue of allowing the granting of compulsory licences based on the absence of local working. This part of the ruling regarding the working of patented inventions locally is remarkable for a number of reasons. Firstly, it proves that compulsory licensing by reason of failure to work a patented invention locally does not violate the TRIPS Agreement, in particular Article 27(1), irrespective of the provision that patents must be available and patent rights can be enjoyed without discrimination as to the place of invention, the field of technology and whether the products are imported or locally produced.²⁰⁹

To confirm this precedent, the IPAB considered the relevant part of the Paris Convention. It reasoned that Article 27(1) of the TRIPS provision meant that the requirement of non-discrimination applied only to the final step of revocation of a patent, and not to the intermediate measure of compulsory licensing.²¹⁰ This was in reference to Paragraph 20 of the IPAB's decision, which quoted Articles 30 and 31 of TRIPS in respect of limited exceptions to patent rights and compulsory licensing.²¹¹ Subsequently, while on the one hand the IPAB seemed to impose an evidentiary burden on the patentee (Bayer) to demonstrate why it could not satisfy the requirements of Section 84(1) to manufacture the patented invention locally, on the other hand, the IPAB appeared to agree that the "local working requirements" could be met by importation.

Another important issue here is that despite the IPAB appreciating that certain patents are workable only by importation, it failed to provide a detailed framework or precise instances where this was reasonably applicable, except to say that failure to work a patented invention locally still conflicted with the fundamental objectives of the Indian Patent Act. Subsequently, it is not clear whether the IPAB appeared to contradict its own admission that in certain cases patents may be granted purely for import purposes.²¹² In fact, the IPAB should have taken into consideration the circumstances that made it economically unfeasible to set up a facility in

²⁰⁹ "IPAB's Decision" (n 123) para. 52. For further analysis of Article 27(1) of the TRIPS Agreement, Correa (n 179) 271.

²¹⁰ *id.*

²¹¹ *ibid.* 302, discussing the exceptions to rights conferred by patents under TRIPS.

²¹² "IPAB's Decision" (n 123) para. 51, noting that:

In a given case there may be an invention which cannot be manufactured in India and it is also possible that there is an invention where the reasonable requirement of public itself is small in number and setting up a factory just for the said purpose is not practicable.

India for the manufacture of Nexavar, as claimed by Bayer.²¹³ Nevertheless, this exclusion must be understood, as Bayer failed to provide any evidence before the IPAB in this regard.

In the absence of this clarification, the IPAB's decision has created uncertainty with respect to the extent to which future case can be decided consistently, given that the Indian Patent Act does not make clear the evidence deemed reasonable to justify what amounts to a patent that can be granted for imports and that deemed necessary to meet the local working requirements via direct local manufacturing. Nevertheless, this part of the IPAB's decision assumes a significant implication in the light of the broader orientation of Section 84(1) towards the principle of the reasonable requirements of the public and local working. As acknowledged in the decision itself, one of the foremost considerations as far as the Indian jurisprudence is concerned is that patents are not granted to promote the import monopoly of patentees.²¹⁴

Additionally, the IPAB used Ayyangar's Report to explain the impact of failure to satisfy the reasonable requirements of the public, particularly when foreign patentees do not work patents locally in low-income countries - leaving these countries as losers and depriving their people of the know-how, which does not necessarily benefit underdeveloped economies.²¹⁵ In fact, Ayyangar's Report posited that local realities in low-income countries might cause patent regimes to operate differently.²¹⁶ Significantly, the assertion that the economics of patents in low-income countries work differently finds legitimate support in some contemporary scholarly analyses of the WTO/TRIPS Agreement, which is viewed as only meeting the fundamental interest of developed countries, which are the leaders in terms of technological innovation and exporters of technology.²¹⁷

²¹³ *ibid.* para. 52.

²¹⁴ *ibid.* para. 22.

²¹⁵ Justice Rajagopala Ayyangar, *Report on the Review of the Patents Law* (New Delhi, September 1959) 30. <<http://www.scribd.com/doc/201678355/Ayyangar-Committee-Report>> [Accessed Mar. 23, 2016]. Tanuja Garde, "India". In: *INTELLECTUAL PROPERTY IN ASIA: LAW, ECONOMICS, HISTORY AND POLITICS*, Paul Goldstein, Peter Ganeva, Tanuja Garde, Joseph Straus, and Ashley Isaacson Woolley, (eds.), (Springer-Verlag, 2009) 59.

²¹⁶ *ibid.* Ayyangar's Report, paras. 24-25. Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* (Oxford University Press, 2012) 33-42, discussing the sentiments expressed by Ayyangar's Report that patents work differently in different economies.

²¹⁷ Peter Yu, 'The International Enclosure Movement' (2007) 82 *Indiana Law Journal* 4, 888, arguing that from a public health perspective, there is no denial that the TRIPS Agreement is biased against developing countries. Alvind Subramanian, 'Medicines Patents and TRIPS: Has IP Past Opened a Pandora Box for the Pharmaceutical Industry?' (International Monetary Fund-Finance and Development, 2004) 23, stating that for developing countries the economic calculus of patent is different from the developed countries.

Within this context, the IPAB noted that foreign patentees become the beneficiaries of the patent system to the detriment of national economies.²¹⁸ This particular view matches that expressed by Ayyangar in his Report, that the government must retain the right to revoke a patent²¹⁹ when it is not worked locally and then licence patents for local manufacturing as a base carrier to promote local industry development and access to technology.²²⁰ Importantly, Ayyangar's Report suggests that local working requirements will minimise importation because imported medicines protected by patents offer limited opportunities for local people to access essential medicines at an affordable price.²²¹

To this end, Ayyangar's Report discusses compulsory licensing as a remedy to redress the handicap of foreigners not working patented inventions locally to enable national industrialisation to offset the social costs incurred due to the granting of patents to the benefit of the national economy.²²² Referencing Ayyangar's Report, the IPAB then concluded that when patentees fail to work patented inventions and processes in India to the advantage of the public, then compulsory licensing is justified.²²³

2.6. The IPAB's Interpretation of Section 84: The Requirement for Patented Inventions to be Reasonably Affordable to the Public

Section 84(1)(b) stipulates that the reasonable requirements of the public with respect to a patented invention have not been satisfied if the patented invention is not available to the public at a reasonably affordable price.²²⁴ Importantly, the IPAB had to deal primarily with the issue of whether the reasonable requirement of the public was being met by the patentee, including

²¹⁸ "Ayyangar's Report" (n 215) paras. 29-30. Shondeep Banergi, *The Indian Intellectual Property and the TRIPS Agreement*. In: *INTELLECTUAL PROPERTY RIGHTS AND THE EMERGING MARKET*, (ed.) Clarissa Long (The AEI, 2000) 63-69, discussing that Ayyangar's Report was commissioned soon after independence in 1948 due to the general agreement that the patent system in place was not enough to ensure patent rights promote industrial development, therefore legal reform was necessary to adapt patent to conform to national goals particularly local industrialisation.

²¹⁹ Reichman and Hasenzahl (n 1) 10-11, noting that compulsory licensing was originally an alternative to forfeiture for violating numerous restrictions in early patent law.

²²⁰ Ayyangar's Report (n 215) para. 611, citing Section 3 of the UK Patent and Designs Act, 1902, 2. Edw. 7. c. 34, which introduced the principle of "revocation of patent for abuse of the monopoly by non-working" on the ground that the "reasonable requirement of the public with reference to the patented inventions have not been satisfied."

²²¹ *ibid.* paras. 37-38.

²²² *ibid.* para. 38.

²²³ "IPAB's Decision" (n 123) paras. 28-29.

²²⁴ Section 83(g) of the Indian Patent Act, 1970 states that: 'That patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public'.

whether Nexavar was available at a reasonably affordable price in India. According to Bayer, the so-called reasonably affordable price could not be fixed, ignoring the cost burden of the patentee (Bayer).²²⁵ This was where Bayer tended to argue that the term “reasonably affordable price” should be construed not only from the viewpoint of the differential classes of the public in relation to the price of any product but also in the light of the market situation of the patentee.²²⁶

According to the appellant Bayer, the Controller did not take note of their (Bayer’s) development costs.²²⁷ Rejecting this contention, the IPAB reiterated that the reasonably affordable price has to be fixed from the viewpoint of the public since they are the ones purchasing the patented invention.²²⁸ Similarly, Bayer filed several affidavits showing a comparative analysis that the price being charged by the patentee was comparable to what it was charging in other developing countries.²²⁹ Bayer’s affidavit in this direction also stated that the originator’s products were more expensive than generic ones since they also involved R&D costs, which are not borne by person’s who merely copy a medicine. Thus, if medicines are made available in the market at a reasonably affordable price and not necessarily by the patentee, then Section 84(1)(b) will not be relevant; similarly, if someone other than the patentee meets the reasonable requirements of the public then Section 84(1)(a) will not be applicable.²³⁰

This contention is necessary given that CIPLA was selling Nexavar at a very low price and Bayer claimed that under this condition, the appellant (Bayer) could not work the invention. CIPLA did not have the same cost burden that the appellant (Bayer) had to bear with regard to innovation, so it could sell at any price. In these circumstances, Section 84(1)(c) will not be applicable either.²³¹ Therefore, according to Bayer, the appellant being the inventor and having invested a substantial amount of resources in developing the product (Nexavar), the same would form a part of the so-called reasonably affordable price for the said product, and thus the price of Nexavar fixed by Bayer constituted a reasonably affordable price.²³²

²²⁵ “IPAB’s Decision” (n 123) 36.

²²⁶ *id.*

²²⁷ *ibid.* para. 22.

²²⁸ *ibid.* para. 40.

²²⁹ *ibid.* para. 36.

²³⁰ *id.*

²³¹ *id.*

²³² *id.*

Dismissing Bayer's argument, the IPAB asserted that the main aim of granting a compulsory licence related to whether the patented product was available to the public at a price that was reasonably affordable. Confirming the legality of the requirement that patented inventions are reasonably affordable to the public as a substantive condition for granting compulsory licences, the IPAB affirmed that: 'This leaves us in no doubt that it is the appellant who should make the benefit of the patented invention available at a reasonably affordable price to the public and it cannot take shelter under the sale by CIPLA'.²³³ Here, the IPAB relied on Section 83(g), which clearly states that patents are granted to make the benefit of the patented invention available at a reasonably affordable price to the public.

This shows that the reasonable requirements of the public under Sections 84(1), concerning the general principles applicable to the working of patented inventions locally as an independent condition for the granting of compulsory licences are legitimate and consistent with the TRIPS Agreement. Interpreting the consistency of Section 84 with TRIPS, the IPAB reflected on the Doha Declaration and concluded that Paragraph 5(b) is explicitly clear regarding WTO Members' right to grant compulsory licences and their freedom to determine the grounds on which to do so.²³⁴

Therefore, this reference is more supportive of the interpretation that nothing in the light of TRIPS would, in fact, preclude the possibility of other low-income countries that rely heavily on the importation of essential medicines from implementing a model similar to Section 84(1) as a practical means to mitigate the high costs and shortages resulting from the failure of patentees to work patented medicines locally. Specifically, the overriding implication of Section 84(1) and the Bayer v Natco decision, if followed, would enable Ghana to issue compulsory licences for any patent protecting a product solely because that product is not being manufactured locally and thereby satisfying the reasonable requirements of the public.

²³³ *ibid.* para. 29.

²³⁴ *ibid.* para. 20.

2.7. Conclusion

This chapter has assessed the legal context of the working of patented inventions and the granting of compulsory licences in India pursuant to Section 84. The review of the Section 84 decision in *Bayer v Natco* reveals that Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is consistent with TRIPS. As seen from IPAB's interpretation, the main argument for enforcing the working of patented inventions in India is the consideration that, in order to promote affordable medicines, patents for invention should not be used merely to block the working of the invention in the country or to monopolise importation of the patented article by the patent owner.

A strict view in line with the reasonable requirement of the public under Section 84 denotes that the importation of patented products for sale, even on reasonable terms, will not satisfy the general principles applicable to the working of patented inventions locally, a legal prerequisite, which actually demands that patentees locate and manufacture, or apply their patented processes, locally in India. Therefore, patents should be worked within the territory of the country. Notably, the consistency of the Section 84 decision in *Bayer v Natco* with TRIPS remains unchallenged in the WTO DSU system. The failure of the WTO members to challenge this decision provides adequate evidence to sustain the hypothesis that Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is consistent with TRIPS and therefore would provide a suitable model for Ghana. The next chapter draws on applicable sources of law in an attempt to examine the consistency of Section 84 with TRIPS.

Chapter 3

Consistency of Section 84 of the Indian Patents Act with TRIPS

3.1. Aim of the Chapter

The aim of this chapter is to draw on applicable sources of law with a view to offering an interpretation regarding whether Section 84 is consistent with TRIPS.

3.2. Introduction to the Chapter

Section 84 was designed to be TRIPS-compliant.²³⁵ Notwithstanding the fact that Section 84 has a similar drafting structure to Article 5(A)(4) of the Paris Convention, the former being referenced in Article 2 of TRIPS, suggesting its consistency with TRIPS, still, there are conflicting views regarding whether Section 84 is inconsistent with TRIPS.²³⁶ Where a dispute or conflict arises as to the correct interpretation of any provisions pursuant to TRIPS, Article 64(1) of the Agreement confirms that the relevant procedure for resolving that dispute within the WTO system is the DSU mechanism.²³⁷ Article 3(7) of the DSU provides that the aim of the dispute settlement mechanism is to secure a positive solution to any dispute. The DSU presents itself as the sole means of reaching a satisfactory legal interpretation, and members shall abide by the rules and procedures of the DSU.²³⁸ In the WTO, the DSB plays this role and attempts to clarify any conflicting provisions in accordance with ‘customary rules of interpretation of public international law’.²³⁹

More specifically, the DSB prefers to take guidance from the context of the whole agreement to settle on an acceptable explanation.²⁴⁰ This is because it is not possible to concentrate on a paragraph, an article, a section, a chapter or a part of any provision to reach any persuasive conclusion that TRIPS completely forbids the granting of compulsory licensing on grounds of

²³⁵ The Patents (Amendment) Act, No. 17 of 1999. The Patents (Amendment) Act, No. 38 of 2002. Patents (Amendment) Act, 2005, No. 15 of 2005. Prabhu Ram, ‘India’s New “TRIPS-Compliant” Patent Regime Between Drug Patents and the Right to Health’ (2006) 5 *Chicago-Kent Journal of Intellectual Property* 2, 195-206.

²³⁶ Bonadio (n 53) 720.

²³⁷ The TRIPS Agreement (n 22).

²³⁸ Article 23 of the DSU.

²³⁹ Article 3(2).

²⁴⁰ Mercurio and Tyagi (n 76) 307.

failure to work locally,²⁴¹ as the text of a treaty must be read as a whole in order to understand the point of a single provision.²⁴² In this context, applicable sources of WTO law will help to establish the consistency of Section 84 with TRIPS. It is well established in international law that the VCLT provides a definitive guide on treaty interpretation.²⁴³ Importantly, WTO case law accepts that the VCLT is a codification of customary international law.²⁴⁴ That direction ‘reflects a measure of recognition that the General Agreement is not to be read in clinical isolation from public international law’.²⁴⁵ More significantly, it is well settled in WTO case law that the principles codified in Articles 31 and 32 of the VCLT are relevant in the interpretation of WTO law.²⁴⁶

Under Article 31 of the VCLT, a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.²⁴⁷ Moreover, a relevant part of Article 31 of the VCLT provides that in addition to the text, its article and preambles, the context for the purpose of interpretation of a treaty shall comprise: (a) any agreement relating to the treaty made between all of the parties in connection with the conclusion of the treaty; and (b) any instrument made by one or more parties in connection with the conclusion of the treaty, and accepted by the other parties as an instrument related to the treaty.²⁴⁸ The interpretation of international law also includes the writings of the most “highly qualified publicists”.²⁴⁹ Nevertheless, while the writings of the

²⁴¹ Champ and Attaran (n 58) 38.

²⁴² *id.*

²⁴³ Article 2(1)(A) of the VCLT (n 112).

²⁴⁴ United States - Standards for Reformulated and Conventional Gasoline (Report of the Appellate Body, WT/DS2/AB/R Apr. 29, 1996) 17.

²⁴⁵ Report of the Appellate Body in United States - Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany (WT/DS213/AB/R, Nov. 28, 2002) paras. 61–62.

²⁴⁶ Report of the Appellate Body in Japan - Taxes on Alcoholic Beverages (WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, Oct. 4, 1996) 10-12, Section D. See also Appellate Body Report, United States - Continued Existence and Application of Zeroing Methodology (WT/DS350/AB/R, Feb. 4, 2009) paras. 268-273:

The principles of interpretation that are set out in Articles 31 and 32 are to be followed in a holistic fashion. The interpretative exercise is engaged so as to yield an interpretation that is harmonious and coherent and fits comfortably in the treaty as a whole so as to render the treaty provision legally effective... The purpose of such an exercise is therefore to narrow the range of interpretations, not to generate conflicting, competing interpretations. Interpretative tools cannot be applied selectively or in isolation from one another. It would be a subversion of the interpretative disciplines of the Vienna Convention if application of those disciplines yielded contradiction instead of coherence and harmony among, and effect to, all relevant treaty provisions. [Emphasis added].

²⁴⁷ Article 31(1).

²⁴⁸ Article 31(2).

²⁴⁹ Article 38(1)(d) of the Statute of the International Court of Justice, 33 UNTS 993, 1945 provides that the court whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply, among other things, the teachings of the most highly qualified publicists of the various nations, as a subsidiary means for the determination of rules of law. Note that this provision is given a very restricted interpretation in

most “highly qualified publicists” constitute a subsidiary means for the determination of rules of law, “subsidiary” does not indicate a lack of importance, and therefore, the writings of the most “highly qualified publicists” in WTO law could possibly apply to the interpretation of TRIPS provisions.²⁵⁰ Thus, the Paris Convention is important for outlining the legal provisions that frame any discussion regarding the consistency of Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India in line with TRIPS.

3.3. Consistency of Section 84 with Article 5(A) of the Paris Convention

As a treaty, the Paris Convention formally recognises the right of its Members to demand as an affirmative duty that patentees work their patented inventions locally. Compulsory licences under Article 5(A) of the Paris Convention are permitted to solve the problem of failure to work or underutilised patents.²⁵¹ The reason is straightforward: because abuse means the use of rights in a way that is contrary to the objectives of the law, the notion of abuse is symbiotically linked to the very objectives that the law sets out for patents.²⁵² The TRIPS

International Court of Justice jurisprudence, and only a very small number of scholars have been cited. See Baron Descamps, *League of Nation. Procès-Verbaux of the Proceedings of the Advisory Committee of Jurist, June 16th-July 24th* (The Hague, Van Langenhuysen, 1920) 318-319, stating that the judge render decisions in keeping with the dictates of the legal conscience of civilised peoples and for this same purpose make use of the doctrines of publicists carrying authority. However, Manley Ottmer Hudson, *The Permanent Court of International Justice 1920-1942* (New York: MacMillan, 1943) 612, argues that the teachings of publicists are not rules to be applied, but sources to be resorted to for finding applicable rules. Manfred Lachs, *Teachings and Teaching of International Law. 151 Hague Recueil des Cours 161* (The Hague: Martinus Nijhoff Publishers, 1976-III) 169, stating that teachers are not legislators, nor lawmakers in international relations and therefore, teachings of the most highly qualified publicists of various nations are only subsidiary means for the determination of rules of law. See also Michael Peil, ‘Scholarly Writings as a Source of Law: A Survey of the Use of Doctrine by the International Court of Justice’ (2012) 1 *Cambridge Journal of International and Comparative Law* 3, 141.

²⁵⁰ Note that WTO/DSU Panels and Appellate Body have invoked the teachings and writings of highly qualified publicist in their reports, it does not seem to follow the ICJ’s practice of being extremely selective. See US - Measures Affecting Alcoholic and Malt Beverages (GATT B.I.S.D. 39th Supp. Jun. 19, 1992) 206, 285 citing the works of Professor John Jackson and Professor Robert Hudec. Argentina - Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items (WT/DS56/R, Nov. 25, 1997) at n.176, John H. Jackson, at n.184, Keith Highet, at n.185, Mojtaba Kazazi. India-Patent Protection for Pharmaceutical and Agricultural Chemical Products (AB-1997-5, WT/DS50/AB/R, Dec. 19, 1997) at n. 26 Frieder Roessler and Ernst-Ulrich Petersmann at n. 28, Ernst-Ulrich Petersmann, at n. 52, Ian Brownlie. EC-Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States (WT/DS26/R/USA, Aug. 18, 1997) at n.92, Philippe Sands, Armand de Mestral, and Daniel Bodansky. For further analysis see David Palmetier and Petros Mavroidis, ‘The WTO Legal System: Sources of Law’ (1998) 92 *American Journal of International Law* 3, 407-408.

²⁵¹ Ford (n 30) 957, citing the Paris Convention for the Protection of Industrial Property, July 14, 1967, reprinted in *International Treaties on Intellectual Property* (Michael Leaffer (ed.) 1999) 24, stating in Article 5(A)(3) that the problem of misuse also can be addressed by forfeiture of the patent, but only after the compulsory licences process has been attempted.

²⁵² “Refusals to Licence IP Rights” (n 19) 9. Halewood (n 18), stating that as a condition the local working requirement has:

Agreement also recognises that patent rights shall not be abused.²⁵³ The TRIPS Agreement is built on principles that are more than a century old, many of which are embodied in the Paris Convention. Consequently, almost all of the substantive provisions of the Paris Convention are incorporated by reference directly in the TRIPS Agreement.²⁵⁴

Concerning patents, the TRIPS Agreement requires that all WTO Members comply with Articles 1 through to 12 and Article 19 of the Paris Convention, in respect of Parts II, III and IV of the Agreement.²⁵⁵ Under the Paris Convention, the term “patent” is interpreted broadly to encompass all forms of patent laws created within its member nations.²⁵⁶ As a matter of principle, the Paris Convention sought to eliminate unequal treatment by any nation’s domestic laws towards foreign patent holders.²⁵⁷ Under this scope, it is important to note that the rules of international law and its general principles act in relation to, and should be interpreted against the background of other rules and principles. As a legal system, the rights and obligations under WTO law are not a random collection of norms; rather there are meaningful relationships between them.²⁵⁸

Therefore, in applying WTO jurisprudence as a functional international law, it is often necessary to determine the precise relationship between two or more rules and principles that are both valid and applicable in respect of a situation, such as the consistency of compulsory licensing for failure to work under the Paris Convention and TRIPS. Notably, the principle of

The effect of forcing foreign patentees to situate production facilities within the patent granting country. Such transfers of technology are desirable from the patent granting country’s point of view because they contribute to a variety of public policy goals such as employment creation, industrial and technological capacity building, national balance of payments, and economic independence.

²⁵³ Article 8(2), suggests that appropriate measures may be needed to prevent the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. Article 31 to deal with an anti-competitive behaviour, and Article 40 to control of anti-competitive practices in contractual licences.

²⁵⁴ WIPO Intellectual Property Handbook: Policy, Law and Use (WIPO Publication, No. 489 (E), 2n edn. 2004) para. 5.683

²⁵⁵ Article 2(1) of TRIPS.

²⁵⁶ Defining patent in Article 1(4) as including various kinds of industrial patents recognised by the laws of the countries of the Union. Stephen Bent, Richard Schwaab, David Conlin and Donald Jeffery, *Intellectual Property Rights in Biotechnology Worldwide* (Stockton Press, 1987) 400-401, noting that the definition is purposely broad to include all types of patents.

²⁵⁷ Leaffer (n 251) 17.

²⁵⁸ Conclusions of the Work of the Study Group on the Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law (International Law Commission, UN Doc A/CN.4/L.702, Jul. 18, 2006) 7, para. 14. See Andre Nollkaemper, *National Courts and the International Rule of Law* (Oxford University Press, 2012) 225. Arthur Watts, Arnold Pronto and Michael Wood, *The International Law Commission 1999- 2009: Volume IV: Treaties, Final Draft Article and other Materials* (Oxford University Press, 2010) 614.

legal harmonisation has been generally accepted as a standard such that when several norms bear on a single issue they should be interpreted as fully as possible in order to give rise to a single set of compatible requirements.²⁵⁹ This is the case where one norm assists in the interpretation of another. In the case of a conflict between the hierarchical provisions in different treaties, the latter should, to the broadest degree possible, be interpreted in a manner consistent with the former – for example, the conflicting view of Section 84 and Article 27(1) of TRIPS in relation to Article 5(A) of the Paris Convention.

The starting point is Article 31(3)(c) of the VCLT, which stipulates a requirement that when the treaty (TRIPS) is explicitly silent on the applicable law (failure to work locally as abuse of patent rights and an independent condition for granting compulsory licences) it is necessary for the interpreter to consider other treaty-based rules to arrive at a consistent meaning.²⁶⁰ This is a well-founded principle in international treaty interpretation.²⁶¹ According to Article 30(3) of the VCLT, when all of the parties to a treaty are also parties to an earlier treaty on the same subject, and the earlier treaty has not been suspended or terminated, then it applies only to the extent that its provisions are compatible with those of the later treaty.²⁶² In this situation, both the Paris Convention and the TRIPS Agreement deal with patent regimes.

Consequently, it is necessary for the interpreter, in applying any rules developed in another part of the WTO system and international law, to clarify all of the ambiguities surrounding any controversy resulting from the incompatibility of any treaty provisions, such as Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India. In so doing, it is worth noting that TRIPS also makes such a provision for the relationship between the Agreement and the incorporated Paris

²⁵⁹ Henning Grosse Russ-Khan, *Overlaps and Conflict Norms in Human Rights: Approaches of European Court to Address the Intersections with Intellectual Property Rights*. In: *RESEARCH HANDBOOK ON HUMAN RIGHTS AND INTELLECTUAL PROPERTY*, Christophe Geiger (ed.), (Edward Elgar, 2015) 75. Ian Laird, Borzu Sabahi, Frederic Sourgens, Nicholas Birch and Kabir Duggal, *International Investment Law and Arbitration 2002 in Review*. In: *YEARBOOK ON INTERNATIONAL INVESTMENT LAW AND POLICY 2012-2013*, Andrea Bjorklund, (ed.), (Oxford University Press, 2014) 196.

²⁶⁰ Article 31(3) of the VCLT maintains that in treaty interpretation: ‘There shall be taken into account, together with the context: (c) Any relevant rules of international law applicable in the relations between the parties’.

²⁶¹ “Fragmentation of International Law” (n 258) para. 20(c), stating that if the treaty is silent on the applicable law and it is necessary for the interpreter [to] apply [any] presumption [must] to look for rules developed in another part of international law to resolve the point. [Emphasis added in brackets]. *ibid.* para. 21 states that:

Such other rules are of particular relevance where parties to the treaty under interpretation are also parties to the other treaty, where the treaty rule has passed into...or where they provide evidence of the common understanding of the parties as to the object and purpose of the treaty under interpretation or as to the meaning of a particular term.

²⁶² *ibid.* para. 24.

Convention. As seen above, Article 2 of TRIPS explicitly imposes those older obligations on the future actions of the Members under the TRIPS Agreement. It stipulates that ‘Nothing in Parts I to IV of the Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention’.²⁶³ This includes all of the substantive conditions and the procedural requirements under the Paris Convention. The Paris Convention contains the terms for the regulation of compulsory licences.²⁶⁴

Article 5(A) of the Paris Convention does, however, place limitations on the extent to which members should grant compulsory licences to remedy failure to work. In other words, the possibility of granting compulsory licences under the Paris Convention is subject to a number of substantive conditions as set out in Article 5(A)(4).²⁶⁵ The Paris Convention provides a time period within which the patent holder must work the patent to avoid the granting of a compulsory licence.²⁶⁶ In other words, the Convention creates time restrictions before an application for a compulsory licence can be submitted and creates limitations regarding licences when the patentee can justify insufficient application or usage of the patent.²⁶⁷

For example, the patent holder must have sufficient time to work the patent (defined in Article 5(A)(4) and Section 84 as a period of four years from the date of filing of the patent application or three years from the date of the granting of the patent, whichever period expires last), and a compulsory licence will not be issued if the patent holder has legitimate reasons for not working the patent. However, the Members’ discretion in doing so is not limited in as much as these essential conditions are followed.²⁶⁸ The same is true under Section 86(1) of the Indian Patents Act, which orders the Controller to allow patentees to provide reasons why a patented invention could not be worked in the determination of the granting of a compulsory licence.

²⁶³ Article 2(2) of TRIPS.

²⁶⁴ Blakeney (n 73) 89, noting that Article 5A of the Paris Convention was one of the most controversial parts of the agreement.

²⁶⁵ Article 5(A)(4) of the Paris Convention.

²⁶⁶ Bent, *et al* (n 249) 401-402, finding that these were the very concepts for which developing nations did not want to provide equal treatment for foreign patent holders. Christopher Mayer, Note, ‘The Brazilian Pharmaceutical Industry Goes Walking from Impanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?’ (1998) 12 *Temple International Law and Comparative Law Journal* 2, 382, asserting the negative role of the national treatment provision in the Paris Convention allowed member nations to implement very low levels of IP protection as long as foreigners were treated similarly, thus opening the door for nations like India and Brazil to eliminate all domestic patent protection.

²⁶⁷ Article 5(A)(4) of the Paris Convention. Blakeney (n 73) 89, defining the legitimate reasons as those pertaining to legal, economic, or technical hurdles to utilising the patent.

²⁶⁸ Mercurio and Tyagi (n 76) 282.

These key provisions are important, given that the immediate exploitation of a patented invention in all countries where patents are granted for the invention is generally impossible.²⁶⁹ The idea of providing a space of four years was to allow patentees sufficient time to organise work or licence another to do so in the granting countries concerned. Nevertheless, the notion of legitimacy was contingent on domestic legal provisions rather than anything else. This, according to the interpretation of some legal scholars, did not necessarily make it easy to justify any failure on the part of the patentee not to manufacture the patented invention locally.²⁷⁰

This is based on the presumption that what constitutes “an abuse” and “failure to work” is a matter for the legislation of Members to determine.²⁷¹ Moreover, the Paris Convention did not define what the term “working” meant, and each Member could assign it a meaning that suited its national interest.²⁷² Within this spirit, Members have generally interpreted “local working” as meaning something that entails manufacturing or organising the industrial use of a patented invention in the country that issued the patent.²⁷³

Article 5(4) of the Paris Convention reinforces the notion that under international law failure to work a patented invention locally remains an example of an abuse of patent rights, and an independent condition on which WTO Members have the wider discretion to grant compulsory licences.²⁷⁴ If a historical legislative approach is considered then this will reinforce the understanding that patentees have always been under a legal obligation to exploit or manufacture their patented inventions locally in accordance with the laws of the granting country,²⁷⁵ and failure to work has been considered a *prima facie* abuse of patent rights under international law and Members have the freedom to grant compulsory licensing as the remedy of first resort.²⁷⁶

²⁶⁹ Samuel Oddi, ‘The International Patent System and Third World Development: Myth or Reality?’ (1987) 1987 *Duke Law Journal* 5, 862. See “WIPO Intellectual Property Handbook” (n 254) para. 2.141.

²⁷⁰ Reichman and Hasenzahl (n 1) 10. Ladas (n 15) 524.

²⁷¹ *id.*

²⁷² Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights (World Intellectual Property Organisation Standing Committee on the Law of Patents - Thirteenth Session: SCP/13/3, Feb. 2, 2009) 174.

²⁷³ “WIPO Intellectual Property Handbook” (n 254) para. 2.135, commenting that as a rule, the working requirement may be fulfilled through the working of the patented invention either by the owner of the patent for invention or by another entity or person under a licence contract.

²⁷⁴ Jayashree Watal, Implementing the TRIPS Agreement on Patents: Optimal Legislative Strategies for Developing Countries. In: COMPETITIVE STRATEGIES FOR THE PROTECTION OF INTELLECTUAL PROPERTY, Owen Lippert (ed.), (Fraser Institute, 1999) 111.

²⁷⁵ Reichman and Hasenzahl (1) 11.

²⁷⁶ Article 5(A)(3) of the Paris Convention.

Therefore, should a patentee fail to manufacture patented inventions or apply the processes locally then invocation of compulsory licences would be justified as per that Member State's statutory requirements.²⁷⁷ Arguably, going by this reference, it is asserted that as part of the general principles of international law applicable in dealing with the fundamental relationship between Members, TRIPS recognises the consistency of certain substantive provisions of the Paris Convention (Article 5(A) and Section 84), as the former has patently referenced failure to work a patented invention locally as an example of abuse of patent rights for which WTO Members' have the freedom to choose compulsory licences as the essential remedy of first resort.²⁷⁸

This fundamental reasoning was confirmed by the Arbitrators in the *EC – Bananas* case, which explicitly held that when TRIPS incorporates other instruments, membership of the WTO/TRIPS Agreement does not excuse compliance with one instrument's obligations at the expense of another.²⁷⁹ Therefore, it is essential to consider the scope of the obligation in Article 27(1) of TRIPS in the wider context of WTO/TRIPS in relation to the provision in Article 5(A) of the Paris Convention, incorporated into TRIPS under Article 2, as a non-derogable responsibility imposed on each Member to exercise the discretion to take legislative measures to provide for the granting of compulsory licences to prevent abuse, for example, failure to work. If this is the case, then Section 84 is consistent with TRIPS.

²⁷⁷ Ladas (n 15) 530.

²⁷⁸ Article 5(A)(3) of the Paris Convention states that:

Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

²⁷⁹ Decision of the Arbitrators, *EC - Regime for the Importation, Sale and Distribution of Bananas: Recourse to Arbitration by the European Communities under Article 22.6 of the DSU (WT/DS27/ARB/ECU, Mar. 24, 2000)* para. 149.

3.4. Consistency of Section 84 with Article 31: Substantive Conditions and Procedural Requirements for the Granting of Compulsory Licences under TRIPS

Like Section 83, Article 5(A) of the Paris Convention only gives failure to work as one example of the grounds under which members can grant a compulsory licence. The Members remain free to determine other grounds in their domestic regimes.²⁸⁰ Apart from failure to work, members may grant compulsory licences to prevent other abuses, for example refusal or unreasonable terms for contractual licences or other restrictive measures that hamper industrial development.²⁸¹ Illustrations defined in several Members' domestic patent regimes include failure to supply the national market with sufficient quantities of the patented product or demanding excessive prices for such a product.²⁸²

Moreover, compulsory licences may also be granted in cases where there is no abuse by the patent owner of his rights — for example, for reasons related to the public interest.²⁸³ Article 31 of TRIPS builds on this legal position by recognising that the use of a patented article may be allowed under national law without the authorisation of the right holder, and only sets out the conditions of such use that shall be respected without limiting the possibility or WTO Members' independence in doing so, in as much as their national law permits.²⁸⁴ Furthermore, TRIPS allows Members to make virtually all decisions regarding the granting of compulsory licences, including those concerning compensations or appeals, through administrative processes, in as much as the procedure is fair and transparent.²⁸⁵ However, the procedural requirements appear to be vague and complex.²⁸⁶

²⁸⁰ Correa (n 15) 8, observing that compulsory licences may be granted on a great variety of grounds. In India, there are broadly speaking three such grounds apart from Section 84(1) to prevent the abuse of patent rights; first, to work a related patent; (Section 91(1) second, to address cases of national emergency or extreme urgency, or for purposes of a public non-commercial use; (Section 92(1) and third, to export a pharmaceutical patent to a country with no or insufficient manufacturing capacity (Section 92A(1)). Chopra (n 161) 347-348.

²⁸¹ "WIPO Intellectual Property Handbook" (n 254) para. 5.50.

²⁸² *ibid.* 20, citing Actes de la conférence réunie à La Haye, Oct. 8 to Nov. 6, 1925 (Bureau International de L'Union, 1926) 434. *ibid.* paras. 158-177, citing Argentina, Brazil, Chile, China, France, India, Mexico and Switzerland as countries that have maintained compulsory licensing on different grounds in their patent regimes.

²⁸³ *ibid.* 10, 11 & 13, discussing that the grounds for granting compulsory licences including non-working and inadequate supply, public interests. Beier (n 13) 265. Fauver (n 11) 671. "WIPO Intellectual Property Handbook" (n 254) para. 5.51.

²⁸⁴ Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell, 4th edn. 2012) 165.

²⁸⁵ Article 31(c), 31(i), 31(j), 31(k) of TRIPS. See James Love, *Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord* (Consumer Project on Technology, prepared for the UNDP, 2001) 17.

²⁸⁶ Ho (n 29) 462. Jennifer Andrew, 'Swine Flu, Bird Flu, Sars, Oh My! Applying the Precautionary Principle to Compulsory Licensing of Pharmaceuticals Under Article 31 of TRIPS' (2011) 2011 *Michigan State Law Review* 2, 416.

Still, unlike the Paris Convention, which mentions “failure to work” as a basis for granting compulsory licences subject to the expiration of a period of four years from the date of filing of the patent application or three years from the date of the granting of the patent, the TRIPS Agreement does not specifically list the grounds that might be used to justify compulsory licensing or set any time limitations for that purpose.²⁸⁷ This means that under TRIPS, compulsory licences in the public interest can be granted without waiting for the expiration of the time limits provided for compulsory licences that relate to failure to work or insufficient working.²⁸⁸ It can be deduced from this viewpoint that the TRIPS Agreement places WTO Members in an even better legal position with regard to granting compulsory licences, as members are left with a very broad scope of action with regard to the grounds on which they can grant compulsory licences in as much as the substantive conditions and key procedural requirements are met.²⁸⁹

In this connection, India’s use of Section 84 is justified and consistent with TRIPS. Like the substantive conditions under TRIPS, the Indian Patents Act conditions the granting of compulsory licences. Section 90 sets out detailed terms and conditions regarding compulsory licences to be granted under Section 84, which are consistent with those procedural requirements enumerated in Article 31 of TRIPS. Under Section 84, the Controller, while granting a compulsory licence, is required to consider those conditions.²⁹⁰ For example, Section 84(6)(iv) is consistent with Article 31(b), which conditions the granting of a compulsory licence if the proposed user has made efforts to obtain authorisation from the right holder with reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time.

In addition, Article 31(b) of TRIPS, which is consistent with Section 92(3), also specifies that efforts to obtain a voluntary licence may be waived in the case of a national emergency or other

²⁸⁷ Daniel Gervais, *The TRIPS Agreement: Drafting Analysis and Negotiating History* (Sweet & Maxwell, 1998) 165, commenting that the fact that the grounds for issuing a compulsory licence was left open means that compulsory licensing for failure to work locally is permitted.

²⁸⁸ “WIPO Intellectual Property Handbook” (n 254) para. 5.53.

²⁸⁹ “Doha Declaration” (n 6) para. 5(b). German Velasquez and Pascale Boulet, *Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement* (Revised: WHO Doc. Reference WHO/DAP/98.9, 1999) 35. Mercurio and Tyagi (n 76) 282.

²⁹⁰ Section 84(6)(1); The nature of the invention, (2) measures already taken by the patentees or any licences to make full use of the invention, (3) ability of the applicant to work the invention to the public advantage, (4) time elapsed since the grant of the patent.

circumstances of extreme urgency or in cases of public non-commercial use. In this situation, the right holder shall, nevertheless, be notified as soon as is reasonably practicable. In a similar vein, a relevant part of Section 92(1)(i) allows any person interested to make an application to the Controller for the granting of a compulsory licence any time after the granting of the patent if the Central Government is satisfied that it is necessary that compulsory licences should be granted in situations of national emergency, circumstances of extreme urgency or in cases of public non-commercial use government use upon an official notification in the gazette.

Additionally, Article 31(c) of TRIPS is a direct reflection of the Section 90(1)(viii) provision, which requires that in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use. Also, Article 31(d) of TRIPS is consistent with Section 90(1)(iv), which maintains that such use shall be non-exclusive. Also, Article 31(e) of TRIPS is consistent with Section 90(1)(v), which denotes that the right of the licensee is non-assignable. Likewise, Article 31(f) of TRIPS is consistent with Section 90(1)(vii), which demands that the licence is granted with a predominant purpose of supply in the Indian market. Furthermore, Article 31(g) of TRIPS is consistent with Section 94(1), which postulates that any compulsory licence under Section 84 may be terminated when the circumstances that gave rise to the granting thereof no longer exist and such circumstances are unlikely to recur.

More importantly, Article 31(h), which states that the right holder shall be paid adequate remuneration in the circumstances of each case, considering the economic value of the authorisation, is consistent with Section 90(1)(i), which enjoins the Controller to settle the terms and conditions of a licence under Section 84 to secure a reasonable royalty and other remuneration for the patentee or another person beneficially entitled to the patent. Lastly, Article 31(i) of TRIPS specifies that, 'the legal validity of any decision relating to the authorisation of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member'. Similarly, Article 31(j) of TRIPS requires that 'any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member'.

In the same vein, Section 117A(2) in part provides that an appeal shall lie to the Appellate Board from any decision, order or direction of the Controller or Central Government under

Section 84. The decision of the IPAB, although final under the Patents Act,²⁹¹ is subject to judicial review under the Constitution of India.²⁹² Notably, the provisions for challenging a compulsory licence order issued by the Controller, both by way of an appeal to the IPAB under Section 117A(2), as well as by way of judicial review under the Constitution of India, are consistent with Articles 31(i) and 31(j) of the TRIPS Agreement.²⁹³

3.5. Consistency of Section 84 with the Objectives of TRIPS

Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is derived from the general principles applicable to the working of patented inventions under Section 83. The local working guiding principles express the cardinal objectives of the Indian patent system. Among these principles is Section 83(c), which is a direct replication of the objectives of TRIPS under Article 7. This proves that Section 84 is consistent with TRIPS, as both regimes have similar objectives. They stipulate that:

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 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 focus of the objectives under TRIPS and the Indian patent system become clearer when they are viewed in the light of the Preamble to TRIPS, which arguably can be viewed as a ‘condensed expression of the underlying objectives’ of the entire TRIPS Agreement.²⁹⁴ The Preamble contains the overriding values that the protection of IP laws is meant to serve, as it recognises ‘the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives’. Therefore, the consistency of any provision with TRIPS should be assessed in the light of Article 7 and of the

²⁹¹ There is no provision for further appeal against a decision rendered by the IPAB under Section under 117B.

²⁹² The constitutional validity of a decision rendered by the IPAB can be challenged by invoking the writ jurisdiction of the state High Courts under Article 226 of the Constitution of India. In similar vein, the IPAB’s decision can also be challenged before the Supreme Court of India by invoking its writ jurisdiction under Article 32 of the Constitution of India. See Harshad Pathak, ‘The Jurisdictional Dilemma Surrounding the Intellectual Property Appellate Board’ (2015) 20 *Journal of Intellectual Property Rights* 1, 54, stating that that the exercise of judicial review by the state high courts and the Supreme Court, acting under their respective writ jurisdiction, is part of the “basic structure” of Constitution of India, and therefore, a tribunal established under ordinary legislations, such as the IPAB, cannot exercise its quasi-judicial or appellate functions in a manner so as to exclude the writ jurisdiction of the state High Courts and the Supreme Court of India.

²⁹³ Chopra (n 161) 359.

²⁹⁴ Gervais (n 284) 80.

Preamble, that is, taking the balance of rights and obligations and social and economic welfare into account.²⁹⁵ Therefore, in interpreting the rights and obligations within the Agreement a WTO/DSU Panel once recognised that the Preamble text co-exists with TRIPS, and they are to be borne in mind when the substantive rules of TRIPS are being examined.²⁹⁶

Thus, the rules for the interpretation of international treaties allow for specific readings of the language to be considered for TRIPS interpretation. The WTO confirmed under Paragraph 5(a) of the Doha Declaration that in 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 fact, Article 31 of the VCLT confirms this approach in regard to the interpretation of WTO law and TRIPS. It specifies that: ‘A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose’. Article 31(2) of the VCLT provides that the ‘context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes’. The WTO Appellate Body attaches great significance to the Preamble language of TRIPS in its decisions.²⁹⁷ This is rooted in the belief that the Preamble is an indication of intention visible in the text of an Agreement.

In the *US - Shrimp* case the Appellate Body noted that: ‘preambular language reflects the intentions of negotiators of the WTO Agreement, we believe it must add colour, texture and shading to our interpretation of the agreements annexed to the WTO Agreement’.²⁹⁸ Significantly, the Preamble of the TRIPS Agreement forms part of the “context” as an element mentioned in Article 31(2) of the VCLT. In the preamble to TRIPS, Members prefaced the Agreement to the terms of IP protection with several points, disclosing the intention that Members had with regard to the rights and obligations to be followed. In coming to an agreement, the Members, through the TRIPS Preamble, considered the need to promote effective and adequate protection of IP rights, as well as developmental and technology transfer goals.²⁹⁹ Nevertheless, the so-called developmental aspects of the TRIPS Agreement can be

²⁹⁵ Correa (n 179) 104.

²⁹⁶ “United States - Continued Existence and Application of Zeroing Methodology” (n 239) para. 268.

²⁹⁷ Panel Report in Egypt - Definitive Anti-Dumping Measures on Steel Rebar from Turkey (WT/DS211/R, Aug. 8, 2002) para. 7.154.

²⁹⁸ Appellate Body Report in United States - Import Prohibition of Certain Shrimp and Shrimp Products (WT/DS58/AB/R, 12 Oct. 12, 1998) para. 153.

²⁹⁹ Correa (n 179) 343.

properly served or obtained when patent inventions are worked locally as opposed to being imported.

A patentee can achieve this by either manufacturing the product locally or by granting a licence to a third party to apply the patented invention or process in that direction. This will contribute to job creation, and has implications for economic growth, as importation alone will serve the development needs of other countries exporting the patented invention.³⁰⁰ It is worth noting that Article 7 replicates the search for a balanced approach to IP protection that considers the interests of both producers and users of technological inventions.³⁰¹ Patent protection is expected to contribute not only to the promotion of technological innovation, but also to the transfer and dissemination of technology nationally and internationally in a way that benefits both its producers and users (balance of rights and obligations) with the overall goal of promoting social and economic welfare.³⁰²

However, some have attempted to weaken this conceptual balance by arguing that the strongest possible legal protection for private rights results in the maximum public good.³⁰³ In short, they contend that stronger patent protection creates a greater incentive to innovate, which is in the public interest, and even argue against the use of TRIPS flexibilities.³⁰⁴ Article 7 of TRIPS was primarily designed to establish a definitive confirmation of the intention or purpose of Members in entering into the agreement.³⁰⁵ Article 7 should therefore carry greater weight in the process of implementation and interpretation of TRIPS.³⁰⁶ In the final report of the UK Commission on Intellectual Property Rights, it was interpreted that IPRs should be regarded ‘as instruments of public policy which confer economic privileges on individuals or institutions solely for the purposes of contributing to the greater public good’ and that the conferred privileges should be ‘a means to an end, not an end in itself’.³⁰⁷

³⁰⁰ Halewood (n 18) 246.

³⁰¹ Correa (n 179) 343.

³⁰² “Egypt - Definitive Anti-Dumping Measures” (n 297) para. 7.154.

³⁰³ Fauver (n 11) 676, explaining that compulsory licences reduce the inventor’s incentive to develop new technology.

³⁰⁴ “Canada – Patent Protection of Pharmaceutical Products” (n 68) para. 5.33, argument by the US as a third party. Epstein and Kieff (n 11) 92.

³⁰⁵ *id.*

³⁰⁶ *ibid.* 123-124.

³⁰⁷ Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (Report of the Commission on Intellectual Property Rights, 2002) 7. Marco Ricolfi, ‘Is There an Antitrust Antidote Against IP Overprotection Within TRIPS?’ (2006) 10 *Marquette Intellectual Property Law Review* 3, 326.

Such an emphasis is important, because interest groups often lose sight of the basic mission of the WTO, which, as stated in the Preamble of the WTO Agreement, is to preserve the basic principles and to further the objectives underlying the multilateral trading system to promote trade and economic development, not to protect the interests of particular private IPR-holding interest groups.³⁰⁸ Additionally, the legal effect in the reference to social and economic welfare, and to a balance of rights and obligations, could serve to justify exceptions to exclusive rights where the right holder has failed to participate in social and economic development. In fact, there is a strong case for the obligations in TRIPS to be considered as important as the rights provided in the Agreement - an argument that some scholars continue to make with respect to exceptions.³⁰⁹ In other words, where the patentee uses his/her rights without performing his obligations, particularly failure to work the patented invention locally as a means of satisfying the reasonable requirements of the public, then compulsory licences will be justified.³¹⁰

Thus, without the compulsory licensing mechanism under Article 31 of TRIPS there would be no other reasonable instrument consistent with the Agreement that could ensure that patentees meet the developmental objectives of TRIPS.³¹¹ As the Appellate Body in the *EC – Hormones* case noted: ‘We cannot lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome, obligation’.³¹² Furthermore, Paragraph 19 of the Ministerial Declaration in part states explicitly that the work of the TRIPS Council shall be guided by the objectives set out in Article 7 of TRIPS and shall take into account fully the development dimension.³¹³ Thus, to some extent, Article 7 of TRIPS paves the way for India to defend the usage of compulsory licensing to restore the balance of the global IP system, given that it is often the users of technologies manufactured abroad that entail high costs and shortages.³¹⁴ This may lead a Panel to take a longer look at how these provisions

³⁰⁸ “Resource Book on TRIPS” (n 16) 10.

³⁰⁹ James Boyle, *Shamans, Software and Spleens: Law and the Construction of the Information Society* (Harvard University Press, 1996) 138, noting that exceptions and limitations are just as important as the grant of the right itself. Peter Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (2009) 46 *Houston Law Review* 4, 1007.

³¹⁰ Gervais (n 284) 116. Correa (n 179) 97.

³¹¹ Olasupo Ayodeji Owoeye, ‘Compulsory Patent Licensing and Local Drug Manufacturing Capacity in Africa’ (2014) 92 *Bulletin of the World Health Organisation* 3, 214, stating that compulsory licensing is a practical way of preventing the abuse of patent rights.

³¹² Decision by the WTO Appellate Body in *EC - Measures Concerning Meat and Meat Products (Hormones)*, [Original Complaint by the United States, Recourse to Arbitration by the EC Under Article 22(6) of the DSU] (WT/DS26/ARB, Jul. 12, 1999) para. 165, footnote 154.

³¹³ World Trade Organisation, Doha Ministerial Declaration. WT/MIN(01)/DEC/1; 41 ILM 746 (2002), adopted on Nov. 14, 2001.

³¹⁴ Correa (n 179) 99. Yu (n 309) 1005.

should be interpreted in the context of the Agreement as a whole, especially with respect to the need for “balance”.³¹⁵ As the TRIPS Resource Book declares:

Article 7 makes clear that TRIPS negotiators did not mean to abandon a balanced perspective on the role of intellectual property in society. TRIPS is not intended only to protect the interests of right holders. It is intended to strike a balance that more widely promotes social and economic welfare.³¹⁶

3.6. Consistency of Section 84 with the Principles of TRIPS

Within the framework of Section 84 lies the legislative intent of the Indian patent regime to promote the reasonable requirement of the public, which is central to the general principles applicable to the working of patented inventions in the territory of India as a principal foundation of the Indian patent regime. The general principles applicable to the working of patented inventions under Section 83 merely provide the guiding principles for the granting of compulsory licensing under Section 84 if the reasonable requirement of the public is not satisfied. Importantly, Section 84(7)(e) defines the circumstances in which the law deems the reasonable requirement of the public not to have been met. According to this substantive provision the reasonable requirement of the public is deemed not to have been met when the working of a patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article.

Notably, Article 8 of TRIPS also lays out the normative public interest principles of the TRIPS Agreement.³¹⁷ Article 8 of TRIPS echoes the Agreement’s Preamble, which recognises the special needs of certain Members in respect of maximum flexibility in the domestic implementation of laws in order to enable them to create a sound and viable technological base.³¹⁸ In this direction, Article 8(1) of TRIPS is important in limiting the potential scope of violation or impairment provisions to patentable subject matter, as it makes clear that a wide range of public policy measures should be reasonably expected when Members amend their national laws to protect public health.³¹⁹ This provision allows Members, when formulating or amending their patent regimes, to adopt TRIPS consistent measures to accommodate the

³¹⁵ Gervais (n 284) 120.

³¹⁶ “Resource Book on TRIPS” (n 16) 126.

³¹⁷ Abdulqawi Yusuf, *TRIPS: Background, Principles and General Provisions*. In: *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT*, Carlos Correa and Abdulqawi Yusuf (eds.), (Kluwer Law International, 2nd edn. 2008) 13-15, discussing extensively the public interest principle of TRIPS.

³¹⁸ Yu (n 309) 1008.

³¹⁹ Correa (n 179) 108.

protection of public health and sectors of vital importance in their socio-economic and technological development.

It is significant that Article 8 of TRIPS does not refer to laws and regulations on IPRs at the international level but national measures that are required to serve the public interest. Coherent with Article 8 of TRIPS, India followed this autonomy and enacted its patent law to accommodate several key principles that aimed to promote the public interest. It dubbed these: “The reasonable requirement of the public”. Remarkably, given that public health is explicitly mentioned in Article 8(1) of TRIPS as one of the exceptions that requires necessary measures worth protecting, India included the principle that ‘patents granted do not impede protection of public health and nutrition and should act as an instrument to promote the public interest especially in sectors of vital importance for the socio-economic and technological development of India’.³²⁰

In EC — Trademarks and Geographical Indications, in the course of explaining why the TRIPS Agreement did not contain a general exceptions provision, the Panel referred to the principles of the Agreement set out in Article 8(1):

These principles reflect the fact that the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement.³²¹

This makes Section 84, which allows the granting of a compulsory licence provided that the reasonable requirements of the public with respect to the patented invention have not been satisfied, consistent with Article 8 of TRIPS, where failure to work any pharmaceutical patents in the territory of India affects the commercial or industrial development of the pharmaceutical sector, which is of vital importance to India.³²² Moreover, within its public policy goal to

³²⁰ Section 83(d).

³²¹ Panel Reports in EC – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs (US), WT/DS174/R, Mar. 15, 2005, para. 7.210, and (Australia), para.7.246.

³²² Resource Book on TRIPS (n 16) 126-127, arguing that Article 8(1) measures adopted by members to address public health, and matters of vital socio-economic importance should be presumed to be consistent with TRIPS, and that any member seeking to challenge the exercise of discretion should bear the burden of proving inconsistency. See also Henning Grosse Ruse-Khan, ‘A Comparative Analysis of Policy Space in WTO Law’ (Max Planck Institute for Intellectual Property, Competition & Tax Law, Research Paper Series No. 08-02, 2008) 36-38, suggesting the difficulty in reversing the burden of proof as proposed by “The UNCTAD-ICTSD Resource Book on TRIPS and Development”.

protect public health, the Indian patent regime provided for another principle, which maintains that ‘patents granted do not in any way prohibit Central Government in taking measures to protect public health’.³²³ In this context, Section 84 is highly relevant to public health because it allows the government to potentially intervene if a patent holder refuses to work a patent locally and allow the generic manufacture of essential pharmaceuticals.³²⁴

Furthermore, it is significant that Article 8 of TRIPS allows Members, when formulating or amending their laws and regulations, to adopt appropriate measures consistent with TRIPS to prevent the abuse of IPRs by right holders, or when they have resorted to practices that unreasonably restrain trade or adversely affect the international transfer of technology.³²⁵ In the light of this, it is also arguable that Article 8(1) of TRIPS allows the granting of compulsory licences on the grounds of lack of local working, or when such failure undermines the promotion of the public interest norm for the granting of patent rights, that is, to promote the legitimate interest of the public.³²⁶ This is significant especially when a failure to work, which international patent law under Article 5(A) of the Paris Convention recognises as an abuse of patent rights, additionally results in significant consequences for the public interest such as high costs and shortages of essential medicines required to protect public health.

Consistent with Article 5(A) of the Paris Convention, Article 8 of TRIPS recognises as a major principle the need to prevent abuse of patent rights, and makes the measures required to do so a matter of national public policy. Thus, the context, given the textual correlation of Section 84 with Article 5(A) of the Paris Convention, which is inclusively referenced in Article 2 of TRIPS, and carefully following Article 8 of the TRIPS provision, which is consistent with the reasonable requirement of the public under Section 83 of the Indian Patents Act, casts serious

³²³ Section 83(e).

³²⁴ Section 93: Special provision for compulsory licences on notifications by Central Government. See also Mercurio and Tyagi (n 76) 284.

³²⁵ Note that the Panel in *Canada - Patent Protection of Pharmaceutical Products* case did not pay sufficient attention to the interpretation of Articles 7 and 8 of TRIPS because it was “unnecessary for the purposes of the present case to determine the precise scope of Article 8”. However, it was noted that “it was essential that it not be rendered meaningless”....”as societal interests identified in Article 8 could be protected by measures that met the standards of Article 30”. Moreover, it was considered that Article 30 was the vehicle by which Members were able to give effect to the societal values referred to in Article 7 of TRIPS. That is, the legitimate interests of third parties were ascertained, *inter alia*, by reference to the societal interests mentioned in the TRIPS Agreement itself, including the first recital of the Preamble and Article 7, as well as Article 8. Thus, public policy considerations were highly relevant to the determination of what was “consistent with the provisions of this Agreement”. See “*Canada - Patent Protection of Pharmaceutical Products*” (n 68) 71, para. 4.37(a).

³²⁶ Mercurio and Tyagi (n 76) 281, noting that the traditional view of patent rights is as instruments of public policy that confer economic privileges on individuals solely for the purpose of contributing to the greater public good.

doubt on any conflicting interpretation that urges us to assume that Section 84 is inconsistent with TRIPS. This viewpoint is further strengthened as Article 8(2) of TRIPS only provides recognition that appropriate measures may be needed to prevent abuse of patent rights. It does not specifically stipulate what constitutes an abuse of IP rights, nor does it define the legal basis of what would generally constitute an abuse of patent rights, unlike Article 5(A)(2) of the Paris Convention, which provides failure to work as an example.

Furthermore, the Agreement does not provide a definition of the kind of appropriate measure deemed reasonable for Members to use to prevent such abuses. This is left to the discretion of Members' interpretation or domestic statutory provisions to determine.³²⁷ In fact, it is not evident anywhere in TRIPS, nor can it be constructively inferred from any provision in TRIPS, that the Agreement prevents Members from granting compulsory licences if a patented invention is abused, or if a product is not worked or a process is not used within the territory of protection. In this regard, India introduced into its patent regime a consistent principle similar to those enumerated under Article 8(2) of TRIPS, which stipulates that the patentee should not abuse the patent right or must not resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.³²⁸

Recognising that abuse of patent rights, as exemplified by failure to work locally, could lead to excessive importation and its attendant effects of high costs and shortages, Section 83(b) provides that patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. To mitigate the potential high costs of patented inventions that can undermine the public interest, Section 84(1)(b) stipulates that 'patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public'.³²⁹ Moreover, where non-working or insufficient working in the territory of India is being prevented or hindered by the importation from abroad of the patented article,³³⁰ and this further results in insufficient supply of appropriate quantities, considerations of public health support the granting of a compulsory licence when the situation seriously compromises the country's needs to avoid unreasonably high prices and shortages of essential medicines.³³¹

³²⁷ Graeme Austin, 'The Role of National Courts: Valuing "Domestic Self-Determination" in International Intellectual Property Jurisprudence' (2002) 77 *Chicago-Kent Law Review* 3, 1193-1194.

³²⁸ Section 83(f).

³²⁹ See also Section 83(g).

³³⁰ Section 84(7)(e).

³³¹ Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use (Part I) (Twenty-First Session of WIPO Standing Committee on the Law of Patents, SCP/21/4 REV. Nov. 3, 2014) 3, para. 9.

Therefore, Article 8 of TRIPS becomes even more important in the light of the ambiguities built into Article 27(1) of TRIPS, which only prohibits discrimination based on the place of invention, the field of technology and whether products are imported or locally produced. More importantly, there is no reasonable basis to say that WTO Members have the right only to grant and enforce exclusive patent rights without the discretion to prevent any abuse of the same. All things considered, the granting of compulsory licences to prevent abuse typified by failure to work in the exercise of patent rights would not amount to an unjustified detriment to patentees or constitute a material breach of Article 27(1) of TRIPS, when as a matter of fact Article 8(2) of TRIPS strengthens Members' discretion to adopt appropriate measures to prevent the abuse of patent rights.³³² It follows logically that just as Members remain under obligations pursuant to Article 27(1) of TRIPS to grant and enforce patent rights, they have inherent discretion to prevent abuses that may arise from the exercise of the granted rights. The Doha Declaration confirms this deductive reasoning. It has been confirmed that the principles of the TRIPS Agreement should be taken into account in its interpretation.³³³

With Article 27(1) of TRIPS in mind, the members affirmed that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. According to Reichman, 'if interpreted properly, Article 8 of TRIPS and its accompanying clauses, together with the Doha Declaration, would legitimise the *ad hoc* exceptions required by overriding national needs, such as compulsory licensing for public health protection'.³³⁴ This argument gains more strength, as notably the provision uses the term "public interest".³³⁵ Therefore, if within the fundamental justification of that Member such a reasonable measure can prevent the abuse of patent rights, TRIPS will not completely forbid that Member from granting a compulsory licence in that direction.³³⁶ This confirms the

³³² 'A Preliminary Report on How Competition Policy Addresses the Exercise of Intellectual Property Rights' (TD/B/COM.2/CLP/10, UNCTAD, 1999) para. 28. See 'The TRIPS Agreement and Developing Countries' (UNCTAD/ITE/1, UNCTAD, United Nations Publication, Sales No. 96.II.D.10, 1996) 284-285, explaining the principle behind member states, inability to differentiate between the fields of technology and whether products are imported or locally produced.

³³³ "Doha Declaration" (n 6) para. 5(a) reads:

In 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.

³³⁴ Jerome Reichman, 'From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement' (1997) 29 *New York University Journal of International Law and Politics* 1- 2, 35.

³³⁵ Yu (n 309) 1011.

³³⁶ "Resource Book on TRIPS" (n 16) 546, stating that Article 8 only states a principle rather than a specific rule and mirror the intention of the treaty-makers to leave members broad discretion as regards its implementation.

hypothesis that Sections 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is consistent with TRIPS, and therefore it would provide a suitable model for Ghana.

3.7. Conclusion

This chapter has drawn on applicable sources of law and interpreted them and has arrived at the conclusion that Section 84 is consistent with TRIPS. The analysis has focused on some key provisions under the Paris Convention, the Indian Patent Act and the TRIPS Agreement, which share common drafting structures, legislative intents and substantive treatment of key subject matters pertaining to the principles applicable to the working of patented inventions and the granting of compulsory licences. The analysis has reconciled Section 84, which has a textual correlation with Article 5(A) of the Paris Convention, the latter having been incorporated into TRIPS under Article 2. Importantly, the analysis has revealed that the Indian patent regime has incorporated almost all of the substantive conditions and requirements developed under Article 31 of TRIPS to be followed when using Section 84.

Moreover, the objective of TRIPS in Article 7, which is also captured in the Preamble, and its principles under Article 8 have been reconciled with Section 84 concerning the reasonable requirement of the public, which is directly derived from the general principles applicable to the working of patented inventions in India. Central to this overarching principle is an obligation on the part of patentees to work their patented inventions locally or licence another to do so in India in order to achieve the technology transfer obligation of patentees to promote social welfare and developmental needs. More importantly, upon careful reading, one can easily infer that the reasonable requirement of the public under Section 84 is consistent with the principles of TRIPS.

Article 8 of TRIPS allows Members to prevent the abuse of IPRs by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology, protect public health, and promote the public interest in sectors of vital importance to their socio-economic and technological development. Therefore, in the implementation of public health objectives, one situation of abuse of rights could be, for instance, the practice of excessively high import prices of patented pharmaceutical products. This makes India's decision to use Section 84 in granting a compulsory licence to Natco based on the reasonably

affordable requirements justified and consistent with TRIPS. The next chapter argues that Article 27(1) of the TRIPS Agreement would not prohibit WTO Members from adopting and implementing any local working requirements that follow the Indian model in Section 84.

Chapter 4

Section 84: Non-Discrimination, Article 27 of the TRIPS Agreement and the Local Working Requirement

4.1. Aim of the Chapter

This chapter aims to examine whether Article 27(1) of the TRIPS Agreement would prohibit Ghana from implementing any local working requirements. The chapter argues that Article 27(1) of the TRIPS Agreement would not prohibit Ghana and other WTO Members from adopting and implementing any local working requirements that follow the Indian model in Section 84.

4.2. Introduction to the Chapter

As seen from above, Section 84 of the Indian Patents Act is consistent with TRIPS. Nevertheless, Article 27(1) of TRIPS, provides broad subject matter scope for patent protection, extending to products and processes in all fields of technology.³³⁷ It also provides that for example Ghana and other WTO Members shall not “discriminate” with respect to the enjoyment of patent rights based on the place of invention, and whether products are imported or locally produced.³³⁸ The main impact of the non-discrimination clause under Article 27 of TRIPS has probably been in the area of compulsory licensing for failure to work.³³⁹ However, Article 5A of the Paris Convention expressly authorises, on certain conditions, compulsory licensing for failure to work patents locally.³⁴⁰ Nevertheless, the TRIPS Agreement does not contain such a clear and express authorisation, except that Article 5(A) of the Paris Convention is incorporated into TRIPS under Article 2.

The interface between Article 27(1) of TRIPS and Article 5(A)(2) of the Paris Convention clearly causes legal complications, in that where the legislation of countries follows Article 5(A)(2) of the Paris Convention, it is difficult to reconcile with Article 27(1) of the TRIPS Agreement.³⁴¹ The most restrictive interpretation of Article 27(1) of the TRIPS provision is

³³⁷ “Resource Book on TRIPS” (n 16) 368.

³³⁸ Donald Harris, ‘The Power of Ideas: The Declaration of Patent Protection and New Approaches to International Intellectual Property Lawmaking’ (2016) 16 *UC Irvine Law Review* 3, 350.

³³⁹ “Resource Book on TRIPS” (n 16) 373.

³⁴⁰ Article 5(A)(4) of the Paris Convention.

³⁴¹ Cottier, *et al* (n 66) 439.

that ‘discrimination means any form of differential treatment’.³⁴² Some scholars implicitly endorse an interpretation that Article 27(1) of TRIPS would prohibit the imposition of local working,³⁴³ thereby rendering Section 84, which allows India the right to grant a compulsory licence provided that the patented invention has not been worked in the territory of India, inconsistent with TRIPS.

The argument is that Article 27(1) of TRIPS prohibits Ghana and other WTO Members from treating patentees in one field of technology unfavourably relative to patentees in all other fields of technology.³⁴⁴ It seems that the concept of “non-discrimination” is the one stimulating this interpretation and thus creating much tension with regard to its possible negative application to Ghana and similarly situated WTO Members.³⁴⁵ What follows is that often the right of Ghana and other WTO Members to impose local working has been questioned as potentially in conflict with Article 27(1) of TRIPS because such a measure would impair the patent rights enjoyable by patentees, particularly holders of pharmaceutical patents.³⁴⁶ However, some scholars have rejected any strict interpretation of Article 27(1) of TRIPS as potentially prohibiting WTO Members completely from the imposition of local working requirements.³⁴⁷

Remarkably, the non-discrimination provisions in Article 27(1) are the subject of a WTO Panel report in Canada – Patent Protection of Pharmaceutical Products.³⁴⁸ However, it should be

³⁴² Maria Victoria Stout, ‘Crossing the TRIPS Nondiscrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate TRIPS Article 27.1’ (2008) 14 *Boston University Journal of Science & Technology Law* 2, 180.

³⁴³ Bonadio (n 53) 720, stating the ruling might be a violation of Article 27(1) of TRIPS, which precludes India, as a Party to the Agreement, from discriminating between patented products that are imported and those that are locally produced. Jonathan Michael Berger, ‘Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity’ (2002) 17 *Connecticut Journal of International Law* 2, 119. Bryan Mercurio, ‘The Impact of the Australia–United States Free Trade Agreement on the Provision of Health Services in Australia’ (2005) 26 *Whittier Law Review* 4, 1094, observing that ‘the International Federation of Pharmaceutical Manufacturers (IFPMA) felt that the amendments violated the TRIPS Agreement by discriminating against pharmaceutical patent holders and dissuading holders from seeking to protect and enforce their rights’. The IFPMA has reiterated that the provisions violate “the spirit, if not the letter” of Article 27 of TRIPS, which requires members to make patent rights available and enjoyable without discrimination as to the field of technology, and Article of TRIPS, which requires that procedures for promoting patents not be “unnecessary complicated or costly”. See Daniel Pruzin, ‘Global Pharmaceutical Group Slams Amendments to U.S.-Australia FTA’ (2004) 21 *International Trade Representative* 43, 1762.

³⁴⁴ *id.*

³⁴⁵ Beier (n 13) 259-260, finding that majority of patent laws in developed countries permit compulsory licences, but stressing that actual grants of such licences remain rare.

³⁴⁶ Laurence Helfer, ‘Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Law-making’ (2004) 29 *Yale Journal of International Law* 1, 41.

³⁴⁷ Watal (n 274) 111. Correa (n 15) 10. Mercurio and Tyagi (n 76) 282.

³⁴⁸ “Canada – Patent Protection of Pharmaceutical Products” (n 68).

noted here that the Panel in that case made clear that “discrimination” in Article 27(1) of TRIPS is an unhelpful term that means something other than “differentiation”.³⁴⁹ Since the WTO Panel’s rejection of the strict interpretation of Article 27(1), prohibiting any differentiation between fields of technology,³⁵⁰ the more accepted view is that “discrimination” must be distinguished from differentiation for legitimate reasons.³⁵¹ It is therefore argued that Article 27(1) of the TRIPS Agreement would not prohibit Ghana from adopting and implementing any local working requirements that follow the Indian model in Section 84. This argument is enhanced by the fact that India invoked Section 84 in granting a compulsory licence to Natco and to date the inconsistency of this decision with TRIPS, specifically against the non-discrimination principle under Article 27(1), remains unchallenged within the WTO DSU system.

4.3. Non-Discrimination and Article 27(1) of TRIPS

The requirement that patent rights shall be available and enjoyable without discrimination as to the field of technology follows from the general rule of patentability contained in the first sentence of Article 27(1).³⁵² This second sentence, however, adds an important element - the law cannot discriminate in its treatment of different fields, both in terms of availability of rights and capacity to enjoy them.³⁵³ The TRIPS Agreement does not contain provisions that specifically address working requirements. But some scholars have implicitly endorsed the “non-discrimination” provision in Article 27(1) as prohibiting the imposition of working

³⁴⁹ Dispute Settlement: World Trade Organisation. 3.14, TRIPS (New York & Geneva, UNCTAD, UNCTAD/EDM/Misc.232/Add.18, 2003) 19, para. 2.6.3.

³⁵⁰ “Canada – Patent Protection of Pharmaceutical Products” (n 68) para. 7.94, interpreting “discrimination” in Article 27(1) of TRIPS to mean “the unjustified imposition of differentially disadvantageous treatment,” not mere differentiation (emphasis added). Frederick Abbott, ‘Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism’ (2005) 8 *Journal of International Economic Law* 1, 85.

³⁵¹ Carlos Correa, ‘Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses (2004) 26 *Michigan Journal of International Law* 1, 344, commenting that, it is to be noted that differentiation in legal treatment is not the same as discrimination, and that WTO members can adopt different rules for particular areas, provided that the differences are adopted for bona fide purposes. Thomas Cottier, ‘From Progressive Liberalization to Progressive Regulation in WTO Law’ (2006) 9 *Journal of International Economic Law* 4, 796 see note 43 positing that ‘The general principle of equal treatment . . . requires that comparable situations not be treated differently and different situations not be treated alike unless such treatment is objectively justified’. Graeme Dinwoodie and Rochelle Dreyfuss, ‘Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement’ (2007) 13 *Michigan Telecommunication and Technology Law Review* 2, 452, suggesting that those defending an exclusion as compliant with Article 27 should be permitted to rebut a showing of disparate treatment by demonstrating a legitimate purpose.

³⁵² “Resource Book on TRIPS” (n 16) 368.

³⁵³ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of Article 27 and importantly Article 30 permissible exception.

requirements;³⁵⁴ therefore, Ghana and other WTO Members must accept importation as satisfying the working requirement.³⁵⁵

If literally interpreted, it seems that the local working requirement argument has no basis in the TRIPS Agreement, as Article 27(1) of TRIPS has the potential to alter the right of Ghana and other WTO Members to invoke compulsory licences for failure to work patents locally.³⁵⁶ A strict interpretation along this line would suggest that patentees can satisfy local working requirements by importation alone, and that they are not under any legal obligation to produce or apply their patented inventions locally in the patent granting country.³⁵⁷ Under this interpretation, the TRIPS Agreement, with its principle of non-discrimination, will work to repudiate working requirements in Ghana that follow the Indian model in Section 84.³⁵⁸

Accordingly, the so-called “without discrimination” as to the place of invention, the field of technology and whether products are imported or locally produced under Article 27(1) will seek to diminish compulsory licensing for non-working to the extent that TRIPS no longer serves to guarantee the transfer of anything but finished commodities produced from patents irrespective of the granting jurisdictions involved.³⁵⁹ Therefore, limiting the rights of a patentee who engages in importation rather than locally producing his patented invention might be considered an example of discrimination relating to importation within the meaning of Article 27(1) of TRIPS.

Based on this elementary view, some scholars have interpreted the non-discrimination norm in Article 27(1) as requiring patents to be worked for example, in India to be defined as made available in the country including through imports, rather than a direct manufacturing of the patented products or applying the patented processes thereof in India that grants the patent.³⁶⁰

³⁵⁴ Graeme Dinwoodie and Rochelle Dreyfuss, *A Neofederalist Vision of TRIPS: The Resilience of The International Intellectual Property Regime* (New York, Oxford University Press, 2012) 43.

³⁵⁵ Gervais (n 284) 433. Carvalho (n 106) 317. Cottier, *et al* (n 66) 460.

³⁵⁶ Graeme Dinwoodie, ‘The Architecture of the International Intellectual Property System’ (2002) 77 *Chicago-Kent Law Review* 3, 1004, observing that the institutional effect of TRIPS has surely altered the character of international IP relations.

³⁵⁷ Halewood (n 18) 249. Michael Doane, ‘TRIPS and International Intellectual Property Protection in an Age of Advancing Technology’ (1994) 9 *American University Journal of International Law and Policy* 2, 479.

³⁵⁸ Gustavo Ghidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law* (Cheltenham: Edward Elgar Publishing Limited, 2010) 250-251. Carvalho (n 106) 285.

³⁵⁹ Halewood (n 18) 247.

³⁶⁰ Adelman and Badia (n 62) 517.

Under this view, Ghana would be obliged to establish a “one-size-fits-all” patent regime³⁶¹ that does not treat patents protecting medicines any differently than those protecting other inventions.³⁶²

Arguably, the reasoning underlining this claim is that Article 27(1) of TRIPS would treat both locally manufactured and imported patented products in India the same way. Therefore, local working requirements that treat patentees in one field of technology (pharmaceutical patents) unfavourably, or unjustifiably disadvantage certain patentees, remain discriminatory relative to patentees in all other fields of technology.³⁶³ Moreover, critics of patent working requirements often point to the fact that local working requirements are rarely enforced, and therefore Ghana and other WTO Members have implicitly accepted that importation satisfies an obligation to work patented inventions locally.³⁶⁴

Remarkably, the interpretation in the sense that the working of a patent can be satisfied by importation is likely to have led many countries to consider importation as equivalent to local production for the purposes of working an invention.³⁶⁵ Indeed, over the years, many WTO Members have changed their domestic patent legislation by restricting their use of compulsory licences on the grounds of failure to work locally.³⁶⁶ These include Canada, which amended its domestic law to eliminate differential treatment for inventions made in the country with regard to compulsory licences.³⁶⁷

Some courts have also decided that the non-discrimination principle offends local working requirements. For example, the European Court of Justice in the *Commission v Italy* case held that the working requirements of a Member State of the European Union (EU) are satisfied by the importation of products manufactured in another member state of the EU.³⁶⁸ On this basis, some scholars argue that for example, Ghana and other WTO Members have forfeited, or severely limited, their ability to invoke the local working requirement mechanism to mitigate

³⁶¹ Berger (n 343) 200, mentioning food, mechanical devices or software.

³⁶² Robert Bird, ‘Defending Intellectual Property Rights in the BRIC Economies’ (2006) 43 *American Business Law Journal* 2, 346.

³⁶³ Carvalho (n 55) 198.

³⁶⁴ Richard Reik, ‘Compulsory Licensing of Patents’ (1946) 36 *American Economic Review* 5, 815.

³⁶⁵ Cottier, *et al* (n 66) 438.

³⁶⁶ Halewood (n 18) 245, citing Canada, China, India, Mexico, New Zealand and Thailand.

³⁶⁷ Reichman and Hasenzahl (n 1) 19.

³⁶⁸ *Commission of the European Communities v Italian Republic*. - Article 30 of the EEC Treaty - Patent - Compulsory licence. - Case C-235/89 (Judgment of the Court of 18 February 1992) para. 27.

the abuse of patent rights resulting from the non-working of patented products.³⁶⁹ Notably, some complaints have been made alleging violation of the non-discrimination principle under Article 27(1) of TRIPS in the WTO DSU system.³⁷⁰ Significantly, this ambiguity came to a head in the *Canada - Patents Products* case.³⁷¹

4.4. Non-Discrimination and Article 27(1) of TRIPS: Canada - Patent Protection of Pharmaceutical Products' Case

On 19 December 1997, the EU and their Member States requested consultations with Canada under the DSU³⁷² alleging that some provisions of Canadian patent law violated TRIPS obligations.³⁷³ The focus of the EU's complaint was the generic pharmaceutical sector. The EU contended, *inter alia*, that under Canadian law, patent rights were not enjoyable without discrimination as to the field of technology within the meaning of Article 27(1) of TRIPS, which requires patents to be available and patent rights to be enjoyable without discrimination as to the field of technology.³⁷⁴

In this case, the Panel had to consider whether Canada's regulatory review exception was inconsistent with Article 27(1) of TRIPS in the sense of discriminating with respect to the field of technology.³⁷⁵ However, it refused to provide a general definition of what "discrimination" meant. It argued that:

In considering how to address these conflicting claims of discrimination, the Panel recalled that various claims of discrimination, *de jure* and *de facto*, have been the

³⁶⁹ Adam Bierylo, 'Importing Doesn't Work: Justifying Local Working Requirements through a Historical, Theoretical, and Contractual Perspective' (2013) 3 *Western Journal of Legal Studies* 1, 4.

³⁷⁰ For example, see *South Africa — Anti-Dumping Duties on Certain Pharmaceutical Products from India* (G/L/451; G/TBT/D/24; WT/DS233/1, May 30, 2001).

³⁷¹ "Canada - Patent Protection of Pharmaceutical Products" (n 68).

³⁷² *Canada - Patent Protection of Pharmaceutical Products - Request for Consultations by the European Communities* (WTO Docs. G/L221:IP/D11; WT/DS114/1, Jan. 12, 1998).

³⁷³ Note that measure at issue in this dispute is the conformity of "regulatory review provision" found in Section 55(2)(1) and the "stockpiling provision" in Section 55(2)(2) of [Canada's Patent Act, R.S.C., 1985, c. P-4] that allowed stockpiling and regulatory review of pharmaceutical products, without the consent of the patent holder prior to the expiration of the patent term. It was alleged by the EC that this treated the pharmaceutical industry in a discriminatory manner, contrary to Articles 27(1) and 28 of TRIPS. Canada pleaded that the law was a permissible exception under Article 30. See Mohamed Omar Gad, *TRIPS Dispute and Developing Country Interests*. In: *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT*, Carlos Correa and Abdulqawi Yusuf (eds.), (Alphen, aan den Regin, Kluwer Law International, 2nd edn., 2008) 365.

³⁷⁴ "Canada - Patent Protection of Pharmaceutical Products" (n 68) para. 4.2-3, 7.85. Fredrick Abbott, *Intellectual Property Rights in World Trade*. In: *RESEARCH HANDBOOK IN INTERNATIONAL ECONOMIC LAW*, Andrew Guzman and Alan Sykes (eds.), (Cheltenham, Edward Elgar, 2007) 468.

³⁷⁵ *ibid.* Abbott, 470.

subject of legal rulings under GATT or the WTO.³⁷⁶ These rulings have addressed the question whether measures were in conflict with various GATT or WTO provisions prohibiting variously defined forms of discrimination. As the Appellate Body has repeatedly made clear, each of these rulings has necessarily been based on the precise legal text in issue, so that it is not possible to treat them as applications of a general concept of discrimination.³⁷⁷

Given the very broad range of issues that might be involved in defining the word “discrimination” in Article 27(1) of the TRIPS Agreement, the Panel decided that it would be better to defer an attempt to define the term at the outset, and instead determine which issues had been raised by the record before the Panel, and define the concept of discrimination to the extent necessary to resolve those issues.³⁷⁸

Here, the primary TRIPS provisions that deal with discrimination, such as the national treatment and most-favoured-nation provisions of Articles 3 and 4, do not use the term “discrimination”³⁷⁹ but speak in more precise terms. The ordinary meaning of the word “discriminate” is potentially broader than these more specific definitions. It certainly extends beyond the concept of differential treatment.³⁸⁰

Importantly, in explaining its understanding of the term “without discrimination” in Article 27(1) of TRIPS, the Panel advised against using the term “discrimination” whenever “more precise standards are available”, given the potentially “infinite complexity” of the term.³⁸¹ “Discrimination”, when employed, is a term to be interpreted with caution, and with care, so as not to add more precision than the concept contains.³⁸² The Panel pointed out that Article 27(1) of TRIPS refers to “discrimination” regarding the field of technology, which is a pejorative term.³⁸³

Discrimination may arise from explicitly different treatment, which is sometimes called “de jure discrimination”, but it may also arise from ostensibly identical treatment, which, due to

³⁷⁶ For example, see “Japan — Taxes on Alcoholic Beverages” (n 246); European Communities – Regime for the Importation, Sale and Distribution of Bananas (WT/DS27/AB/R Nov. 17, 1997); see “EC - Measures Concerning Meat and Meat Products (Hormones)” (n 312); United States - Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R, Nov. 6, 1998).

³⁷⁷ “Canada - Patent Protection of Pharmaceutical Products” (n 68) para. 7.98.

³⁷⁸ *id.*

³⁷⁹ *ibid.* para. 7.94.

³⁸⁰ *id.*

³⁸¹ *ibid.* paras. 7.94 and 7.98.

³⁸² *ibid.* para. 7.94.

³⁸³ *id.*

differences in circumstances, produces differentially disadvantageous effects; this is sometimes called “de facto discrimination”.³⁸⁴ More importantly, while limited exceptions for patent rights were a major issue of contention, reasonableness as a matter of law favours an understanding that any interpretation of the term “discrimination”³⁸⁵ pursuant to Article 27(1) of TRIPS should require greater attention as discrimination may not be the same as differential treatment.³⁸⁶

The fact that Members may not “discriminate” regarding a field of technology does not imply that they may not “differentiate” among fields of technology for legitimate purposes.³⁸⁷ In that case, the Panel observed that there may be ‘bona fide exceptions to deal with problems that exist only in certain areas’.³⁸⁸ Consequently, the Panel seemed to have accepted the understanding that discrimination which occurs without justification is fatal,³⁸⁹ or as the Panel puts it – ‘without bona fide reasons’, but a compulsory licence that singles out an abuse in the exercise of an exclusive patent right, for example non-working, presumably does so for bona fide reasons.³⁹⁰

In fact, under a normal meaning of the term “discrimination”, treating different cases differently is not discrimination.³⁹¹ Therefore, this is the settled position of the Panel, as a distinction between “discrimination” and “differentiation” was made when it clarified that the conduct prohibited by Article 27(1) of TRIPS is “discrimination” as to the field of technology; that “discrimination” is not the same as “differentiation”; and, that Ghana and other WTO

³⁸⁴ *id.* Note that it is widely accepted that Article 27(1) of TRIPS prohibits both de jure discrimination, where unjustified differentiation is evident from the very nature of the law, and de facto discrimination, where unjustified differentiation occurs in the manner of applying the law. See Stout (n 342) 182. Robert Hudec, GATT/WTO Constrains on National Regulation: Requiem for an ‘Aim and Effects’ Test. In: ESSAYS ON THE NATURE OF INTERNATIONAL TRADE LAW, Robert Hudec (ed.), (London, Cameron May, 1999) 360, arguing that the GATT was more preoccupied with explicit or de jure discriminatory measures than implicit or de facto discrimination.

³⁸⁵ “Canada - Patent Protection of Pharmaceutical Products” (n 68) para. 7.98. See Dinwoodie and Dreyfuss (n 351) 450. Note that the panel almost invites this line of analysis when it declined to provide a comprehensive definition of “discrimination” within the meaning of Article 27(1), but instead sought to “define the concept of discrimination to the extent necessary to resolve the issue raised before the panel.

³⁸⁶ *Compare* para. 7.94, noting the dangers of assimilating “discrimination” and “differential treatment” while suggesting that discrimination can result from nominally identical treatment, and differential treatment might be justified). *ibid.* para. 7.101, listing issues arising in cases of de facto discrimination).

³⁸⁷ *ibid.* para. 7.104.

³⁸⁸ *ibid.* paras. 7.91-2.

³⁸⁹ The Concise Oxford Dictionary (Oxford: Oxford University Press, Main edn., 2011) 274, defines to “discriminate” means “be, set up, or act on the basis of, a difference ... make a distinction, especially unjustly on grounds of race or colour or sex”.

³⁹⁰ *ibid.* paras. 7.91-2.

³⁹¹ Dinwoodie and Dreyfuss (n 351) 450.

Members can adopt different rules for particular product areas, provided that the differences are adopted for bona fide purposes.³⁹²

In any event, the TRIPS Agreement appears to allow Ghana and other WTO Members to apply such differential treatments. Despite requiring that patents be available without discrimination based on technology, the TRIPS Agreement differentiates with respect to licences on semiconductor technology and with respect to pharmaceutical technologies.³⁹³ Moreover, every technology is unique regarding its socio-economic implications. It follows that the demand for legal protection, and the effects of that protection on both the operation of competition and the attainment of other public policy goals may differ according to the technology at issue.³⁹⁴

The need to grant protection and the modalities of such protection may also differ accordingly despite the fact that Article 27 of TRIPS requires WTO Members to provide patent protection on “without discrimination” basis. WTO Members must be able to adjust the scope of exclusive rights in order to accommodate important public interests and confine exclusivity within reasonable limits. The discretion afforded to WTO Members to apply differential treatments on reasonable grounds is ensured by the fact that neither the TRIPS Agreement nor the Paris Convention contains any restriction to that effect. From this standpoint, measures to accommodate these differences cannot be considered contrary to Article 27(1) of TRIPS.

Consequently, while Article 27(1) of TRIPS prohibits discrimination as to the field of technology, it would not prevent Ghana and other WTO Members from treating different situations differently. Differentiation that serves to level the actual conditions of competition across all fields of technology is not discriminatory, but rather the opposite. It constitutes a necessary response to the diversity of technologies.³⁹⁵ Having made these determinations, the Panel found that Canada’s patent legislation neither differentiated nor discriminated, since it was, by its terms and application, neutral as to the field of technology.³⁹⁶

³⁹² *ibid.* paras. 7.91-2.

³⁹³ Champ and Attaran (n 58) 389, stating that not only in terms of compulsory licences for public health under the Doha Declaration, but also in terms of patent extensions.

³⁹⁴ Declaration on Patent Protection: Regulatory Sovereignty under TRIPS (Munich, Max Planck Institute for Innovation and Competition, Apr. 15, 2014). Available at: <<https://www.mpg.de/8132986/%20Patent-Declaration.pdf>> [Accessed Sept. 14, 2017] 7.

³⁹⁵ *id.*

³⁹⁶ Dinwoodie and Dreyfuss (n 351) 451. “Canada - Patent Protection of Pharmaceutical Products” (n 68) para. 7.102. Abbott (n 374) 470.

This conclusion is based on the logic that a clear majority of patent laws are indeed “technology-neutral”, and on the face of it, most scholars agree that Article 27(1) of TRIPS does not stringently necessitate a single level of patent protection for all technologies or industries.³⁹⁷ Therefore, while requiring patent holders to produce their products within a particular territory, such as Ghana may create a distinction between imported products and locally produced products. For example, some WTO Members have granted differential treatment to patents depending on the country of invention. This was the case, for instance, under the Canadian regulation on compulsory licences, introduced in 1988 and in force until Bill C-91 was passed in February 1993.³⁹⁸

Hence, the so-called discrimination now banned was permissible, such as establishing different terms of patent protection according to the field of technology, as provided for under some domestic patent law.³⁹⁹ Thus, it is by no means clear that non-discrimination among technologies (as per the Panel’s interpretation of Article 27 of TRIPS) is an objective of equal importance to the international patent system,⁴⁰⁰ as the Panel acknowledged that: ‘Article 27 does not prohibit bona fide exemptions to deal with problems that may exist only in certain product areas’.⁴⁰¹ This seems to be an analogous approach to that of Article 5(A)(4) of the Paris Convention, which refers to “legitimate reasons” for “failure to work” a patented invention; therefore, Ghana and other WTO Members may treat different fields of patent protection differently if they do so for a legitimate regulatory purpose.⁴⁰²

Moreover, the Panel held that, to the extent that the prohibition of discrimination limits the ability to target certain products in dealing with the important national policies referred to in Articles 7 and 8(1) of TRIPS, including public health, it may well constitute a deliberate limitation rather than a frustration of purpose.⁴⁰³ Importantly, Correa argues that public health

³⁹⁷ Abbott (n 350) 85, arguing that ‘Article 27.1 does not, however, mean that a patent with respect to an Internet search engine must be treated the same as a patent on a steam turbine. . . . Inventions are not neutral with respect to field of technology. The invention of a new variety of disease-resistant rice has fundamentally different implications than the development of a new microprocessor or machine tool’. Carlos Correa, ‘Public Health and Patent Legislation in Developing Countries’ (2001) 3 *Tulane Journal of Technology and Intellectual Property Journal* 1, 7, claiming that ‘Differential treatment does not necessarily mean discriminatory treatment, because different technologies might require different treatment’.

³⁹⁸ For details, see Reichman and Hasenzahl (n 1) part 3.

³⁹⁹ On the term of patent protection under Article 33 of TRIPS. See Resource Book on TRIPS (n 16) 369.

⁴⁰⁰ Dinwoodie and Dreyfuss (n 351) 452.

⁴⁰¹ “Canada - Patent Protection of Pharmaceutical Products” (n 68) paras. 7.91-2.

⁴⁰² “Dispute Settlement” (n 349) 20, para. 2.6.3.

⁴⁰³ “Canada - Patent Protection of Pharmaceutical Products” (n 68) para. 7.93.

is not a “field of technology”, but a problem area that may be addressed with products originating in different technological fields, such as medicines.⁴⁰⁴ If specific rules applicable to pharmaceutical or public health patents are necessary to address important public interests, this does not constitute “discrimination” against the field of pharmaceutical technology.⁴⁰⁵

Differentiation targeted at such effects arguably finds explicit support in the *Canada – Patents Product* case.⁴⁰⁶ WTO Ministers similarly differentiated between fields of technology in the Doha Declaration. In adopting Paragraphs 6 and 7 of the Doha Declaration, Ministers clearly acknowledged that the pharmaceutical sector may be treated differently from other sectors regarding the enjoyment of patent protection. Such determination is fully consistent with Paragraph 4 of the Doha Declaration, which expressly acknowledges the need to support access to medicines for all.

Thus, this affirmation was to permit legitimate distinctions between fields of technology. Paragraph 6 of the Doha Declaration specifically addresses insufficient manufacturing capacity in the pharmaceutical sector and finding a solution to this particular problem regarding compulsory licensing. Therefore, if the imposition of local working in Ghana can promote local manufacturing capacity for the production and distribution of essential medicines, Article 27(1) of TRIPS cannot undermine the stated objectives on the basis of non-discrimination; rather it is discriminatory where Ghana and other WTO Members enforce the same pharmaceutical patents yet, essential medicines are not accessible by all.

More importantly, many of the proposals for tailoring are not aimed at the nominal legal rights created by patent law, but rather at the economic effects of these patents, for example, the timely availability of essential medicines in Ghana to protect public health and the issue of the high costs and shortages of essential medicines. Therefore, placing too much emphasis on the fundamental principle of non-discrimination in patent protection could take away key flexibilities or, if extended too broadly as an interpretive device, would undermine the efforts

⁴⁰⁴ Carlos Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health (Geneva, WHO, Essential Drugs and Medicine Policy, WHO/EDM/PAR/2002.3, 2002) 42.

⁴⁰⁵ Dinwoodie and Dreyfuss (n 351) 451.

⁴⁰⁶ “Canada - Patent Protection of Pharmaceutical Products” (n 68) paras. 7.57-58, discussing normal exploitation under Article 30.

of Ghana and other WTO Members in certain circumstances to assess and justify discrimination by reference to marketplace effects.⁴⁰⁷

Significantly, if the *Canada – Patents Product* case is read more objectively and confined to its core holding, it can be understood simply as saying that benefits flowing from non-patent law realities (such as public health considerations) cannot be the basis for a claim of guaranteed rights. This latter interpretation, which is more favourable than the foregoing view, sits well with the overall and net effects of a tailored system, and is consistent with the idea that the TRIPS Agreement is aimed primarily at ensuring a minimum obligation, and thus, a key margin exists for Ghana and other WTO Members' discretion in protecting the public interest.⁴⁰⁸

By this reference, there is good reason to conclude that Article 27(1) of TRIPS will not completely prevent Ghana and other WTO Members, for bona fide reasons, from adopting rules that differentiate among patents in diverse fields of technology. In the Panel's view, what was important was that in the rights available under national law, that is to say those resulting from the basic rights and any permissible exceptions to them, the forms of discrimination referred to in Article 27(1) should not be present.⁴⁰⁹

Significantly, if the view is taken that the imposition of local working by Ghana using the Section 84 model would be discriminatory and arbitrary as per Article 27(1) of the TRIPS provision, then other cases of remedial differential treatment laws for pharmaceutical patent term extension,⁴¹⁰ which give pharmaceutical patented products extra years of patent protection

⁴⁰⁷ Compare, Graeme Dinwoodie and Rochelle Dreyfuss, 'TRIPS and the Dynamics of Intellectual Property Lawmaking' (2005) 36 *Case Western Journal of International Law* 95, 112-113, arguing that adjudicators should take into account how changing social practices and new technological opportunities alter the balance of protection accorded to innovative works.

⁴⁰⁸ *id.*

⁴⁰⁹ "Canada - Patent Protection of Pharmaceutical Products" (n 68) para. 7.90.

⁴¹⁰ The Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 STAT 1585 (codified at 21 USC 355(b), (j), (l), informally known as the "Hatch-Waxman Act" (codified under 35 USC 156, 271 & 282). This law amended Federal Food, Drug, and Cosmetic Act, 21 USC Pub. L. 75-717, 52 STAT. 1040. The rationale behind extending patent protection for pharmaceuticals is that subjecting products entering commerce to time-consuming regulatory requirements in effect subtracts several years from the nominal 20 years of market exclusivity that a patent confers. The law offers pharmaceutical patents differential treatment see Sections 155-156 (2001). The maximum extension is five years and the total market exclusivity time cannot exceed fourteen years. See Gerald Mossinghoff, 'Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process' (1999) 54 *Food and Drug Law Journal* 2, 190. The Act sought to eliminate two distortions to the normal patent term. The first distortion was that the patent owner loses patent term during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency. The second distortion occurred after the end of the patent term because competitors could not immediately enter the market upon expiration of the patent because they were not allowed to begin testing and other activities necessary to receive Food and Drug

relative to other fields of technology, would equally be proved inconsistent with TRIPS, given that Article 33 of the TRIPS provision provides for a 20-year patent term.⁴¹¹ The Panel also considered the applicability of the non-discrimination clause to exceptions regulated by Article 30 of the TRIPS Agreement.

4.5. Non-Discrimination under Article 27(1) of TRIPS and the General Exception in Article 30

To begin with, the exclusive rights conferred by Article 28(1) of TRIPS empower patent owners to prevent others from making, using, offering for sale, selling, or importing a patented article or process without their permission.⁴¹² Article 28(2) of TRIPS further provides that patent owners shall have the right to assign or transfer the exclusive patent rights, or to enter into voluntary licensing arrangements.⁴¹³ The terms of these licensing agreements are open to negotiation among the parties, subject to domestic laws governing abuse and other anticompetitive practices.⁴¹⁴ The principal limitations on a patentee's exclusive rights are the relatively narrow set of exceptions covered by Article 30,⁴¹⁵ and the rather broad possibilities for imposing compulsory licences under Article 31.⁴¹⁶

The Panel devoted a considerable portion of its decision to interpreting the meaning of the three elements of Article 30 of TRIPS; that is, "limited exception",⁴¹⁷ not unreasonably interfering with the normal exploitation of the patent,⁴¹⁸ and not unreasonably prejudicing the interests of the patent holder, taking into account the legitimate interests of third parties.⁴¹⁹ Conceding that the relevant provision of its patent law contravened the rights of patent holders under Article 28(1) of TRIPS, Canada argued that it had invoked Article 30 of TRIPS - asserting that it was

Administration approval before patent expiration. For further analysis, see Rebecca Eisenberg, 'The Shifting Functional Balance of Patents and Drug Regulation' (2001) 20 *Health Affairs* 5, 121-122.

⁴¹¹ "Canada - Patent Protection of Pharmaceutical Products" (n 68) para. 7.1.

⁴¹² Article 28(1) of TRIPS. See Section 271(d)(4) of 35 USC 1952. *Dawson Chem. Co. v Rohm & Haas Co.*, 448 US 176, 215 (1980) in which the judgment recognised the long-settled view that the essence of a patent grant is the right to exclude others from profiting by the patented invention.

⁴¹³ Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (London & Sterling, VA, Earthscan (Routledge), 2002) 151, explaining that the patent monopoly by its nature gave its owner strong rights over the making of the invention including the terms on which it could be licensed.

⁴¹⁴ Articles 8(2), 28(2), and 40 of TRIPS.

⁴¹⁵ Reichman and Hasenzahl (n 1) 13.

⁴¹⁶ Correa (n 15) 8-9.

⁴¹⁷ "Canada - Patent Protection of Pharmaceutical Products" (n 68) paras. 7.39-49.

⁴¹⁸ *ibid.* paras. 7.51-59.

⁴¹⁹ *ibid.* paras. 60-61.

providing limited exceptions to the rights of patent holders within the scope of that provision.⁴²⁰ Nevertheless, the EU disputed that a violation of Article 27(1) of TRIPS could not be justified under Article 30.⁴²¹

Canada then contended that the prohibition in Article 27(1) of TRIPS against discrimination on the basis of the field of technology did not apply to allowable limited exceptions.⁴²² The Panel initially gave Article 27(1) of TRIPS broad structural effect over Article 30 of TRIPS pursuant to the Canadian legal provision, which explicitly required permissible exceptions for patent rights consistent with TRIPS.⁴²³ The Panel held that Article 27(1) prohibits discrimination as to the enjoyment of “patent rights” without qualifying that term.⁴²⁴ The exceptions in Article 30 are explicitly described as “exceptions to the exclusive rights conferred by a patent” and contain no indication that any exemption from non-discrimination rules is intended.⁴²⁵ A discriminatory exception that takes away the enjoyment of a patent right is discrimination.⁴²⁶

The Panel held that the ‘acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27(1) of TRIPS’, without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30.⁴²⁷ The Panel added that limiting an exception to a particular field of technology does not make it acceptable under the condition of the “limited exception” imposed by Article 30. They argued that:

It is not true that being able to discriminate against particular patents will make it possible to meet Article 30’s requirement that the exception be “limited”. An Article 30 exception cannot be made “limited” by limiting it to one field of technology, because the effects of each exception must be found to be “limited” when measured

⁴²⁰ *ibid.* para. 4.9(1).

⁴²¹ *ibid.* para. 4.8.

⁴²² *ibid.* para. 4.9(2)(A).

⁴²³ *ibid.* para. 7.91, the Panel maintained that it is an acknowledged fact without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30. See Resource Book on TRIPS (n 16) 372.

⁴²⁴ *ibid.* 371. “Canada - Patent Protection of Pharmaceutical Products” (n 68) para. 7.91. See “Resource Book on TRIPS” (n 16) 371.

⁴²⁵ Frederick Abbott, Thomas Cottier, Francis Gurry, *International Intellectual Property in an Integrated World Economy: 2010* (New York, Wolters Kluwer, 3rd edn., 2015) para. 7.91. Dinwoodie and Dreyfuss (n 347) 66.

⁴²⁶ Guide to WTO Law and Practice: WTO Analytical Index (Cambridge, 2nd edn., Volume 1, Cambridge University Press, 2007) 1047.

⁴²⁷ “Canada - Patent Protection of Pharmaceutical Products” (n 68) para 7.91.

against each affected patent. Beyond that, it is not true that Article 27(1) of TRIPS requires all Article 30 exceptions to be applied to all products.⁴²⁸

Remarkably, after the Panel had held that Article 30 exceptions are subject to Article 27(1) of TRIPS, it did not find a violation of Article 27(1) of TRIPS, since the challenged provision of the Canadian law (Section 55.2(1)) was not limited to pharmaceutical products, but was applicable to every product that was subject to marketing approval requirements.⁴²⁹ In sum, the Panel found that the regulatory review exception of Section 55.2(1) is a “limited exception” within the meaning of Article 30 of the TRIPS Agreement.⁴³⁰

Article 30 of TRIPS is an exceptionally important provision and a careful analysis of it may help to provide an understanding that Section 84 is consistent with TRIPS, and therefore, Ghana has the right to adopt such a model to promote affordable medicines. Article 30 of TRIPS allows for limited exceptions to the exclusive rights conferred by a patent.⁴³¹ It is important to note that Article 30 of TRIPS was adopted as a compromise solution during the TRIPS negotiations when the negotiators were unable to agree on a list of exceptions to patent holder rights that might be recognised by Members.⁴³² In determining whether or not Ghana and other WTO Members have the right to grant compulsory licences, the titles of Articles 30 and 31, and their hierarchical positions over Article 27(1), offer some guidance.

Where Article 27(1) of TRIPS sets out the general ground rule that patent rights shall be enjoyable without discrimination as to whether products are imported or locally produced, Article 30 of TRIPS follows with the title “Exceptions to Patent Rights Conferred”. Hence, Ghana’s discretion to limit the exclusive rights of right holders is significantly strengthened by Article 30 of TRIPS, which the country to provide limited exceptions to the exclusive rights conferred by a patent under Article 27(1) of TRIPS. Importantly, the introductory phrase “subject to the provisions of Paragraphs 2 and 3” – which provide for non-mandatory

⁴²⁸ *id.*

⁴²⁹ *ibid.* para. 7.99.

⁴³⁰ *ibid.* para. 7.50.

⁴³¹ Article 30 of TRIPS reads:

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 account of the legitimate interests of third parties.

⁴³² “Dispute Settlement” (n 349) 20.

exceptions to patentability – indicates that, where established by national laws, such exceptions override the general rules contained in Paragraph 1 of Article 27 of TRIPS.

Additionally, Article 31 of TRIPS bears the title “Other Use Without Authorization of the Patent Right Holder”. Notably, the meaning of “other use” is defined in footnote number 7 to the TRIPS Agreement as “use other than that allowed under Article 30”. This indicates that the two Articles are simultaneous and self-governing, and not subordinated to the interpretation of Article 27(1) of TRIPS. More importantly, the Appellate Body made it clear in the *Japan - Alcoholic Beverages* case that: ‘due effect must be given to the distinction between different words and expressions therein’.⁴³³ Reading these provisions together, Article 30 of TRIPS sets out a first tier of “exceptions” related to the “patent rights” referred to in Article 27(1) of TRIPS, while Article 31 of TRIPS sets out a second tier of exceptions that are more liberally called “other use”. Something that is “other” may be a little different from the main rule granting patent rights.⁴³⁴

Accordingly, it is argued that both Articles 30 and 31 of TRIPS express principles other than the usual principles contained in Article 27(1) of TRIPS. In the *Canada - Patent Products* case, Canada contended that in order to preclude discrimination, the non-discrimination norm found in Article 27(1) of TRIPS was made applicable to the limited exception under specified conditions.⁴³⁵ Pointedly, in their report, the Panel agreed with this contention and rejected the claim that the limited exception that Canada sought to impose in Section 55(2)(1) raised any plausible claim of a discriminatory purpose in the context of Article 27(1) of TRIPS.⁴³⁶ The Panel subsequently concluded that: ‘To be sure, such evidence makes it clear that the primary reason for passing the measure was its effect on promoting competition in the pharmaceutical sector’.⁴³⁷ With this conclusion in mind, it is submitted that nothing in the light of TRIPS would, in fact, preclude the possibility of Ghana from adopting and implementing any local working requirements that follow the Indian model in Section 84 if such a measure is intended to promote affordable medicines.

⁴³³ “Japan - Taxes on Alcoholic Beverages” (n 246) 12-13.

⁴³⁴ Champ and Attaran (n 58) 386.

⁴³⁵ “Canada - Patent Protection of Pharmaceutical Products” (n 68) para. 7.90.

⁴³⁶ *ibid.* para. 7.105.

⁴³⁷ *ibid.* para. 7.104.

More significantly, the Panel primarily analysed whether “legitimate interests” is a wider concept than “legal interests”, and concluded in the affirmative.⁴³⁸ The report that deals most extensively with the scope of Article 30 of TRIPS confirms that the public health interest shall not be disregarded.⁴³⁹ Although this dispute occurred between two industrialised countries, such public interest considerations must also be given emphasis in the context of TRIPS implementation in developing countries.⁴⁴⁰ This conclusion underpins the fact that Articles 30 and 31 of TRIPS were not framed in similar terms to Article 27(1). Rather, they were crafted to address a unique situation, such as public health issues, which was made applicable, or to accommodate compulsory licences under specified conditions.

With this understanding, it is argued that the Panel imagined that there were circumstances in which exceptions to patent rights would be justified, distinct from the so-called non-discrimination provision contemplated by Article 27(1) of TRIPS. Therefore, with specific regard to limitations of protection, as set out in Articles 30 and 31 of the TRIPS Agreement, the non-discrimination principle does not apply at all, as TRIPS does not subject these provisions to Article 27(1) of the Agreement. Thus, when designing exceptions and compulsory licences, Ghana and other WTO Members remain free to discriminate with regard to the field of technology, provided that such action is reasonable in the light of other public policy goals.⁴⁴¹ This viewpoint makes Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, consistent with TRIPS.

4.6. Consistency of Local Working with TRIPS: The United States v Brazil Dispute

Prior to the inception of the TRIPS Agreement into the international trading system, the Brazilian Industrial Property Code⁴⁴² excluded patents for pharmaceutical products.⁴⁴³ Upon joining the WTO, Brazil had to amend its domestic patent regime to make it consistent with the TRIPS Agreement.⁴⁴⁴ Since this amendment, Brazil’s law requires patent holders to

⁴³⁸ *ibid.* para. 7.73.

⁴³⁹ *id.*

⁴⁴⁰ Hans Morten Haugen, ‘Human Rights and TRIPS Exclusion and Exception Provisions’ (2009) 11 *The Journal of World Intellectual Property* 5-6, 357.

⁴⁴¹ “Declaration on Patent Protection: Regulatory Sovereignty under TRIPS” (n 394) 8.

⁴⁴² Law No. 5,772/71 of 1971.

⁴⁴³ Stephen Adams, *Information Sources in Patents* (Berlin, Walter de Gruyter, 3rd Revised edn., 2011) 126.

⁴⁴⁴ Lea Shave, *Access to Knowledge in Brazil: New Research on Intellectual Property Innovation and Development* (London and New York, Bloomsbury Academic Publication, 2010) 116.

manufacture their inventions within four years of grant, or else the patented products shall be subject to a compulsory licence or others can subject the products to parallel importing.⁴⁴⁵ This includes failure to work the patented subject matter in Brazil, failure to manufacture or incomplete manufacture of the product, and failure to fully use a patented process locally.⁴⁴⁶

In 1996, the Brazilian government began a national health intervention policy to contain the HIV/AIDS epidemic.⁴⁴⁷ This initiative was highly successful, with the distribution of free antiretroviral medicines in its public health system.⁴⁴⁸ As the costs of this programme grew, the government expanded its health budget and increased its production and imports of generic medicines. Next, for those medicines that were patented in Brazil, the government attempted to negotiate a deal with the patent holders to obtain the medicines at a price that would allow it to provide them to its citizens for free.⁴⁴⁹ When Brazil and the patent holder could not reach an acceptable deal, Brazil would take a hard-line approach and threaten to issue a compulsory licence unless the medicines in question were considerably discounted.

Furthermore, in 2001, Brazil considered issuing compulsory licences for Nelfinavir and Efavirenz, which belonged to Merck,⁴⁵⁰ after starting the local working of patented medicines, which decreased its reliance on importation; this also resulted in the lowering of import costs by as much as 83 per cent of the original price.⁴⁵¹ Brazil relied on its legislation that had come into force in 1997 establishing that, to enjoy exclusive patent rights in the country, the holder of a patent on an invention must satisfy a local working requirement. In other words, the patent holder must work the patent in Brazil to enjoy full patent protection. If it fails to do this, the

⁴⁴⁵ Maskus (n 6) 2.

⁴⁴⁶ Abbott (n 374) 474. For a brief discussion of the Brazilian Industrial Property Law concerning local working requirements, see Evans (n 105) 181.

⁴⁴⁷ National STD and AIDS Program (NAP) of Brazil 1986; Brazil Law No. 9313, Nov. 13, 1996 on free antiretroviral medicines for HIV/AIDS patients. Brazil Law No. 7606, Sept. 8, 1988, extending specified benefits to HIV/AIDS patients.

⁴⁴⁸ Alan Berkman, Jonathan Garcia, Miguel Munoz-Laboy, Vera Paiva and Richard Parker, 'A Critical Analysis of the Brazilian Response to HIV/AIDS: Lessons Learned for Controlling and Mitigating the Epidemic in Developing Countries' (2005) 95 *American Journal of Public Health* 7, 1170.

⁴⁴⁹ Bjornberg (n 28) 220, claiming that Abbott agreed to lower the price of Kaletra from US\$ 1.17 to US\$ 0.63 a pill, saving Brazil \$339 million over the course of six years.

⁴⁵⁰ Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (New York, Oxford University Press, 2009) 230.

⁴⁵¹ Amy Nunn, Elize Fonseca, Francisco Bastos, Sofia Gruskin and Joshua Salomon, 'Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment' (2007) 4 *PLoS Med* 11, e305, stating that Brazil made a cost saving of approximately US\$1 billion.

law says it shall be subject to the possibility of the government issuing a compulsory licence, allowing someone else to use the invention and pay a royalty fee to the patent holder.⁴⁵²

Brazil used the argument that manufacturing generic copies of essential HIV/AIDS medicines fell within the spirit of TRIPS, specifically the “national emergency exemption”, which allows the government to override patents in urgent health circumstances.⁴⁵³ In response to Brazil’s actions, the US, on 30 May 2000, requested consultations with Brazil in respect of the Article 68 provision.⁴⁵⁴ The US asserted that the local working requirement can be satisfied by the importation of the patented subject-matter – and not local production *per se*. The US further noted that the Brazilian law that explicitly defines “failure to work” as “failure to manufacture or incomplete manufacture of the product” or “failure to make full use of the patented process” is inconsistent with Brazil’s obligations under Articles 27 and 28 of the TRIPS Agreement, and Article III of the GATT 1994.⁴⁵⁵

On 5 July 2001, the parties announced a mutually satisfactory solution on the matter by issuing a joint statement, announcing that the US would withdraw its request to the WTO Panel against Brazil.⁴⁵⁶ This intervention deprived us of the true interpretation of the consistency of local working with TRIPS.⁴⁵⁷ As a matter of law, the withdrawal of this case by the US is an important result that can be read as confirming the consistency of local working with TRIPS,⁴⁵⁸ and therefore, Ghana has the right to adopt and implement any local working requirements that follow the Indian model in Section 84.

⁴⁵² Article 68 of Brazil’s Law No. 9279, May 14, 1996.

⁴⁵³ Susan Okie, ‘Fighting HIV-Lessons from Brazil’ (2006) 354 *New England Journal of Medicine* 19, 1977 at 1980, noting that Brazil relied on the relevant part of the Doha Declaration, which say: “in a manner supportive of WTO members’ right to protect public health, and in particular, to promote access to medicines for all” to begin proceedings in 2003 to issue compulsory licences for three imported antiretroviral drugs.

⁴⁵⁴ “Request for Consultations by the United States, Brazil” (n 82).

⁴⁵⁵ Champ and Attaran (n 58) 366.

⁴⁵⁶ “Notification of Mutually Agreed Solution, Brazil” (n 83).

⁴⁵⁷ Bradly Condon and Tapen Sinha, *Global Lessons from the AIDS Pandemic: Economic, Financial, Legal and Political Implications* (Heidelberg, Springer-Verlag, 2008) 40.

⁴⁵⁸ Brazil sought consultations with the US over US Patent Law (See WTO Doc. WT/DS224/1, Feb. 1, 2001. (Note that this case was not pursued.) Brazil had contended had similar provisions to that of Brazil. Under Article 204 of the US Patent Code, small businesses and universities must manufacture their inventions ‘substantially in the US. Article 209 of the US Patent Code also establishes a local work requirement for federally owned patents. See Jose Marcos Nogueira Viana, ‘Intellectual Property Rights, the World Trade Organization and Public Health: The Brazilian Perspective’ (2002) 17 *Connecticut Journal of International Law* 2, 312.

Firstly, concern about the availability of treatments, as fears of an anthrax epidemic loomed, the US Department of Health and Human Services decided to stockpile ciprofloxacin.⁴⁵⁹ Faced with the possibility of compulsory licensing of its Cipro, Bayer agreed to lower the price of Ciprofloxacin,⁴⁶⁰ to avoid the possible grant of a compulsory licence. Secondly, it is significant that the US has initiated more WTO DSU complaints than any other member state,⁴⁶¹ and the way it backed down on this occasion reveals that the country had no case to prove against Brazil over the consistency of its local working requirements pursuant to TRIPS.

While some scholars have concluded that the US dropped its complaint because of the negative publicity, it appears, on the contrary, that it was in fact a matter of legality,⁴⁶² or because the burden of proof was too heavy.⁴⁶³ Significantly, the arbitrators in the *EC – Hormones* case noted that:

WTO Members, as sovereign entities, can be presumed to act in conformity with their WTO obligations. A Party claiming that a Member has acted inconsistently with WTO rules bears the burden of proving that inconsistency.⁴⁶⁴

4.7. The Approach to Interpreting the Consistency of Local Working with Article 27(1) of TRIPS

The TRIPS Agreement, with its principle of non-discrimination, is seen as repudiating local working requirements, while the Paris Convention, seen as providing members with the right to require local production, is lauded by developing countries seeking to enhance their

⁴⁵⁹ Tommy Thompson, Health and Human Service Secretary, threatened to break Bayer's patent for (Ciprofloxacin) Cipro if he didn't get the price, he wanted in 2001, which the US intended to stockpile as a defence against anthrax. See Matt Fleischer-Black, *The Cipro Dilemma-In the Anthrax Crisis, Tommy Thompson Distorted Patent Law to Save Public Health. Good move?* (The American Lawyer, January 2002). Available at: <<http://www.cptech.org/ip/health/cl/cipro/americanlawyer012002.html>> [Accessed Sept. 14, 2017].

⁴⁶⁰ Jill Wechsler, *Bioterrorism Threat Shines Spotlight on Drug Manufacturing* (Washington, Pharmaceutical Technology, December 2001) 17. Jill Carroll and Ron Winslow, *Bayer Agrees to Slash Prices for Cipro Drug* (Wall Street Journal, 25 October 2001 Edition) A3. Frederick Abbott and Jerome Reichman, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 *Journal of International Economic Law* 4, 939.

⁴⁶¹ See the list of DSU cases: <http://www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm> [Accessed Feb. 7, 2017].

⁴⁶² Okie (453) 1980, noting that Brazil relied on the relevant part of the Doha Declaration on TRIPS and Public Health, which says, "in a manner supportive of WTO members' right to protect public health, and in particular, to promote access to medicines for all.

⁴⁶³ Joost Pauwelyn, 'Evidence, Proof and Persuasion in WTO Dispute Settlement, Who Bears the Burden?' (1998) 1 *Journal of International Economic Law* 2, 235-236, explaining that two significant rules related to burden of proof seems to emerge from the panel practice prior to the establishment of the WTO. First, the rule that it is for the complaining party to prove the GATT violation it alleges. Secondly, the rule that the party invoking GATT Article XX, in practice, the defending party, has to convince the panel that the conditions set out in that provision are met.

⁴⁶⁴ "Measures Concerning Meat and Meat Products (Hormones)" (n 312)1110, para. 9.

industrial development.⁴⁶⁵ To date, attempts to reconcile local working requirements and the TRIPS Agreement have resulted in various proposals, for instance to eliminate the references to importation and local production in Article 27(1) of the TRIPS Agreement,⁴⁶⁶ or to strengthen local working requirements in national patent laws.⁴⁶⁷

As emerged above, a major issue in the case brought by the US against Brazil is whether Article 27(1) of the TRIPS Agreement was intended to prohibit WTO Members from adopting and implementing local working requirements, and effectively supersede Article 5(A) of the Paris Convention.⁴⁶⁸ It is useful, therefore, to provide the correct interpretation as to the consistency of local working with TRIPS. In fact, there are legal principles, historical legislative guidance and WTO jurisprudence relating to the TRIPS Agreement and the Paris Convention with regard to how to reconcile these provisions.

From the beginning of the international negotiations on industrial property protection, working requirements were a hotly debated topic, and the international negotiations turned to the appropriate remedy or sanction for the non-working of a patent.⁴⁶⁹ When the Paris Convention was signed in 1883, it stipulated in part that the patentee was to remain bound to work his patent in conformity with the laws of the country into which he introduced the patented objects.⁴⁷⁰ As for importation, the Paris Convention prohibited forfeiture as the sanction, as long as the invention was manufactured in a country of the Paris Union.⁴⁷¹

However, the Convention did not address the question of whether importation satisfied local working requirements.⁴⁷² The recognition in the Paris Convention of the existence of local working requirements was not without its opponents; even before the Convention was signed in 1883, some Members opposed the provision.⁴⁷³ A few Members wanted to broaden the

⁴⁶⁵ Halewood (n 18) 245.

⁴⁶⁶ Annette Kur and Marianne Levin, *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (eds.), (Cheltenham: Edward Elgar Publishing Limited, 2011) 584, see Part II proposed amendments to TRIPS.

⁴⁶⁷ Friedrich-Karl Beier, 'Does Compulsory Use of Patents Promote Technology Transfer to Developing Countries?' (1986) 8 *European Intellectual Property Review* 12, 363.

⁴⁶⁸ Abbott (n 374) 474.

⁴⁶⁹ Marketa Trimble, 'Patent Working Requirements: Historical and Comparative Perspectives' (2016) 6 *UC Irvine Law Review* 3, 490.

⁴⁷⁰ *id.* see Article 5(A)(2) of the Paris Convention, 1883.

⁴⁷¹ Article 5(A)(1) of the Paris Convention, 1883.

⁴⁷² Trimble (n 469) 491.

⁴⁷³ Ladas (n 15) 519, citing the report of the *Conference de Paris* (1880) 66-68 and observing that Belgium, Great Britain, Russia and Turkey urged that the obligation to work a patent should be abolished by the convention,

territorial scope of the working that was required. At the Rome Conference in 1886, Belgium and Italy proposed that Members of the Paris Union should accept any working requirements that the domestic laws of any Member imposed.⁴⁷⁴

Moreover, during the Madrid Conference in 1890, the US again pursued the proposal.⁴⁷⁵ Other countries advanced their own ideas for reforming the Paris Convention with regard to working requirements. For example, France, which at the time did not permit its working requirement to be satisfied by importation, proposed that the Convention be amended to allow Members to forbid importation.⁴⁷⁶ Furthermore, Sweden and Norway proposed that compulsory licensing be introduced as the remedy for non-working.⁴⁷⁷ Ultimately, in the Final Protocol to the 1900 Brussels Revision of the Paris Convention, the Union agreed that a forfeiture for non-working could not occur before three years from the filing of a patent application and could occur only if a patent owner could not justify the non-working.⁴⁷⁸

While some Members seemed at that time to be diminishing the application of their working requirements, the United Kingdom, for example, tightened its working requirement by allowing the revocation of a patent for non-working not only if the ‘patent was not being worked in the United Kingdom’,⁴⁷⁹ but also ‘if the patent was worked . . . exclusively or mainly, outside the United Kingdom.’⁴⁸⁰ During the Washington Conference, Germany and the US both contended in support of eliminating working requirements;⁴⁸¹ however, the idea of a complete abolition of the requirement did not enjoy sufficient support among the other Members.⁴⁸²

together with the prohibition to import articles made under the patent. See Edith Penrose, *The Economics of the International Patent System* (Baltimore, MD: Johns Hopkins Press, 1951) 79.

⁴⁷⁴ *ibid.* 79-81.

⁴⁷⁵ *ibid.* 81.

⁴⁷⁶ *ibid.* 76. See Alexander Stack, *International Patent Law: Cooperation, Harmonization and an Institutional Analysis of WIPO and the WTO* (Cheltenham, Edward Elgar International edn., 2011) 71. Graham Dutfield and Uma Suthersanen, *Global Intellectual Property Law* (Cheltenham, Edward Elgar, 2008) 24, explaining that due to the importance of industrialisation in the granting of patents rights, France held that importing any patented material would automatically revoke the corresponding patent.

⁴⁷⁷ Penrose (n 473) 81.

⁴⁷⁸ The Paris Convention, as revised at Brussels, Dec. 14, 1900.

⁴⁷⁹ Section 22(a) of the Patents, Designs, and Trade Marks Act, 1883, 46 & 47 VICT. c. 57.

⁴⁸⁰ Patents Act, 1902, 2 Edw. 7 c. 34 Article 3 (amending Section 22(5) of the Patents, Designs, and Trade Marks Act, 1883).

⁴⁸¹ Penrose (n 473) 82.

⁴⁸² Trimble (n 469) 493.

During the Hague Conference in 1925, only three members opposed the abolition of the working requirement.⁴⁸³ The resulting Convention text acknowledged Members' rights to take necessary legislative measures to prevent abuses of patent rights, with "failure to work" being listed as the only example of such abuses.⁴⁸⁴ The text also expressed a preference for compulsory licensing as opposed to forfeiture, as long as a compulsory licence would suffice to prevent abuses of patent rights,⁴⁸⁵ and the text maintained in the Convention the three-year period and justification through legitimate excuse.⁴⁸⁶

In addition, the Lisbon Conference in 1958 set the period after which a compulsory licence may be requested as up to four years from the filing of the patent application or three years from the date of the grant of the patent, whichever period expires last.⁴⁸⁷ The 1958 text also specified that the compulsory licence would be non-exclusive and non-transferrable.⁴⁸⁸ The 1958 language concerning the local working requirements remains the current language of the Convention.

The Stockholm Conference in 1967 extended the applicability of the provisions concerning working requirements to utility models but other than this extension introduced no changes to the provisions concerning working requirements.⁴⁸⁹ An early commentary on the Paris Convention, as revised at Stockholm in 1967, states that "working" implies local working:

Normally, working a patent will be understood to mean working it industrially, namely by manufacture of the patented product, or industrial application of a patented process. Thus, importation of the patented article, or of the article manufactured by a patented process, will not normally be regarded as working the patent.⁴⁹⁰

Further to this, in the late 1970s and early 1980s, developing countries pursued a proposal to amend the provisions of the Convention with regard to working requirements; the proposal

⁴⁸³ Penrose (n 466) 84, citing Japan, Poland and Yugoslavia.

⁴⁸⁴ Article 5(A)(2) of the Paris Convention, as revised at The Hague, Nov. 6, 1925, see Carvalho (n 55) 163, critiquing proposals to declare non-working an instance of patent abuse.

⁴⁸⁵ *ibid.* Article 5(A)(3).

⁴⁸⁶ *ibid.* Article 5(A)(4).

⁴⁸⁷ *id.*

⁴⁸⁸ *id.* Note that this condition is found under Article 31(d)&(e) of TRIPS.

⁴⁸⁹ Article 5(A)(5) of the Paris Convention, as revised at Stockholm on Jul. 14, 1967.

⁴⁹⁰ Bodenhausen (n 19), *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* (Bureau for the Protection of Intellectual Property WIPO Publication No. 611(E), 1969. WIPO Reprinted in 1991, 2004) 71. See Carvalho (n 106) 283.

would have allowed stricter local working requirements.⁴⁹¹ Their proposal included a provision according to which importation would not satisfy the working requirement,⁴⁹² and a provision allowing sanctions other than compulsory licences to be imposed for non-working.⁴⁹³ The proposal would also have allowed developing countries to shorten the period for revoking a patent for non-working⁴⁹⁴ and to issue exclusive compulsory licences.⁴⁹⁵ The parties to the Convention opposed the proposal,⁴⁹⁶ and the disagreement over the proposal was one of the reasons why this proposed revision of the Convention was not adopted.⁴⁹⁷

In relation to this, the US made unsuccessful attempts to eliminate the possibility of a Member being able to issue compulsory exclusive licences for failure to work patents from 1979 to 1985.⁴⁹⁸ For example, while during the Conference to Revise the Paris Convention in 1984 developing countries aimed at lowering the international minimum standards of patent protection with controversial proposals to strengthen the capacity of Members to impose non-voluntary licences generally, and even to restrict the ability of affected patentees to remain in the market with the designated licensees, the US however was resolved to elevate these same standards.⁴⁹⁹ Such licences, in the US view, would be a totally unacceptable expropriation of private property and counterproductive to the legitimate desires of developing countries to upgrade their technological capability.⁵⁰⁰

⁴⁹¹ Trimble (n 469) 494, citing Kunz-Hallstein ‘Verschärfter Ausübungsdruck für Patente? GRUR INT’L 234, (1981).

⁴⁹² Draft Text of Basic Proposal for Paris Convention Article 5(A)(1)(b), reprinted in Paul Haar, ‘Revision of the Paris Convention: A Realignment of Private and Public Interests in the International Patent System’ (1982) 8 *Brooklyn Journal of International Law* 1, 107.

⁴⁹³ Wei Zhuang, *Intellectual Property Rights and Climate Change: Interpreting the TRIPS for Environmentally Sound Technologies* (Cambridge, Cambridge University Press, 2017) 52.

⁴⁹⁴ Adrienne Catanese, ‘Paris Convention, Patent Protection, and Technology Transfer’ (1985) 3 *Boston University International Law Journal* 1, 221.

⁴⁹⁵ *ibid.* 219.

⁴⁹⁶ *ibid.* 218-222.

⁴⁹⁷ *ibid.* 218.

⁴⁹⁸ For proposals to institute a preferential regime for developing countries within the framework of the Paris Convention that were debated but not adopted at the Conference to Revise the Paris Convention, 1979-1986, see WIPO Synoptic Tables Concerning Articles 1, 5A, and 5Quater of the Paris Convention for the Protection of Industrial Property (World Intellectual Property Organisation, WIPO Doc. No. PR/DC/INF/51, 1984).

⁴⁹⁹ Reichman and Hasenzahl (n 1) 12.

⁵⁰⁰ Gerald Mossinghoff, ‘The Importance of Intellectual Property Protection in International Trade’ (1984) 7 *Boston College International & Comparative Law Review* 2, 246. Richard Morford, Intellectual Property Protection: A United States Priority (1989) 19 *Georgia Journal of International and Comparative Law* 2, 337, stating that this may also be one of the reasons why the USA proposed the inclusion of intellectual property matters in the negotiations of the Uruguay Round of the GATT. *id.* mentioning that in the Trade and Tariff Act of 1984, Congress clearly linked trade and intellectual property. For further analysis see Judith Bello and Alan Holmer, ‘“Special 301”: Its Requirements, Implementation, and Significance’ (1989) 13 *Fordham International Law Journal* 13, 259-275.

Nevertheless, negotiations broke down, with the entrenched views of developing countries blocking any revision, which led to the collapse of the Paris Revision Conference. Instead, the Paris Convention remains in its last revised form following the Stockholm amendment of 1967. The frustrations endured by the US were instrumental in the decision to remove efforts to reform international industrial property regime from the exclusive jurisdiction of WIPO and to bring them within the legislative and judicial jurisdiction of the GATT and its successor institution, the WTO.⁵⁰¹ The foregoing legislative developments show that there have been some disagreements in regard to the consistency of local working requirements in international law.

4.8. Implementation of Local Working by WTO Members' and the Negotiation History of TRIPS

When the Uruguay Round and TRIPS negotiations began in 1986,⁵⁰² there was a wide variation among Members regarding the nature and scope of patent protection given that the Paris Convention established a potentially international mechanism for allowing patents to be obtained, and prescribed the basic requirements for registration systems, including the rule of national treatment for patent applicants.⁵⁰³ Predominantly, the Paris Convention did not prescribe substantive rules for many aspects of patents, such as the scope of protection of the subject matter, the criterion for entitlement to protection, or the duration of protection.⁵⁰⁴

The inadequacies of the foregoing substantive rules in the Paris Convention are not the only reason for the diverging perspectives in the literature concerning the continuing legislative discretion of WTO Members' right to impose local working requirements. As emerged from the above analysis, the Members' position differed strongly in regard to the position of local working with the international patent regime even before the negotiation of the TRIPS Agreement began. However, despite the Members' differences, it is important to note that the

⁵⁰¹ Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPS Agreement* (London, Routledge, 2002) 12. Peter Drahos, 'Developing Countries and International Intellectual Property Standard-Setting' (2002) 5 *Journal of World Intellectual Property* 5, 772, explaining the country's response to the frustrations it endured, the US, in its Trade and Tariff Act of 1984, had begun adapting Section 301 of its 1974 Trade Act to its objectives on intellectual property, as well as lining its negotiating objectives on the protection of high technology to intellectual property trade barriers.

⁵⁰² Ministerial Declaration of Punta del Este Sept. 20, 1986, World Trade Organization, Ministerial Declaration of 20 September 1986, MIN(86)/W/19, 25 I.L.M. 1623 (1986) (Punta del Este Declaration, launching the Uruguay Round GATT Doc. Min. Dec. No. 86 - 1572).

⁵⁰³ "Dispute Settlement" (n 349) 19, para. 2.6.1.

⁵⁰⁴ *id.*

controversy of whether the granting of compulsory licensing to address failure to work is inconsistent with international patent law intensified after the inception of the TRIPS Agreement.⁵⁰⁵

Perhaps, the conclusion that local working continues to be permitted by the TRIPS Agreement can be confirmed by an examination of the negotiation history of the TRIPS Agreement and the *travaux préparatoires* of the Agreement.⁵⁰⁶ Primarily, three major opinions were advanced in the negotiations with respect to local working. Developing countries wanted local working to be a mandatory obligation of any patentee.⁵⁰⁷ That is, the requirement to work locally was not viewed as an exception to patent rights, but rather as an essential condition for their conferral.⁵⁰⁸ The US was almost alone at the other end of the spectrum, in seeking to bar any possible obligation or remedy there might be for a patentee's failure to work locally.⁵⁰⁹

The EC staked out the middle ground, proposing that local working requirements should be a permissible exception to patent rights but not a patentee obligation.⁵¹⁰ Significantly, the negotiation process was entangled around these opposing views. These respective positions were maintained throughout the negotiations, with developing countries and the US sticking to their preferred local working rules, and subsequent consensus drafts suggesting that the EC's position would prevail.⁵¹¹ In fact, while differences existed, some agreements were reached

⁵⁰⁵ Mercurio and Tyagi (n 76) 275.

⁵⁰⁶ *Travaux préparatoires* is a term referring to the preparatory work of the treaty negotiations, including documents such as proposals, drafts, statements, and reports of negotiation meetings. Lord McNair, *The Law of Treaties* (Oxford, Oxford University Press, 1961) 411, Ch. XXIII. Pursuant to Article 32 of the VCLT, *travaux préparatoires* can be used as a "supplementary means of interpretation". See Draft Articles on the Law of Treaties with Commentaries 1966 (Text adopted by the International Law Commission at its eighteenth session, in 1966, and submitted to the General Assembly as a part of the Commission's report covering the work of that session, Yearbook of the International Law Commission, 1966, vol. II) 218.

⁵⁰⁷ Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay, and Pakistan (GATT Doc. MTN.GNG/NG II/W/71, 14 May 1990) part II, chap. II, Article. See Champ and Attaran (n 58) 369. This document is still officially restricted and unavailable on the WTO website; however, it is published in: *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT*, Carlos Correa and Abdulqawi Yusuf (eds.) (Alphen, aan den Rijn, Kluwer Law International, 1998) 441.

⁵⁰⁸ Champ and Attaran (n 58) 374

⁵⁰⁹ Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights, Communication from the United States (GATT Doc. MTN.GNG/NG11/W/70, 11 May 1990) Article 27. *ibid.* Champ and Attaran, 369 footnote 25, stating that the US proposal restricted compulsory licensing to national emergencies and anti-competitive abuses.

⁵¹⁰ See Draft Agreement on Trade-Related Aspects of Intellectual Property, Communication from the European Communities, GATT Doc. MTN.GNG/NG11W/68 (Mar. 29, 1990) Article 26.

⁵¹¹ There were two major working drafts developed in 1990. Chairman's Report to the GNG on the Status of Work in the Negotiating Group, GATT Doc. MTN.GNG/NG11/W/76 (Jul. 18, 1990) and the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (GATT Doc. MTN.TNCIW/35/Rev.1, 3 December 1990). Gervais (n 284) 165, comparing these two working drafts article by article with the final TRIPS

and well-documented or written down.⁵¹² First, the Brussels Draft included a provision that ‘Patents shall be available without discrimination as to where the inventions were made’.⁵¹³ Thus, the Brussels Draft did include a non-discrimination clause with respect to patented inventions.

However, this clause covered only part of the final provision under Article 27(1) of TRIPS. The Draft referred only to non-discrimination as to the place of invention but did not expressly prohibit discrimination as to the field of technology and as to the place where the protected product is produced. The latter should be distinguished from the place of invention, which may not be the same as the place of production.⁵¹⁴ Notably, the Anell Draft precluded the granting of a compulsory licence where the right holder could justify a lack or insufficiency of local working by legal, technical or commercial reasons. The grant of a compulsory licence would only have been possible to supply the local market.⁵¹⁵

Likewise, the Brussels Draft would have prohibited the granting of compulsory licences where importation was adequate to supply the local market and where the right holder had a legal, technical or economic justification for non-use of the patented invention.⁵¹⁶ Neither the Anell nor the Brussels Drafts provision was ultimately included in the final TRIPS Agreement;⁵¹⁷ thus, WTO Members generally disagree on the issue of working requirements with some even favouring their prohibition.⁵¹⁸ None of this shows that the parties will exclude compulsory licensing for failure to work.⁵¹⁹ If it really were the parties’ intention after such a protracted debate to eliminate local working, one would at least expect to find that remarkable consensus reflected in clear, unambiguous treaty language, such as the US submitted. But this is not the case.⁵²⁰

Agreement. Terence Stewart (ed.), *The GATT-Uruguay Round: A Negotiating History (1986-1992)* (Alphen, aan den Regin, Kluwer Law International, Volume 1, 1993) 2286-2289.

⁵¹² *ibid.*

⁵¹³ “Resource Book on TRIPS” (n 16) 370.

⁵¹⁴ *id.*

⁵¹⁵ Section 5A.3.5 of the Anell Draft, cited in, “Resource Book on TRIPS” (n 16) 464.

⁵¹⁶ *ibid.* 467, citing clause (n) of the Brussels Draft.

⁵¹⁷ The Chairman’s Report to the GNG on the Status of Work in the Negotiating Group, GATT Doc. MTN.GNG/NG11/W/76 (Jul. 18, 1990).

⁵¹⁸ Correa (n 179) 275.

⁵¹⁹ Champ and Attaran (n 58) 378,

⁵²⁰ *id.* 370.

As evidenced in the minutes of the negotiations up to December 1991, nothing indicated that the parties were entertaining the complete prohibition of local working requirements.⁵²¹ Developing countries continued to emphasise in negotiating group meetings from October through to early December 1991 that local working, which could not be eluded by importation, was an issue of fundamental importance for achieving a final agreement,⁵²² except remarkably, for the final draft, which was not negotiated but instead determined by the GATT Secretariat.⁵²³ Given that the GATT Secretariat determined the final draft, which fell outside the negotiated or agreed draft, the actual intentions of the parties at the conclusion of the TRIPS Agreement are difficult to appreciate.⁵²⁴

Thus, the wording in the final TRIPS Agreement does not indicate anything about the negotiators' intentions, at least certainly not in the way that a genuine consensus would have done.⁵²⁵ Importantly, the consequences for a lack or insufficiency of local working, which were included in the Anell⁵²⁶ and Brussels Drafts to the TRIPS Agreement,⁵²⁷ were excluded from the final TRIPS Agreement, and the bottom line is that some countries favoured a direct prohibition of local working requirements, but the TRIPS Agreement did not incorporate a direct prohibition. Instead, it stipulated that patent rights shall be enjoyable without "discrimination" as to whether goods are locally produced or imported.⁵²⁸

Therefore, despite the insertion of the so-called "without-discrimination" clause into the TRIPS Agreement under Article 27(1), still, the relevant patent laws of some WTO Members explicitly provide for the local working requirements where importation cannot serve as a means of satisfying an obligation to work patent locally.⁵²⁹ This suggests that the outcome of

⁵²¹ *ibid.* 378, observing that when negotiations restarted, the views on local working remained as they were reflected in the Brussels Draft: local working should be a mandatory obligation of patentees, and compulsory licensing should definitely be an available remedy for failure to work.

⁵²² Negotiating Group on TRIPS, Minutes of Meeting of 16-22 October 1991 (GATT Doc. MTN.GNGJTRIPS/3, 9 (Nov. 18, 1991)). Negotiating Group on TRIPS, Minutes of Meeting of 25-29 November 1991 (GATT Doc. MTN.GNGiTRIPS/4 (Dec. 9, 1991)), Negotiating Group on TRIPS; Minutes of Meeting of 9 December 1991, GATT Doc. MTN.GNG/TRIPS/5 (Jan. 31, 1992).

⁵²³ *id.*

⁵²⁴ *id.*

⁵²⁵ *id.*

⁵²⁶ The Chairman's Report to the GNG on the Status of Work in the Negotiating Group, GATT Doc. MTN.GNG/NG11/W/76 (Jul. 18, 1990).

⁵²⁷ Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations. MTN.TNC/W/35/Rev.1 (Dec. 3, 1990).

⁵²⁸ Abbott (n 374) 474.

⁵²⁹ For example, Article 68 of Brazilian Industrial Property Law. Section 84(1) of the Indian Patent Act. Section 46-50 of the Thailand Patent Act. B.E 2522 1979, See Carlos Correa, Can the TRIPS Agreement Foster Technology Transfer to Developing Countries? In: INTERNATIONAL PUBLIC GOODS AND TRANSFER OF

the lengthy negotiations, and the inclusion into the TRIPS Agreement of the without-discrimination principle under Article 27(1) did not render local working inconsistent with the agreement. This argument gains strength when Article 5(A) of the Paris Convention, which allows for the imposition of local working, is boldly incorporated into the TRIPS Agreement under Article 2.

Importantly, apart from abuse of patent rights in general and failure to work, which is only mentioned by way of example, the Paris Convention does not mention other grounds for the granting of compulsory licences. The TRIPS Agreement deals with compulsory licensing under Article 31, where the practice is referred to as “use without authorisation of the right holder” but left open in regard to the grounds on which Members may pursue the granting of compulsory licences, including non-work.

The TRIPS Agreement only conditions the granting of compulsory licences subject to other procedural requirements and does not prevent Members completely from invoking any grounds which are within the laws of that Member.⁵³⁰ Importantly, India has invoked Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, in granting a compulsory licence to Natco, and this legal measure has not been challenged as to its inconsistency with the so-called “without discrimination” norm under Article 27(1) of TRIPS.⁵³¹

4.9. Section 84 Model: Compatibility of Article 5(A) of the Paris Convention with Article 27(1) of TRIPS

Notably, any interpretation of the non-discriminatory obligation as meaning that TRIPS would completely prohibit Ghana from the implementation of Section 84 or imposition of local working would be quite contentious, particularly, when it is not explicitly clear from TRIPS that WTO Members intended that Article 27(1) would supplant Article 5(A) of the Paris Convention, which allows for the right to grant compulsory licences for failure to work. Thus, there is sufficient flexibility for Ghana to implement the Section 84 model to promote

TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, Keith Maskus and Jerome Reichman (eds.), (Cambridge, Cambridge University Press, 2005) 241, footnote 69, citing Indonesia, Ghana, Ireland, South Africa, Sudan, Zimbabwe, Greece, Losotho, Turkey, Spain, Portugal, Sweden, Norway, Finland, Iceland, India, Israel, Zaire, Thailand, Pakistan and Liberia.

⁵³⁰ Article 31 of TRIPS.

⁵³¹ Ho (n 29) 416.

affordable medicines. This argument gains strength, as the right of Ghana to implement the Section 84 model or WTO Members to impose local working requirements may be justified on policy grounds, and this would not amount to discrimination in terms of Article 27(1) of TRIPS given that Article 5(A) of the Paris Convention is incorporated into TRIPS under Article 2.⁵³²

Put differently, the question of whether India has the right to exercise its discretion to impose local working requirements as provided under Section 84 in treating a failure to work locally as an abuse of the exclusive rights relative to the TRIPS Agreement depends to a certain extent on how Article 27(1) of TRIPS is interpreted. Article 27(1) of TRIPS must not be read alone, as there is room for reconciliation in reading Section 84 and Article 5(A) of the Paris Convention. Remarkably, the non-discrimination clause provides for a principle that is not stated, as such, in national laws, but that should be respected while establishing the rights and obligations of patent owners.

In other words, neither the Paris Convention nor national laws contain a provision comparable to Article 27(1) of TRIPS. Hence, whether the non-discrimination provision in Article 27(1) of TRIPS would suffice to repeal the pre-existing right of Ghana and other WTO Members to continue to treat local non-working as an abuse, as some contend,⁵³³ or whether this right survives as an option that for example, Ghana and other WTO Members retain within the framework of their laws and regulations, as others contend,⁵³⁴ remains an open question.

Despite the inconsistent interface between Article 27(1) of TRIPS and Article 5A of the Paris Convention, the former being more recent than the latter, it cannot simply be given an automatic predominance. This is because there is no obvious evidence from the text of TRIPS that Article 27(1) was intended to prohibit working requirements and supersede Article 5(A) of the Paris Convention. Therefore, this rule is not absolute because local working requirements have been a common feature in patent laws of developed and developing countries in

⁵³² For arguments that working requirements are in compliance with the TRIPS Agreement, see Halewood (n 18) 282. Champ and Attaran (n 58) 393.

⁵³³ Joseph Straus, Implications of the TRIPS Agreement in the Field of Patent Law. In: FROM GATT TO TRIPS: THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, Friedrich-Karl Beier and Gerhard Schricker (eds.) (Weinheim, 1996) 100 *et seq.* Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Alphen, aan den Regin, Kluwer Law International, 2002) 318.

⁵³⁴ Correa and Yusuf (n 507) 203.

conformity with Article 5(A) of the Paris Convention, and working was only satisfied by local production (not by importation).⁵³⁵

Article 5(A)(1) of the Paris Convention provides that ‘Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent’. This provision appears to have a similar drafting structure to Article 27(1) of TRIPS, suggesting that patented products can be imported. Therefore, if one misreads this as meaning that the essence of compulsory licensing is that it is an instrument for forfeiture as opposed to limiting the patent right conferred then reading Article 5(A)(1) of the Paris Convention and Article 27(1) of TRIPS may lead to a conflicting conclusion, i.e. that Section 84 can be held to be inconsistent with TRIPS.⁵³⁶

However, this is not the correct legal interpretation. In fact, Article 5(A)(2) of the Paris Convention, which allows Ghana and other WTO Members the right to grant compulsory licences to prevent abuses, for example failure to work, is relevant. This provision suggests that the patentee shall remain under the obligation to exploit his patent in accordance with the laws of Ghana and other WTO Members in which he introduces the patent.⁵³⁷ Importantly, since the interpretation of the requirement for “working” can vary from case to case, mere importation into Ghana can only imply that the manufacturer’s patent cannot be revoked; however, a compulsory licence can still be granted for failure to work without amounting to discrimination.⁵³⁸

This viewpoint suggests that the compulsory licensing regime under Article 5(A) of the Paris Convention is compatible with Article 31 of TRIPS in relation to Article 27(1) of TRIPS. The starting point with regard to envisioning the compatibility of Article 5(A) of the Paris Convention with Article 27(1) pursuant to Article 31 of TRIPS is to understand that Article 27(1) only imposes a general obligation on Ghana and other WTO Members to make patents available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. This provision does

⁵³⁵ Halewood (n 18) 246.

⁵³⁶ *ibid.* 252-253, explaining that Article 5(1) was designed to end what was widely felt to be an abuse of the working requirement-forfeiture on the basis of some importation. There is nothing in the Paris Convention, or in any of the legal historical commentary regarding the section, to suggest that Article 5(1) redefined “working” to include the possibility of being satisfied by 100 per cent imports.

⁵³⁷ *ibid.* 252.

⁵³⁸ Bodenhausen (n 19) 71.

not attempt to define the context in which for example, Ghana and other WTO Members must give effect to such an obligation, and this is left for their legislations to determine.

Therefore, Article 27(1) of TRIPS suffers from lack of clarity as to the scope of the general obligation imposed on Ghana and other WTO Members to make patents available and patent rights enjoyable without discrimination. In contrast, Section 84 and Article 5(A) of the Paris Convention provide a more specific right to impose compulsory licences when the patentee has failed to work in India. Consequently, judging by the fact that Article 27(1) of TRIPS lacks clarity, it is not logical to rely on an unclear provision to determine the consistency of Section 84, which allows for the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India in line with TRIPS.

The standard maxim *lex specialis derogat legi generali* would help us establish the compatibility of Section 84 and Article 5(A) of the Paris Convention with Article 27(1) of TRIPS in relation to Article 31 of TRIPS, and hence make Section 83 a suitable model for Ghana. The rationale for this principle is that a specific rule has priority over a general rule.⁵³⁹ This principle is justified by the fact that such a specific rule or provision, being more concrete, often takes better account of the particular features of the context in which it is to be applied than any applicable general rule.

Using this standard doctrine to establish the compatibility of Articles 5(A) of the Paris Convention, and 27(1) and 31 of TRIPS will create a more equitable result or interpretation, which will better reflect the intent of the issue - whether or not Section 84 is consistent with TRIPS, and hence, its adoption by Ghana. According to the International Law Commission, also adopted by the WTO Appellate Body as a principle of treaty interpretation, ‘When a treaty is open to two interpretations one of which does and the other does not enable the treaty to have appropriate effects, good faith and the objects and purposes of the treaty demand that the former interpretation should be adopted’.⁵⁴⁰

⁵³⁹ “Fragmentation of International Law” (n 258) para. 1(5).

⁵⁴⁰ Report of the International Law Commission (International Law Commission, Eighteen Session, 2 Year Book, U.N. Doc. A/CN.4/SER.A/1966/Add.1, 1966) 219. “Japan—Taxes on Alcoholic Beverages” (n 246) 11, footnote 21. See also Arthur Watts (ed.), *The International Law Commission 1949-1998: Volume Two: The Treaties*, Part 2 (Oxford, Oxford University Press, 1999) 684.

It is significant that pursuant to WTO law, the Section 84 provision ordinarily arises with regard to the construction of an earlier-enacted specific provision (Article 5(A) of the Paris Convention) when a more general provision was later passed (Article 27(1) of TRIPS). The sequential overlap seems to occur because the obligation not to discriminate with regard to whether patented products are imported or locally produced in TRIPS is a general obligation that applies continuously to regulate conduct, while the rights granted under the Paris Convention by virtue of Article 5(A) are individual in that they are invoked in the specific circumstance of failure to work.

The incorporation of most of the substantive parts of the Paris Convention into the TRIPS Agreement suggests that the two treaties are distinct Agreements. Therefore, when faced with a situation in which there is likely to be a conflict between the Ghana's obligation under Article 27(1) of TRIPS, and its rights to use Article 31 of TRIPS in relation to the inclusive reference of the Paris Convention as incorporated into TRIPS by Article 2(2), it seems logical to frame the discussion within the scope of the specific provision addressing the issue rather than the general one.

The general principles on treaty interpretation under the VCLT are very clear on this.⁵⁴¹ It has been suggested that whenever two or more norms deal with the same subject matter, priority should be given to the norm that is more specific.⁵⁴² In so doing, it is argued that the standard not to discriminate regarding the protection of patent rights, whether the product is locally produced or imported, set out in Article 27(1) of TRIPS, is a general obligation and that compulsory licensing under Section 84, Article 5(A) of the Paris Convention and Article 31 of TRIPS are specific principles.

In this instance, Article 5(A) of the Paris Convention provision, as reflected in Article 31 of the TRIPS Agreement, provides the specific legal interpretation that would allow Ghana to adopt and implement any local working requirements that follow the Indian model in Section 84 with sufficient flexibility. Thus, the legitimacy of Section 84, which allows for the granting of a compulsory licence provided that the patented invention has not been worked in the

⁵⁴¹ "The VCLT" (n 119).

⁵⁴² See "Fragmentation of International Law" (n 258) para. 1(5).

territory of India, is enhanced by the fact that Article 5(A) of the Paris Convention, which is also a substantial part of TRIPS, uses words such as “failure to work”.

The weight of the foregoing interpretive guidance appears to favour the conclusion that if a requirement to work patents in India can be justified under the specific provision of Article 31 of TRIPS under its patent regime, such as Section 84, then a more moderate claim would be that Article 31 of TRIPS, as a specific standard, will supersede the general provision of Article 27(1) of TRIPS,⁵⁴³ and the same will allow Ghana to implement the Section 84 model to promote affordable medicines as India did.

More specifically, if the WTO Members truly intended to limit their own discretion regarding the grounds on which compulsory licences were to be granted, this would have been stated clearly in the relevant part of the TRIPS Agreement, such as in the case of semi-conductor technology, stipulated in Article 31(c).⁵⁴⁴ It should be noted that there is no comparable non-discrimination clause in other sections of TRIPS, and in hindsight the obligation under Article 27(1) is limited only to discrimination based on the three elements indicated in the provision, that is, place of the invention, field of technology, and whether products are imported or locally produced.⁵⁴⁵

In fact, pursuant to TRIPS, discriminations based on other factors are not completely prohibited.⁵⁴⁶ Significantly, the Paris Convention does not oblige Ghana and other WTO Members to prohibit, in their domestic legislation, the discrimination of patents as to the place of invention, the field of technology or whether products are imported or locally produced. As long as these sorts of discrimination are applied to both nationals and foreigners, the general principle of national treatment is respected.⁵⁴⁷ Here, the TRIPS Agreement goes a step further than the standard set by the Paris Convention; that is, not only must Ghana and other WTO

⁵⁴³ Gervais (n 284) 167. Doane (n 357) 479.

⁵⁴⁴ For example, Article 21 of TRIPS prohibits the grant of compulsory licensing for trademarks and this is clearly stated in the agreement. ‘...it being understood that the compulsory licensing of trademarks shall not be permitted....’.

⁵⁴⁵ “Resource Book on TRIPS” (n 16) 368.

⁵⁴⁶ For example, under Article 3 of TRIPS, protection must be offered on a national treatment basis, and Article 4 of TRIPS requires that member states provide protection on a most favoured nation basis. Dinwoodie and Dreyfuss (n 351) 448.

⁵⁴⁷ *id.*

Members ensure equal treatment of nationals and foreigners, but they must also comply with certain minimum standards prohibiting, in general, the abovementioned discriminations.⁵⁴⁸

The diverging perspectives in the literature on this point are partly due to the fact that the definition of the relevant key terms, “failure to work” and “insufficient working”, in the Paris Convention is left to Ghana and other WTO Members. Article 5(A) of the Paris Convention, which allows Ghana and other WTO Members to prevent abuses resulting from the exclusive rights conferred by a patent, does not define those “abuses” beyond “failure to work”, which some do not consider abusive.⁵⁴⁹ Importantly, apart from the abuse of patent rights in general and failure to work, which is only mentioned by way of example, the Paris Convention does not mention other grounds for the granting of compulsory licences.

The TRIPS Agreement incorporates the Article 5(A) provision and supplements it with conditions to be satisfied subject to procedural rules under Article 31. However, TRIPS left open in regard to the grounds on which Ghana and other WTO Members may pursue the granting of compulsory licences, including non-work. The Agreement does not prevent Ghana and other WTO Members completely from invoking any grounds which are within the laws of that Member.⁵⁵⁰

Remarkably, Article 2(1) of TRIPS obligates compliance with local working under Article 5(A) of the Paris Convention, while Article 2(2) of TRIPS precludes derogation from the existing obligations under that agreement,⁵⁵¹ and this makes local working consistent with TRIPS. Importantly, India has invoked Section 84, which allows the Controller to grant a compulsory licence provided that the patented invention has not been worked in the territory of India, in granting a compulsory licence to Natco, and this decision has not been challenged as to its inconsistency with non-discrimination under Article 27(1) of TRIPS.⁵⁵² This provides Ghana with potentially a sufficient flexibility to adopt and implement the Section 84 model as India did, and the same will be consistent with TRIPS.

⁵⁴⁸ “Resource Book on TRIPS” (n 16) 373.

⁵⁴⁹ Michael Pflüger, Article 5 Paris Convention. In: *CONCISE INTERNATIONAL AND EUROPEAN IP LAW: TRIPS, PARIS CONVENTION, EUROPEAN ENFORCEMENT AND TRANSFER OF TECHNOLOGY*, Thomas Cottier and Pierre Veron (eds.), (Alphen aan den Rijn, Kluwer Law International, 2008) 231.

⁵⁵⁰ Article 31 of TRIPS.

⁵⁵¹ “Dispute Settlement” (n 349) 19, para. 2.6.1.

⁵⁵² Ho (n 29) 416.

4.10. Conclusion

As emerged from the above discussions, there is sufficient flexibility for Ghana to adopt and implement the Section 84 model, which is consistent with TRIPS to promote affordable medicine. In fact, the debate arising from the negotiated language of Article 27(1) of TRIPS is the purported implications of its broad non-discrimination clause,⁵⁵³ as the Agreement sets out minimum standards and requirements for the protection of patents.⁵⁵⁴ Specifically, Article 27(1) of TRIPS imposes an obligation on Ghana and other WTO Members to treat patented inventions in all fields of technology on a non-discriminatory basis.⁵⁵⁵ That is, Article 27(1) of TRIPS provision would not allow Ghana to discriminate between products that are imported and those that are locally produced.⁵⁵⁶

A corollary to this argument is that Article 27(1) of TRIPS allows for working, not local working, and importation therefore satisfies this requirement.⁵⁵⁷ The non-discrimination principle therefore lies at the centre of the debate regarding the continued legitimacy of the working requirements under TRIPS. Consequently, the patent laws of Ghana and other WTO Members must meet the standards and requirements in relation to Article 27 of TRIPS, and any restriction or permission regarding the unauthorised use of patent rights, as found in the relevant patent regime of India such as, Section 84 will be held as inconsistent with the requirements of TRIPS.⁵⁵⁸

Therefore, where local working requirements exist such as, Section 84, any provision that sought to limit the granting and enjoyment of patent rights to inventions made within another WTO Member State would clearly be contrary to the principle of non-discrimination under Article 27(1). One argument that is consistent with the foregoing viewpoint posits that local working includes the possibility of being satisfied by importation alone, and therefore, TRIPS

⁵⁵³ Champ and Attaran (n 58) 368.

⁵⁵⁴ Reichman (n 66) 347-348, stating that the perhaps the most important basic principle that applies virtually across board is that of national treatment of (that is, non-discrimination against) foreign right holders.

⁵⁵⁵ Cottier, *et al* (n 66) 438.

⁵⁵⁶ Carvalho (n 106) 285.

⁵⁵⁷ Bernard Hoekman, *Trade Laws and Institutions: Good Practices and the World Trade Organisation* (Washington, DC: The World Bank, 1995) 52. Taubman (n 59) 104. Katharina Gamharter, *Access to Affordable Medicines: Developing Responses under the TRIPS Agreement and EC Law* (Vienna, Springer-Verlag, 2004) 27-28.

⁵⁵⁸ Reichman (n 66) 351.

prohibits Ghana and other WTO Members from the invocation of compulsory licences or something that has the same practical end as a remedy for non-working.⁵⁵⁹

Notwithstanding the argument that TRIPS incorporated the non-discrimination principle under Article 27(1) of TRIPS, and therefore this provision would prohibit for example, Ghana completely from the imposition of local working, notably, many WTO Members today maintain a patent working requirement in some form in their national patent regimes that is consistent with the TRIPS Agreement.⁵⁶⁰ Importantly, Article 5A of the Paris Convention has been incorporated bodily into Article 2 of TRIPS, which allows Ghana and other WTO Members to grant compulsory licences on the grounds of failure to work subject to satisfaction of Article 5(A)(4) and Article 31 of TRIPS in relation to the procedural requirements applicable.

More significantly, India invoked Section 84, which allows the Controller to grant a compulsory licence provided that the patented invention has not been worked in the territory of India, in granting a compulsory licence to Natco, and this legal measure has not been challenged as to its inconsistency with the non-discrimination provision under Article 27(1) of TRIPS. Therefore, in terms of reconciling local working requirements and the principle of non-discrimination, local working in Ghana that would potentially sanction failure by a patentee to work a patented invention would not constitute discrimination within the terms of Article 27(1) of TRIPS.

Taking the view of the Panel in *Canada - Patent Products* case, it is concluded that such a local working requirement in Ghana can be considered justified differential treatment and there is no discrimination where differentiations are justified, i.e. where there are bona fide reasons for differentiating, such as, to promote affordable medicines. Therefore, Article 27(1) of TRIPS would not prohibit Ghana from adopting and implementing any local working requirements that followed the Indian model in Section 84, in as much as all of the conditions and the procedural requirements under Article 31 of TRIPS are satisfied.

⁵⁵⁹ Halewood (n 18) 249. Doane (n 357) 478.

⁵⁶⁰ An important exception is Article 68 of the Brazilian patent law, as amended in 1996 which, as noted above, was challenged by the USA. Also, the Indonesian patent law, as revised in 2001, provides that the patent holder is obliged to make the patented products or use the patented process in Indonesia. He can be exempted from this obligation if the making of the product or the use of the process is only suitable to be implemented on a regional scale. Article 17 of the Law of the Republic of Indonesia No. 13 of Jul. 28, 2016, on Patents.

As will be seen in the next chapter, while Article 27(1) of TRIPS would not prohibit Ghana from the implementation of Section 84 or imposition of local working requirements, the conditions and procedural requirements imposed by Article 31 of TRIPS to be satisfied when granting compulsory licensing are complex and burdensome. Moreover, the Doha Paragraph 6 Programme, which aimed at providing a solution that would have enabled Ghana to grant compulsory licences to obtain affordable medicines, has further compounded the restrictions imposed by TRIPS; therefore, Section 84 remains a feasible model that can promote affordable medicines in Ghana.

Chapter Five

Section 84: A Feasible Option for Ghana to Circumvent the Complex Restrictions Imposed by Article 31 of TRIPS and the Doha Solution

5.1. Aim of the Chapter

The aim of this chapter is to examine the procedural complexities Ghana would face in the event that it sought to implement the complex substantive conditions under Article 31 of TRIPS and the burdensome formal procedural requirements developed by the Doha Paragraph 6 Programme. The chapter argues that Article 31 and the Doha Paragraph 6 Solution are too restrictive and difficult to satisfy, therefore, a Section 84 model remains a feasible option for Ghana to use in order to promote affordable medicines.

5.2. Introduction to the Chapter

Ghana has urgent need for essential medicines,⁵⁶¹ and while Ghana's Patents Act, the TRIPS Agreement and the Doha Paragraph 6 Programme offer the country sufficient legal basis to make effective use compulsory licences to promote affordable medicines,⁵⁶² this is not the case.⁵⁶³ Although, the TRIPS Agreement permits Ghana and other WTO Members to grant of compulsory licences, the substantive conditions and key procedural requirements necessary to comply with the requirements set out in Article 31 of TRIPS are complicated and unduly bureaucratic, and in practice, few WTO Members have actually used the instrument to promote affordable medicines.⁵⁶⁴

In this sense, a WTO Member could grant a compulsory licence only for domestic purposes or to a manufacturer locally. This created a precarious situation, because the Members that need the essential medicines the most are countries that do not have manufacturing capabilities. Accordingly, WTO Members who needed affordable medicines could not use the compulsory

⁵⁶¹ Blanca Escribano-Ferrer, Françoise Cluzeau, Derek Cutler, Christiana Akufo and Kalipso Chalkidou, 'Quality of Health Care in Ghana: Mapping of Interventions and the Way Forward' (2016) 50 *Ghana Medical Journal* 4, 238.

⁵⁶² Section 13 of Ghana's Patent Act 2003 allows for the Minister to decide that, even without the consent of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention.

⁵⁶³ Evans (n 105) 182-183. See Jillian Clare Cohen, 'Canada's Initiative to Reform Patent Law for Pharmaceuticals to Help the Poor' (2004) 137 *Canadian Pharmaceutical Journal* 2, 21-22, citing inadequate know-how and the lack of administrative infrastructure.

⁵⁶⁴ Evans (n 105) 183.

licensing instrument under Article 31 of TRIPS to protect public health.⁵⁶⁵ Thus, one of the practical effects of TRIPS was the increased costs of patented medicines and restrictions on obtaining affordable generic versions.⁵⁶⁶ It was therefore not surprising that the Doha Paragraph 6 recognised that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS Agreement.

In this case, Ghana could face potential difficulties trying to use the comprehensive procedural requirements under Article 31 of TRIPS. Therefore, while TRIPS flexibilities exist and are unquestionably available to Ghana and other WTO Members the requirements are uncertain in application, subject also to unfavourable political pressure, the fear of hostile criticism or even retaliatory action from some developed countries, such as, the US and the EU.⁵⁶⁷ For example, the US has openly expressed its discontent when developing country governments have brought in measures to prioritise access to affordable medicines in ways that limit the full enjoyment of the patent rights of US businesses.⁵⁶⁸

The US widely criticised actions created legitimate fears that Ghana and other WTO Members could be subject to reprisal in the form of sanctions, litigation, and trade restrictions if they

⁵⁶⁵ Anderson (n 40) 96.

⁵⁶⁶ Obijiofor Aginam, John Harrington and Peter Yu (eds.) *The Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines* (Cheltenham, Edward Elgar, 2013) 2, stating that high prices ration to life-saving drugs, and these prices are a function of the international intellectual property regime. *ibid.* 4, observing that legal provisions interact with the commercial calculations of drug producers in determining the availability of affordable medicines. See Philippe Cullet, 'Patents and Medicines: The Relationship Between TRIPS and Human Right to Health' (2003) 79 *International Health* 1, 160. Ellen 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha' (2002) 3 *Chicago Journal of International Law* 1, 27. See also Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development. Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover (Eleventh session, agenda item 3, Human Rights Council Resolution: A/HRC/11/12, Mar. 31, 2009) 8, para. 19, observing that in regard to medicines, a product patent enables a patentee to set high prices.

⁵⁶⁷ A Letter Written by EU Commissioner Challenging the Use of Compulsory Licensing (Brussels, CAB24/PM/RN/saA(08)694 – D(08)738, Jun. 16, 2008). Available at: <<http://test.tacd.org/wp-content/uploads/2013/09/TACD-IP-2008-Response-from-Comissioner-Mandelson-regarding-compulsory-licensing.pdf>> [Accessed Sept. 16, 2017]. See Evans (n 105) 185, stating that the reality is that while TRIPS contains the flexibilities required to allow developing countries to procure medicines, the legislative balance between the rights of the patent holder and the right to public health is not capable of being fully realised — at least not without developing countries engaging in legal battle and withstanding considerable economic and political duress.

⁵⁶⁸ The US threatened to respond forcefully in accordance with appropriate trade remedy if South Africa does not repeal, suspend, or terminate the amendment of Section 15(c). Available at: <<http://www.cptech.org/ip/health/sa/stdept-feb51999.html>> [Accessed Sept. 13, 2017]. Graham Dutfield, 'Delivering Drugs to the Poor: Will the TRIPS Amendment Help?' (2008) 34 *American Journal of Law and Medicine* 2&3, 115.

invoke compulsory licences. For example, as highlighted earlier, in 2000, when Ghana tried to import affordable medicines from India, the country was threatened with a legal challenge by GSK, and this initiative was eventually abandoned.⁵⁶⁹ Moreover, as already indicated, due to GSK's intervention, in 2005 Ghana continued to face shortages of Duovir, and the country attempted to utilise the compulsory licensing regime under TRIPS to obtain affordable medicines for public non-commercial use but later abandoned the initiative.⁵⁷⁰

In this situation, access to medicines by means of compulsory licensing under Article 31 of TRIPS is neither feasible nor sustainable.⁵⁷¹ Subsequent work in the TRIPS Council prepared the ground for the adoption of two important General Council decisions establishing the Paragraph 6 System, which were both adopted in the light of a Chairman's statement setting out several key shared understandings of the Members on how the Paragraph 6 System would be interpreted and implemented.⁵⁷²

Nevertheless, the additional flexibilities made available under the Paragraph 6 System were optional, not mandatory and to take advantage of them, a number of WTO Members have adopted domestic implementing laws or regulations that incorporate the Paragraph 6 System into their respective legal frameworks.⁵⁷³ Nevertheless, Ghana is yet to accept the amendment.⁵⁷⁴ Notably, the formal procedural requirements developed under Article 31*bis* are numerous, and many criticise the amendment for imposing too many unnecessary obstacles.⁵⁷⁵

⁵⁶⁹ Schoofs (n 5).

⁵⁷⁰ "Notification of Emergency and Issuance of Government Use Licence by Ghana" (n 8).

⁵⁷¹ Evans (n 105) 185.

⁵⁷² For this purpose, the "Implementation of Paragraph 6 of the Doha Declaration on TRIPS" (n 47), waives under certain circumstances (i) the obligation on exporting Members to ensure that compulsory licences are only granted for the purpose of predominantly supplying the domestic market (Article 31(f)) and (ii) the obligation on importing Members to pay adequate remuneration to the right holder if a compulsory licence is granted (Article 31(h)). Given that the waivers contained in the 2003 Decision are of a temporary nature, paragraph 11 of that decision called for the TRIPS Council to prepare a permanent amendment to the TRIPS Agreement, based, where appropriate, on the 2003 Decision. Agreement on such an amendment was reached on Dec. 6, 2005 when the General Council adopted a "Protocol Amending the TRIPS Agreement" (n 49) in the light of a Chairman's statement along the lines accepted in August 2003 (n 48).

⁵⁷³ Among the WTO Members with implementing laws or regulations, three categories can be observed, i.e. (i) those Members that have implemented the Paragraph 6 System to act exclusively as exporters, (ii) those Members that have implemented the Paragraph 6 System to act exclusively as importers, and (iii) those Members that have put in place laws or regulations allowing them to act both as exporters or importers under the Paragraph 6 System. See Brook Baker, 'Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (2004) 14 *Indiana International and Comparative Law Review* 3, 672.

⁵⁷⁴ Amendment of the TRIPS Agreement. See the list of WTO Members and dates of acceptance. <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> [Accessed Feb. 10, 2018].

⁵⁷⁵ Dutfield (n 568) 123. Abbott and Reichman (n 460) 932.

Additionally, there is no guidelines or model rules for a legislative and institutional framework that could be adopted by Ghana and other WTO Members to use the system effectively.⁵⁷⁶ Drafting the required legislation from scratch without guidelines or model rules is a demanding process.⁵⁷⁷ Ghana will be expected to expend significant resources, both from a financial and a legal expertise perspective, to create sound public policy and legislation.⁵⁷⁸ This explains why perhaps Ghana has not yet enacted the required legislation to pass compliance with Article 31*bis* amendment.⁵⁷⁹

Therefore, the requirement to implement domestic implementing laws has created a significant financial and political burden on Ghana and other WTO Member who export medicines because such a legislation must not only meet the requirements imposed by the WTO to importing countries, but it must also benefit the exporting country.⁵⁸⁰ Remarkably, some Members have agreed not to use the system as importers and some have stated that they will use the system only in national emergencies or other extremely urgent circumstances.⁵⁸¹ The Doha Paragraph 6 Programme's inadequacy is evidenced by the eagerness of certain WTO Members to use the system.⁵⁸²

In fact, key developed countries have committed themselves not to use the system to import.⁵⁸³ In that circumstances, if Ghana were to rely on the Doha Paragraph 6 Solution, it would find it difficult to find several WTO Members that are willing to supply the country with the needed medicines made under Doha Paragraph 6 system. Therefore, in practice, Ghana and other WTO

⁵⁷⁶ Report on the Workshop on the WTO Decision on Access to Medicines at Affordable Prices for Countries with No or Insufficient Manufacturing Capacities (Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/439, Feb. 23, 2005) paras. 26-28.

⁵⁷⁷ Anderson (n 50) 178, observing that it took over nine months for Canada to draft its legislation. Nine months is too long for a developing country to wait once it has declared a public health emergency.

⁵⁷⁸ Anderson (n 40) 106, noting that developing countries may lack the legal and technical expertise required to draft appropriate legislation in compliance with TRIPS.

⁵⁷⁹ Michael Westerhaus and Arachu Castro, 'How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy?' (2006) 3 *Public Library of Science Medicine* 8, 1232.

⁵⁸⁰ Jessica Greenbaum, 'TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of the Paragraph 6 Waiver' (2008) 25 *Journal of Contemporary Health Law and Policy* 1, 157.

⁵⁸¹ *id.*

⁵⁸² See "WTO, General Council Chairman's Statement: Minutes of Meeting" (n 48) para. 29, Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

⁵⁸³ *id.*

Members such as, India with manufacturing capacity may be reluctant to exercise such rights given concern about the international trade and political ramifications.

More importantly, the Article 31*bis* amendment to the compulsory licensing provisions of the TRIPS Agreement, which is designed to facilitate the manufacture and export of medicines to countries like Ghana has been distinguished only by its lack of use.⁵⁸⁴ Since the 2003 Decision, relatively about 14 years now, only one country or two set of countries have used the Doha Paragraph 6 Programme.⁵⁸⁵ In 2007, Canada provided HIV medicines to Rwanda under the system.⁵⁸⁶ While Rwanda filed its original notice of intent with TRIPS in July 2007, its first shipment of medicines from the Canadian generic manufacturer (Apotex) was not sent until September 2008, almost fifteen months later.⁵⁸⁷

The result of a such protracted process can lead to even bigger problems than what was sought to be addressed, as Rwanda's ability to receive the necessary medicines was not expeditious.⁵⁸⁸ Critics have found that the process is too complicated and costly.⁵⁸⁹ The UN High Level Panel on Access to Medicines report found that the system proved not to be a viable solution for its

⁵⁸⁴ Evans (n 105) 183.

⁵⁸⁵ Notification by Canada under Paragraph 2(C) of the Decision of Aug. 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Council for Trade-Related Aspects of Intellectual Property Rights, IP/N/10/CAN/1, Oct. 5, 2007). See Rwanda's Notification, WTO Doc. IP/N/RWA/1, 19 July 2007.

⁵⁸⁶ On May 14, 2004, Canada passed BILL C-9: 37th Parliament, 3rd Session. An Act to amend the Patent Act (R.S.C., 1985, c. P-4) and the Food and Drugs Act (R.S.C., 1985, c. F-27), creating Canada's Access to Medicines Regime (CAMR). Carlos Correa, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Geneva, World Health Organisation Essential Drugs and Medicines Policy, WHO/EDM/PAR/2004.4, 2004) footnote 13, observing that Canada and Norway have adopted legislative changes to implement Decision. The purpose of the legislation is to allow Canadian manufacturers to export antiretroviral drugs to countries lacking production capacity. Norway - Section 49 of Norway's Patents Act was Amended by the Act of Dec. 13, 2003 (No. 127). The following paragraph was added: 'A compulsory licence shall be issued mainly with a view to supplying the domestic market. The King may by regulations prescribe rules that deviate from this'. See Emily Ng and Jillian Clare Kohler 'Finding Flaws: The Limitations of Compulsory Licensing for Improving Access to medicines – An International Comparison' (2008) 16 *Health Law Journal* 1, 148-149, see footnote 22, observing that as of August 2008, the EU, India, China, Korea and the Netherlands have joined Canada and Norway and implemented domestic legislation allowing for compulsory licensing of pharmaceuticals primarily for export.

⁵⁸⁷ Jillian Cohen-Kohler, Laura Esmail and Andre Perez Cosio, 'Canada's Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy?' (2007) 3 *Globalization and Health* 12, 6-7.

⁵⁸⁸ Anderson (n 50) 180.

⁵⁸⁹ See Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patent and Related Rights* (New York, Oxford University Press, 2011) 217. Apotex Inc. Press Release, Second Shipment of Life-Saving Aids Drug Leaving for Africa (Sept. 18, 2009). Available at: <<https://www.newswire.ca/news-releases/canadian-made-life-saving-hiv-aids-drug-heading-to-africa-under-canadas-access-to-medicines-regime-camr-536649071.html>> [Accessed Feb. 10, 2018].

intended purpose.⁵⁹⁰ In view of this, the Doha Paragraph 6 Programme fails to represent the expected effective and expeditious solution that Ghana and other WTO Members expect in order to promote affordable medicines.

Judging from this, it will not be prudent for Ghana to rely on such a complex and failed system. Therefore, this failure makes the Section 84 model a feasible option to promote affordable medicines for public health protection because there would be relatively less complex rules, procedures and conditions to satisfy in order to determine the granting of compulsory licensing, as in the case of Article 31 of TRIPS and the Doha scheme.

5.3. Complex Conditions and the Procedural Requirements Under Article 31 of TRIPS

As already indicated, Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is consistent with TRIPS and therefore would provide a suitable model for Ghana. Acknowledging the probability that a patent owner may abuse his/her exclusive rights, for example non-working as envisaged by Article 5(A) of the Paris Convention, also incorporated into TRIPS, the compulsory licensing instrument, which remains a tool to remedy non-working, was written into the Agreement.⁵⁹¹

Not only that, the TRIPS Agreement further enhances Ghana and other WTO Members' right to act to prevent patent owners from abusing the right so granted, which could unreasonably restrain trade, or hamper the international transfer of technology.⁵⁹² To deal with that possibility, TRIPS provides that Ghana and WTO Members can issue compulsory licences, allowing a competitor to produce the product or use the process without the authorisation of its owner.⁵⁹³ However, this authorisation can only be given if a number of conditions and procedural requirements, set out in detail under Article 31 of TRIPS, are satisfied.⁵⁹⁴

⁵⁹⁰ Report of the UN Secretary General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies (New York, United Nations, September 2016) 23.

⁵⁹¹ Understanding the World Trade Organisation (Geneva, World Trade Organisation, 5th edn., 2015) 42.

⁵⁹² Articles 8 and 40 of TRIPS.

⁵⁹³ TRIPS and Pharmaceutical Patents: Fact Sheet (Geneva, World Trade Organisation, 2006) 4.

⁵⁹⁴ Gervais (287) 165, noting that the fact that the grounds for issuing a compulsory licence was left open means that compulsory licensing for failure to work locally is permitted.

This is because Article 31 of TRIPS is an exception to the exclusive rights of the patent holder, and therefore, use of the provision is restricted by several conditions aimed at protecting the rights of the patent holder.⁵⁹⁵ In the context of public health, the compulsory licensing provision is intended to permit Ghana and WTO Members to produce or import generic medicines that are more affordable than patented ones.⁵⁹⁶ Its wording does not include the term “compulsory licence”, but refers to “Other Use Without Authorization of the Right Holder”.⁵⁹⁷

Article 31 of TRIPS does not expressly state that compulsory licences should be made available by WTO Members; it just clarifies that where Ghana’s law for example, allows for other use of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, then Ghana has the right to do so.⁵⁹⁸ Article 31(a) of TRIPS requires that authorisation of such use shall be considered on its individual merits. Article 31(b) of TRIPS requires a country applying for a licence to first attempt to negotiate a voluntary licence from the patent holder under reasonable commercial terms and for a reasonable period of time.

However, in situations of national emergency, other circumstances of extreme urgency, or in cases of public non-commercial use, there is no need to try to negotiate for a voluntary licence.⁵⁹⁹ Moreover, in situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as is reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows he has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. Additionally, under the compulsory licence, adequate remuneration must still be paid to the patent holder taking into account the economic value of the authorisation in each case.⁶⁰⁰

The scope and duration of the use of the compulsory licence is limited to the purpose for which it was authorised,⁶⁰¹ and authorisation of such use can be terminated if, and when the

⁵⁹⁵ “TRIPS and Pharmaceutical Patents Fact Sheet” (n 593) 4.

⁵⁹⁶ Correa (n 179) 313–314.

⁵⁹⁷ Chapeau of Article 31 of TRIPS.

⁵⁹⁸ This means that a country’s domestic legislation may also contain other, additional conditions affecting the issuance of compulsory licences.

⁵⁹⁹ Article 31(b) of TRIPS.

⁶⁰⁰ Article 31(h) of TRIPS.

⁶⁰¹ Article 31(c) of TRIPS.

circumstances that led to it cease to exist and are unlikely to recur.⁶⁰² Furthermore, Article 31(f) of TRIPS states that a compulsory licence shall be authorised predominantly for the supply of the domestic market of the Member authorising such use. This condition has the practical effect of preventing the export of generic medicines to countries like Ghana that do not have sufficient pharmaceutical industries to produce the medicines themselves.⁶⁰³

Under Article 31(c) of TRIPS, the scope and duration of such use shall be limited to the purpose for which it was authorised, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive. Furthermore, such use shall be non-exclusive,⁶⁰⁴ nor shall it be assignable,⁶⁰⁵ and, as per Article 31(i), any decision relating to the authorisation of such use shall be subject to judicial review or other independent review by a higher authority

5.4. The Right of Ghana and other WTO Members to Determine the Grounds to Grant Compulsory Licences

The general purpose of Article 31 of TRIPS is to allow Ghana and other WTO Members to grant a compulsory licence.⁶⁰⁶ The TRIPS Agreement does not expressly refer to the right of Members to grant compulsory licences on non-working grounds, but this is implied when Article 31 of TRIPS is read along with Article 5(A)(2) of the Paris Convention in relation to Article 2(1) of TRIPS. Importantly, other possible grounds can be deduced from other TRIPS provisions, such as for instance, Article 8, which allows Ghana and other WTO Members to take measures necessary to protect, *inter alia*, public health and to prevent abuse by right holders provided that such measures are consistent with the Agreement.

Furthermore, the TRIPS Agreement neither mentions nor specifically excludes Ghana and other WTO Members from the imposition of local working requirements, except to say that where the law of a Member allows for it, that Member is free to do so,⁶⁰⁷ in as much as the

⁶⁰² Article 31(g) of TRIPS.

⁶⁰³ Correa (n 179) 321.

⁶⁰⁴ Article 31(d) of TRIPS.

⁶⁰⁵ Article 31(e) of TRIPS.

⁶⁰⁶ Richard Hunter, 'Compulsory Licensing: A Major Issue in International Business Today?' (2009) 11 *European Journal of Social Sciences* 3, 372. See Jon Matthews, 'Renewing Healthy Competition: Compulsory Licenses and Why Abuses of the TRIPS Article 31 Standards Are Most Damaging to the United States Healthcare Industry' (2010) 4 *The Journal of Business, Entrepreneurship and the Law* 1, 125.

⁶⁰⁷ Chapeau of Article 31 of TRIPS.

grounds being invoked are not frivolous.⁶⁰⁸ In fact, with the single exception of semiconductor technology, which shall only be for public non-commercial use or to remedy an anti-competitive practice,⁶⁰⁹ Article 31 of TRIPS does not limit the grounds on which Ghana and other WTO Members can implement compulsory licences.⁶¹⁰ Therefore, in as much as the procedural requirements and other substantive conditions are met, the TRIPS Agreement does not limit the possibility of Ghana grant compulsory licences on any grounds, such as failure to work, and due to public health considerations.⁶¹¹

Remarkably, Article 31 of TRIPS does not specify the grounds on which compulsory licences can be issued.⁶¹² In other words, the TRIPS Agreement does not limit the grounds on which Ghana and other WTO Members can grant compulsory licences, such as non-working, as the Agreement leaves open the cases in which such licences can be granted.⁶¹³ Although some non-exclusive grounds for granting compulsory licences are expressly mentioned in Article 31 of TRIPS - including national emergency or other circumstances of extreme urgency, and public non-commercial use by governments or third parties⁶¹⁴ - these are only examples to guide WTO Members and they do not limit the possibility of Ghana and other WTO Members granting compulsory licences on other grounds.⁶¹⁵ In fact, Article 31 of TRIPS does not specify whether “third parties” authorised by governments should be local or foreign manufacturers, other than

⁶⁰⁸ Carvalho (n 106) 232, commenting that the grant of a compulsory licence on frivolous grounds, such as the individual interest of a competitor, is not a legitimate ground because compulsory licences are exceptions to patent rights and, as such, may only be used in exceptional circumstances.

⁶⁰⁹ Article 31(c) of TRIPS.

⁶¹⁰ Gervais (n 287) 165. Note that Gervais participated in the negotiation of TRIPS. He explains that Article 31 of TRIPS sets specific conditions for the grant but does not list or define the cases where a licence may be granted (except for semiconductor technology). He further confirmed that negotiators weighed both options and preferred to leave open the cases where compulsory licensing (defined here as use by governments or by third parties authorised by governments) may be allowed.

⁶¹¹ Carlos (n 12) 9, noting that the interpretation of this clause [Article 27(1) of TRIPS] is debatable. Further, observing that though Article 27(1) has been understood as prohibiting national laws from imposing an obligation to execute locally a patented invention, this interpretation is not unanimous. Citing Article 68(1) of the Brazilian Industrial Property Law [Law No. 9.279, of May 14, 1996 as amended by Law 10.196 of Feb. 14, 2001]. It reads:

The following also shall occasion a compulsory license: I. non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted; or II. commercialization that does not satisfy the needs of the market.

⁶¹² Correa (n 179) 311, for a detailed discussion of other use without authorisation of the right-holder.

⁶¹³ Abbott, *et al* (n 425) 196.

⁶¹⁴ Article 31(b), and chapeau of Article 31 of TRIPS

⁶¹⁵ The only case in which members’ freedom to determine grounds for compulsory licences is restricted is on semi-conductor technology, which can only be subject to compulsory licenses for public non-commercial use and to remedy anti-competitive practices under Article 31(c).

to say that any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use.⁶¹⁶

Within this spirit, the TRIPS Agreement also allows Ghana and other WTO Members to make virtually all decisions regarding the granting of compulsory licences, including those regarding compensation or appeals, through administrative processes, in as much as the process is fair and transparent.⁶¹⁷ Therefore, Ghana and other WTO Members are left with a very broad scope of action in regard to the grounds on which they can grant compulsory licences subject to the satisfaction of the conditions and procedural requirements.⁶¹⁸ Recalling a few of the conditions and procedural requirements, they include the need to authorise such use on its individual merits;⁶¹⁹ the need to be non-exclusive;⁶²⁰ and the need for a prior request to the patent holder on reasonable commercial terms and the obligation to pay adequate compensation.⁶²¹

The need to request a voluntary licence is not applicable in cases of emergency and public non-commercial use.⁶²² It is also important to note that TRIPS specifically does not require Ghana and other WTO Members to grant injunctive relief to patent holders⁶²³ in cases where government authorisations of patent use satisfy the Article 31 framework.⁶²⁴ So, reading Article 31 critically it is obvious that the TRIPS Agreement leaves Ghana and other WTO Members with wider discretion as to the granting of compulsory licences, and the determination of the grounds on which to do so, including local working. Put differently, the restrictions are not strictly legal in nature and Ghana and other WTO Members must only satisfy certain substantive conditions in relation to the application of the procedural requirements.

5.5. Difficulties of Ghana and other WTO Members Satisfying the Conditions and the Procedural Requirements in Article 31 of TRIPS

Ghana as a WTO Member must comply with the conditions to be met and the procedural requirements to be followed when using the exceptions to the patent rights. However, TRIPS

⁶¹⁶ Article 31(f) of TRIPS.

⁶¹⁷ Article 31(c), 31(i), 31(j), 31(k) of TRIPS. Love (n 285) 9.

⁶¹⁸ Velasquez and Boulet (n 289) 35.

⁶¹⁹ Article 31(a) of TRIPS.

⁶²⁰ Article 31 (d) of TRIPS.

⁶²¹ Article 31(h) of TRIPS.

⁶²² Article 31(b) of TRIPS.

⁶²³ Article 44(2) of TRIPS.

⁶²⁴ Love (n 285) 11.

and its exceptions are complex and vague, and have caused much controversy.⁶²⁵ The procedural hurdles prior to issuing a compulsory licence are too complicated,⁶²⁶ and although the terms of Article 31 of TRIPS appear to be in general permissive and flexible, there is substantial inflexibility regarding the legal infrastructure, the financial and technical capacities, and the administrative processes as preconditions that Ghana and other WTO Members must satisfy.⁶²⁷

Thus, the conditions imposed by Article 31 of TRIPS and the difficult procedures have rendered the compulsory licensing instrument essentially useless,⁶²⁸ as Ghana and other WTO Members often do not meet the conditions.⁶²⁹ This reflects why, to date, Ghana and other WTO Members have made limited use of compulsory licences to address the high costs and shortages of essential medicines.⁶³⁰ Ambiguities in the interpretation of TRIPS due to the lack of substantive guidelines or definitions also hinder its effective use by increasing the risk of litigation.⁶³¹ For example, the vagueness of Article 30 of TRIPS resulted in the Panel in Canada – Patent Protection of Pharmaceutical Products having to give Article 27(1) of TRIPS broad structural effect over Article 30 of TRIPS.⁶³² This can impede the quest for access to medicines in Ghana where such a narrow interpretation exists.⁶³³

Under Article 31(a) of TRIPS, the purpose of disallowing a blanket authorisation of compulsory licences is to ensure that each case is scrutinised individually. This means not

⁶²⁵ Dina Halajian, 'Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem' (2013) 38 *Brooklyn Journal of International Law* 3, 1191.

⁶²⁶ Harris (n 85) 390.

⁶²⁷ Frederick Abbott, WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries (UK Commission on Intellectual Property Rights Study Paper 2a, 2002) 16.

⁶²⁸ Anderson (n 40) 96. Vera Zolotaryova, 'Are We There Yet? Taking "TRIPS" To Brazil and Expanding Access to HIV/AIDS Medication' (2008) 33 *Brooklyn Journal of International Law* 3, 1102.

⁶²⁹ Abbott (n 627) 16.

⁶³⁰ *id.*

⁶³¹ Vishal Gupta, 'A Mathematical Approach to Benefit-Detriment Analysis as a Solution to Compulsory Licensing of Pharmaceuticals under the TRIPS Agreement' (2005) 13 *Cardozo Journal of International and Comparative Law* 2, 637, stating that though TRIPS sets forth minimum standards, patent protection is not equivalent in each member state since each state can independently interpret these standards. Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (New York, Oxford University Press, 2007) 247, stating that members may take different views as to the interpretation, but also that a member relying on one interpretation risks litigation from another member relying on a different interpretation.

⁶³² "Canada – Patent Protection of Pharmaceutical Products" (n 68) para. 7.91, the Panel maintained that it is an acknowledged fact without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30. "Resource Book on TRIPS" (n 16) 372.

⁶³³ Hestermeyer (n 631) 235, arguing that the scope of Article 30 exceptions is "notoriously vague," which could have allowed the Canada-Patent Panel to interpret it broadly in light of a right to access to medicines, but it failed to do so.

granting licences automatically or arbitrarily on the grounds of the type of technology, for example.⁶³⁴ A case-by-case basis is a more effective control on the frequency of compulsory licensing and benefits the rights holder.⁶³⁵ Specifically, the vagueness of Article 31(b) complicates the legitimate determination of any individual compulsory licence, for example, requiring such measures to be “necessary” or “compensation” to be adequate.⁶³⁶ Pursuant to Article 31(b) of TRIPS, this provision requires that a party pursuing a compulsory licence makes a reasonable effort within a reasonable period to negotiate reasonable commercial terms and conditions with the patent holder prior to licensing.

“Reasonable” is not defined and this has been described as the key to its flexibility.⁶³⁷ There are, however, obstacles to these commercial negotiations. If a patent holder is unwilling to permit bargain price access, they may delay the negotiations to buy time and therefore increase their profits while still appearing to be conforming with the provision. Sometimes they have no intention of accepting licensing but want to avoid a clear refusal. In cases involving urgency, Article 31(b) of TRIPS allows Ghana and other WTO Members to avoid this process, to enable expediency. Such circumstances include cases of national emergency, although no definition is given in the text.⁶³⁸

There have been some discussions as to the possible interpretations of “national emergency” with semantic difficulties over the use of “extreme urgency” as opposed to “moderate urgency” as meaning urgent enough to invoke the process. What is claimed is that a formal declaration of national emergency is probably not required.⁶³⁹ This view is illustrative of the possible complications that Ghana and other WTO Members may face in deciding what the criteria within the Agreement mean. Violation carries the consequences of huge litigation costs, which Ghana and other WTO Members simply cannot afford.⁶⁴⁰

⁶³⁴ Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (London, Sweet & Maxwell, 2nd edn., 2003) 250.

⁶³⁵ *id.*

⁶³⁶ David Degen, Thailand’s Compulsory Licenses and the Increase of Investment Arbitration. In: RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND THE LIFE SCIENCES, Duncan Matthews, Herbert Zech (eds.), (Cheltenham, Elgar Edward, 2017) 436.

⁶³⁷ “Resource Book on TRIPS” (n 16) 469.

⁶³⁸ Duncan Matthews, ‘TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements’ (2005) 27 *European Intellectual Property Review* 11, 421

⁶³⁹ *ibid.* 441.

⁶⁴⁰ The controversy of South Africa’s Medicine Act 1997 and the subsequent legal action pursued by Pharmaceutical Industry is a very real reminder of the potential consequences of alleged violation of TRIPS. When South African tried to grant compulsory licensing to promote affordable medicines (The Medicines and Related Substances Control Amendment Act No. 90 of 1997, South African Government Gazette No. 18,505, Dec. 12,

Article 31(f) of TRIPS is one of the most contentious and disputed clauses in regard to access to affordable medicines for Ghana and other WTO Members. Without sufficient manufacturing capacity, expertise and financing to set up a feasible pharmaceutical company, Ghana and other WTO Members have been unable to satisfy this condition, and this has prevented them from seeking help from other WTO Members with a reasonably sufficient manufacturing capacity that they are willing to make available for the export of affordable medicines. This provision was clearly not devised to meet the fundamental interests of developing countries that compare closely with Ghana and reflects developed countries' fears that to allow the export/import of affordable medicines, for example, would result in loss of control over the licensing market, and therefore threaten their monopoly.⁶⁴¹

In relation to Article 31(g) of TRIPS, which provides for a licence to be terminated if, and when the circumstances that led to it cease to exist and are unlikely to recur, it has been stated that the requirement of termination need not apply to HIV/AIDS medicines, as it is difficult to accurately predict how long effective treatment will take.⁶⁴² Article 31(h) of TRIPS is yet another ambiguously worded requirement. There is little guidance on what constitutes "adequate" and it is subject to many economic factors. While the language of equity was advanced and supported by many WTO Members, who saw this particular provision as

1997 [amending the Medicines and Related Substances Control Act No. 101 of 1965, as amended by Acts Nos. 65/1974, 17/1979, 20/1981 and 94/1991]) some pharmaceutical file a suit challenging the legality of the national measure in court (*Pharmaceutical Manufacturers' Association of South Africa v President of the Republic of South Africa*. Case No 4183/98, filed Feb 18, 1998). The US threatened to respond forcefully in accordance with appropriate trade remedy if South Africa does not repeal, suspend, or terminate the amendment of Section 15(c). Available at: <<http://www.cptech.org/ip/health/sa/stdept-feb51999.html>> [Accessed Sept. 13, 2017]. See Chang-Fa Lo, *Compulsory Licensing: Threats, Use and Recent Trends*. In: *CONTEMPORARY ISSUES IN PHARMACEUTICAL PATENT LAW: SETTING THE FRAMEWORK AND EXPLORING POLICY OPTIONS*, Bryan Mercurio and Daria Kim (eds.), (New York, Routledge, 2017) 157. Michelle Nerozzi, 'The Battle over Life-Saving Pharmaceuticals: Are Developing Countries Being TRIPped by Developed Countries' (2002) 47 *Villanova Law Review* 3, 616, noting that the US has threatened to curtail economic aid programs and to impose trade sanctions on the governments of South Africa. Grace Avedissian, 'Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of Super-Terrorism' (2002) 18 *American University International Law Review* 1, 256, stating the US contested South Africa's compulsory licensing law for two years before capitulating to public and interest group pressure. Ford (n 30) 950. See 'Time-Line of Disputes over Compulsory Licensing and Parallel Importation in South Africa' (Consumer Project on Technology, Version 1.03, Aug. 5, 1999) showing that the USTR placed South Africa on its Special 301 Watch List on May 1, 1998. Available at: <<http://www.cptech.org/ip/health/sa/sa-timeline.txt>> [Accessed Sept. 19, 2017].

⁶⁴¹ Deborah Halbert, *Resisting Intellectual Property* (London, Routledge Studies in Global Political Economy 2005) 95, South Africa's Fight for AIDS medication.

⁶⁴² Kumariah Balasubramaniam, *Access to Medicines and Public Policy Safeguards under TRIPS*. In: *TRADING IN KNOWLEDGE. DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY*, Christophe Bellmann, Ricardo Melendez-Ortiz and Graham Dutfield (eds.) (London, Earthscan, 2003) 154.

possibly difficult, the idea of “adequate” was the wording the US preferred and was selected over “fair and equitable”.⁶⁴³

Calculating adequate remuneration for payment to the patent holder under Article 31(h) of TRIPS when a compulsory licence is granted is an obstacle to its successful use,⁶⁴⁴ and is further complicated by the requirement to take the economic value of the authorisation into account, as TRIPS does not provide guidance in regard to determining what is “adequate” and what is the authorisation’s “value”.⁶⁴⁵ Commercial market royalty rates are one possible benchmark for remuneration, but may be difficult to ascertain or be unreflective of the value of the licence for a variety of reasons.⁶⁴⁶

Moreover, due to the distinctive interest between developing countries that compare closely with Ghana and developed countries, defining the specific grounds for compulsory licences will always remain unrealistic.⁶⁴⁷ Even if Ghana is ultimately successful in authorising a compulsory licence, delays in authorisation due to the probability of judicial review or other independent review may discourage licensees from producing generic versions, as they will have to attend hearings that are meant to frustrate the granting of such a licence.⁶⁴⁸

5.6. Doha Declaration: Confirmation of Ghana and other WTO Members Right to Grant Compulsory Licences

⁶⁴³ Gervais (n 634) 252.

⁶⁴⁴ Abbott (n 627) 35, explaining that “adequate” refers to a sufficient amount meeting minimum standards.

⁶⁴⁵ Daniel Chow and Edward Lee, *International IP: Problems, Cases, and Materials* (Detroit, Michigan, Gale Cengage, 2006) 452–453, listing possible methods to determining adequate remuneration. For example, Thailand considers a royalty rate of 0.5 per cent of the total sales to be compliant but this was rejected by Merck inadequate. See Cynthia Ho, ‘A New World Order for Addressing Patent Rights and Public Health’ (2007) 82 *Chicago-Kent Law Review* 3, 1469.

⁶⁴⁶ Abbott (n 627) 35, stating that actors such as government subsidisation of research and development and tax treatment are relevant. Royalties may be based on wholesale selling prices, net of tax liabilities.

⁶⁴⁷ Degen (n 636) 436.

⁶⁴⁸ Savoie (n 8) 239.

By the end of 1999, data suggest that HIV was spreading at an alarming rate in Ghana⁶⁴⁹ and Africa.⁶⁵⁰ In 2001, the nations of Africa declared that the HIV/AIDS Tuberculosis and Malaria epidemics were a complete emergency on the continent, and the African Union offered their commitments to strengthen their responses to fighting the diseases.⁶⁵¹ Although the reasons for the lack of access to essential medicines in Ghana and other developing countries are generally manifold,⁶⁵² concerns were raised about the consequences of TRIPS and access to medicines soon after the inception of the TRIPS Agreement into the international trading system.⁶⁵³

Importantly, compulsory licensing, as an instrument of government policy, would have offered Ghana and other African countries that are considerably burdened with diseases, a practical means to mitigate the high costs and shortages of essential medicines,⁶⁵⁴ however, they face legal difficulties in using the compulsory licensing instrument to promote affordable medicines.⁶⁵⁵ For example, as stated already, in 2000 when Ghana tried to import affordable medicines from India, GSK tried to block such a measure.⁶⁵⁶

⁶⁴⁹ ‘HIV/AIDS in Ghana: Background, Projections, Impacts, Interventions, and Policy’ (National AIDS/STI Control Programme–Disease Control Unit, Ministry of Health, 3rd edn. 2001). ‘Ghana Population and AIDS Programme’ (Ghana: Ministry of Health, 1993). See Ghana’s AIDS Commission Act 2002 (Act 613) and the setting up of the Ghana AIDS Response Fund with initial seeding money of US\$ 25 million provided by the World Bank. See Project Performance Assessment Report. Ghana AIDS Response Project (The World Bank, Report No.: 39557, Jun. 19, 2007) vii. Country Health System Fact Sheet Ghana’ (WHO, 2006) 1, estimating that in 2000 there were 350,000 cases of HIV and by 2003 the prevalence rate among adults was 3.1 per cent. See ‘Scaling up Towards Universal Access and Working Actively and in Partnership to Combat HIV/AIDS’ (The National Strategic Framework 2006-2010 (NSF II), AIDS Commission of Ghana, 2005) 6, recognises that the spread of the epidemic remains a challenge to socio-economic development.

⁶⁵⁰ AIDS Epidemic Update (Report of the Joint United Nations Program on HIV/AIDS, WHO/CDS/CDR/NCS/2001.2, December 2001) 2, finding that HIV/AIDS killed 2.3 million African people. The estimated 3.4 million new HIV infections in Sub-Saharan Africa in the past year mean that 28.1 Africans now live with the virus. Without adequate treatment and care most of them will not survive the next decade.

⁶⁵¹ Abuja Declaration on HIV/AIDS, Tuberculosis, and Other Related Infectious Diseases. Abuja, African Union, 2001) 4.

⁶⁵² t Hoen (n 566) 28, citing logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, and prohibitive prices.

⁶⁵³ Ellen t Hoen, *The Revised Drug Strategy: Access to Essential Medicines, Intellectual Property, and the World Health Organization*. In: *ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY*, Gaelle Krikorian and Amy Kapczynski (eds.), (New York, Zone Books, 2010) 134, citing the Health Action International, the Consumer Project on Technology (CPTech, now Knowledge Ecology International, KEI), Act Up–Paris, the Health GAP coalition, Oxfam, and the Access to Medicines campaign of Medecins Sans Frontieres (MSF).

⁶⁵⁴ Statement by the African Group on TRIPS and Public Health (Informal Session of TRIPS Council for the Special Discussion on IP and Access to Medicines (IP/C/W/296, Jun. 20, 2001) para. 30. Available at: <http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm> [Accessed Aug. 28, 2017].

⁶⁵⁵ *ibid.* para. 8, citing the lawsuit brought by a Pharmaceutical Industry Association and 39 of its affiliate pharmaceutical companies against the Government of South Africa regarding provisions of its Medicines and Related Substances Control Amendment Act. See Communication from the European Communities and their Member States (IP/C/W/280, Jun. 12, 2001) para. 18.

⁶⁵⁶ *Glaxo Blocks Importation of Generic Combivir into Ghana* (TAGLine, Volume 7, Issue 9, Treatment Action Group, December 2000). <<http://i-base.info/htb/4062>> [Accessed Mar. 10, 2017]. Bradley Condon, ‘NAFTA, WTO, and Global Business Strategy: How AIDS, Trade, and Terrorism Affect our Economic Future’ (Greenwood Publishing, 2002) 101. See Anthony So and Cecila Oh, ‘Approaches to Intellectual Property and Innovation that

Nevertheless, it was originally envisioned that the compulsory licensing provision contained under Article 31 and other safeguard provisions in the TRIPS Agreement could be used by WTO Members to facilitate access to essential medicines in a time of public health crisis or circumstances of a national emergency by allowing for the production of affordable medicines.⁶⁵⁷ However, this was not the case. When some WTO Members, specifically Brazil and South Africa, tried to use compulsory licences to promote affordable medicines, they became the subject of lawsuits and political pressure from mainly the US and some pharmaceutical companies.⁶⁵⁸

It was reported at the same time that one-third of the world's population lacked access to the most basic essential drugs,⁶⁵⁹ while at the same time many of the WTO Members including India were scheduled to comply fully with the patent standards under TRIPS by 2005.⁶⁶⁰ This technically meant that those with insufficient or no manufacturing capacity will not be able to grant a compulsory licence either for the local production or for the importation of affordable generic medicines, and they will depend entirely upon expensive patented versions.⁶⁶¹ There were concerns about whether Ghana and other African governments would feel free to use, for instance, compulsory licensing flexibility to the full, without fearing pressure from the pharmaceutical industry and their home governments.⁶⁶²

This led to the extraordinary meeting held by the TRIPS Council on 20 June 2001 on the TRIPS Agreement and access to medicines, at the request of the African WTO Members.⁶⁶³ The African Group maintained that the flexibilities contained in TRIPS required clarification and that the Agreement itself may possibly need an amendment.⁶⁶⁴ They also claimed that

Meet the Public Health Challenge of AIDS' (Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, July 2011) 3.

⁶⁵⁷ Ng and Kohler (n 586) 145.

⁶⁵⁸ For example, see note 640 and the text accompanying.

⁶⁵⁹ WHO Medicines Strategy: 2000–2003 Framework for Action in Essential Drugs and Medicines Policy (Geneva, Department of Essential Drugs and Medicines Policy, WHO/EDM/2000.1, World Health Organisation, 2000) 9, finding that irrespective of the fact that the number of people with access to essential drugs grew from roughly 2.1 billion in 1977 to 3.8 billion in 1997.

⁶⁶⁰ Article 65 of TRIPS.

⁶⁶¹ Carlos Correa, 'TRIPS Agreement and Access to Drugs in Developing Countries' (2005) 3 *International Journal on Human Rights* 3, 26.

⁶⁶² "Submission by the African Group" (n 39) para. 30.

⁶⁶³ TRIPS Council's discussion on "Intellectual Property and Access to Medicines". Available at: <https://www.wto.org/english/tratop_e/trips_e/counciljun01_e.htm> [Accessed Sept. 5, 2017].

⁶⁶⁴ See "Statement by the Africa Group on TRIPS and Public Health" (n 654) para. 29.

justification for compulsory licensing may need clarification since the TRIPS Agreement does not specifically set out the grounds on which Ghana and other WTO Members can grant compulsory licences.⁶⁶⁵

Central to this problem is the failure of some WTO Members that compare closely with Ghana with insufficient or no domestic manufacturing capacity to avail themselves of the use of compulsory licensing under TRIPS given the restrictions of Article 31(f), which obliges production under compulsory licence to be predominantly for the supply of the domestic market. This kept Ghana and other WTO Members from manufacturing necessary medicines for exportation or importation, further constraining access to life saving essential medicines for Ghana and other WTO Members.

As already indicated, in 2001, the WTO took initial steps to counter the legal ambiguity created by the TRIPS Agreement in relation to the lack of essential medicines and the right of Ghana and other WTO Members to grant compulsory licences, as this had raised anxiety that exporting Members may have problems exporting adequate amounts to meet the needs of Ghana and other WTO Members with insufficient or no manufacturing capacity. The Doha Declaration did not set out specific solutions, but rather openly accepted the problems with public health,⁶⁶⁶ the concerns about the effect of patents on prices,⁶⁶⁷ and the uncertainty regarding TRIPS and committed to developing remedies.⁶⁶⁸

In making this declaration, the WTO took the opportunity to encourage its Members to make use of the compulsory licensing instrument under Article 31 of TRIPS,⁶⁶⁹ and further reiterated their commitment to leave each Member free to establish its own regime for such exhaustion without challenge.⁶⁷⁰ When considering the local working requirement and compulsory licensing the legal force of the Doha Declaration is not to be underestimated,⁶⁷¹ as it referred to the customary rules approach of public international law in the interpretation of each

⁶⁶⁵ “The African Group” (n 39) para. 1.

⁶⁶⁶ “Doha Declaration” (n 6) para. 1.

⁶⁶⁷ *id.* para. 3.

⁶⁶⁸ Anderson (n 40) 97.

⁶⁶⁹ “Doha Declaration” (n 6) para. 5(b).

⁶⁷⁰ *ibid.* para. 5(d).

⁶⁷¹ Yu (n 309) 997, making a strong argument that the Doha Declaration was a mere restatement of Article 31(1) of the VCLT, which stipulates that ‘a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty . . . in the light of its object and purpose’.

provision of TRIPS in the light of the object and purpose of the Agreement, as expressed,⁶⁷² in particular, its objectives and principles.⁶⁷³

Importantly, since the WTO Panels and the Appellate Body began their operations, they have embraced the provision as part of the customary rules of interpretation as required by the DSU.⁶⁷⁴ Thus, the Doha Declaration established a specific rule of interpretation that gave context to the general interpretive provisions of public international law via the Vienna Convention, upon which the legal principles of WTO law and its interpretation have been built. The panel in *Korea – Procurement* held that the customary rules of international law apply to WTO treaties.⁶⁷⁵ This reflects a measure of recognition that the general agreements embodied under the WTO are not to be read in clinical isolation from public international law.⁶⁷⁶

According to the canons of treaty interpretation, the interpreter is also required to consider any agreement or instrument relating to the treaty that was made between all of the parties in connection with the conclusion of the treaty.⁶⁷⁷ In the *EC – Bananas* case, the Report of the Appellate Body noted that:

⁶⁷² Gervais (n 284) 120, mentioning that a possible practical impact of the Doha insistence of Articles 7 and 8 may serve as a basis for the interpretation of certain provisions of the Agreement. Robert Howse and Makau Mutua, *Protecting Human Rights in a Global Economy: Challenges for the World Trade Organization*. In HUMAN RIGHTS IN DEVELOPMENT YEARBOOK 1999/2000: THE MILLENNIUM EDITION. Hugo Stokke and Anne Tostensen (eds.) (The Hague, Kluwer Law International, 2001) 63, stating that the Preamble of WTO Agreement states a number of objectives of the WTO system that may relate to certain human rights obligations, especially elements of social and economic rights.

⁶⁷³ “Doha Declaration” (n 6) para. 5(a). Yu (n 309) 995, stating that the Doha Declaration strongly reinforced the objectives and principles set forth in Articles 7 and 8 of the TRIPS Agreement. See “Resource Book on TRIPS” (n 16) 126, interpreting that Article 7 objective is particularly important to less-developed countries, which are largely users of technologies produced abroad.

⁶⁷⁴ See “WTO Dispute Settlement Understanding” (n 76). Article 3(2) of the DSU in part, expressly states that the dispute settlement system is intended to clarify the provisions of the WTO Agreement ‘in accordance with customary rules of interpretation of public international law.’ See Howse and Makau (672) 64, arguing that Article 31 of the Vienna Convention, which states the basic rules of treaty interpretation, is a fundamental reference point for WTO dispute settlement.

⁶⁷⁵ The Panel in *Korea – Measures Affecting Government Procurement* (WT/DS163/R, May 1, 2000) para. 7.96. See Joost Pauwelyn, ‘The Role of International Law in the WTO: How Far Can We Go?’ (2001) 95 *American Journal of International Law* 3, 583, footnote 25, stating that with one possible exception, no academic author (or WTO decision or document) disputes that WTO rules are part of the wider corpus of public international law.

⁶⁷⁶ “US - Standards for Reformulated and Conventional Gasoline” (n 244) para. 16. See Howse and Mutua (n 672) 66, stating that human rights norms should always be taken into account when interpreting international trade and investment obligations. *ibid.* 76, trade policies and globalisation affect economic, social and cultural rights, in particular, hence, the necessity of safeguarding these rights within the context of the GATT/WTO regime. See also Gabrielle Marceau, ‘WTO Dispute Settlement and Human Rights’ (2002) 13 *European Journal of International Law* 4, 780, arguing that the term “rules of international law” seems to refer to all sources of international law. Customs, general principles of international law (Article 38(1)(b) of the ICJ Statute) or general principles of (domestic) law accepted by nations (Article 38(1)(c) of the ICJ Statute), including those relating to human rights, would have to be taken into account in the interpretation of WTO provisions.

⁶⁷⁷ Article 31(2) of the VCLT (n 119).

We consider that a multilateral interpretation pursuant to Article IX: 2 of the WTO Agreement can be likened to a subsequent agreement regarding the interpretation of the treaty or the application of its provisions pursuant to Article 31(3)(a) of the Vienna Convention, as far as the interpretation of the WTO agreements is concerned.⁶⁷⁸

Pursuant to Article 31(3) of the VCLT, ‘there 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’.⁶⁷⁹ The Declaration is relevant as a legal instrument, as it was made by all Members in connection with the conclusion of TRIPS and accepted by the wider international community as an instrument related to the Agreement. Based on an extension of that logic, one can make a strong argument that the Doha documents should constitute a subsequent agreement.⁶⁸⁰

Thus, with regard to Ghana, the Doha Declaration contains important provisions for the interpretation and application of compulsory licensing triggered by non-working under the TRIPS Agreement. The Declaration is, at the very least, an instrument that provides the relevant context in regard to any reading of the consistency of local working with TRIPS. Significantly, the WTO body, that is, the Ministerial Conference that has the exclusive authority to issue such interpretations regarding WTO laws delivered the Declaration.⁶⁸¹ In the *Japan - Alcoholic Beverages* case, the Appellate Body confirmed that Article IX: 2 of the WTO Agreement provides that:

The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements ... The fact that such an [exclusive] authority in interpreting the treaty has been established so specifically in the WTO Agreement is reason enough to

⁶⁷⁸ EC – Regime for the Importation, Sale and Distribution of Bananas’ (Second Recourse to Article 21.5 of the DSU by Ecuador and Recourse to Article 21.5 of the DSU by the United States (WT/DS27/AB/RW2/ECU, WT/DS27/AB/RW/USA, WT/DS27/AB/RW2/ECU/Corr.1, WT/DS27/AB/RW/USA/Corr.1, Nov. 26, 2008) para. 383.

⁶⁷⁹ Article 31(3)(a) of the VCLT (n 119). See Yu (n 309) 999.

⁶⁸⁰ Yusuf (n 317) 15, arguing that the Doha Declaration may be considered to constitute a subsequent agreement between the parties to a treaty regarding its interpretation in accordance with Article 31.3(a) of the VLCT. Ruse-Khan (n 315) 42, finding that formally, the Declaration on TRIPS and Public Health can be considered as a source for interpreting TRIPS equivalent to treaty “context” as it amounts to a ‘subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions’ under Article 31.3(a) of the Vienna Convention.

⁶⁸¹ Andrew Mitchell and Tania Voon, ‘Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law’ (2009) 43 *Journal of World Trade* 3, 581, commenting on the Doha Declaration on TRIPS and Public Health in relation to Article IX(3)&(4) of the WTO Marrakesh Agreement, which stipulates, ‘In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member by this Agreement or any of the Multilateral Trade Agreements...’. By that reference, the authors concluded that member states, ‘intended as a binding waiver of certain TRIPS obligations...’

conclude that such authority does not exist by implication or by inadvertence elsewhere.⁶⁸²

In relation to public health, through the Doha Declaration, the WTO has tempered the conflicting interpretations, in particular the opposing view urged upon us, which has tended to indicate that Article 27(1) of TRIPS would prohibit Ghana and other WTO Members from granting a compulsory licence provided that the patented invention has not been worked locally. Thus, the Doha Declaration has settled this controversy, and has provided the correct interpretation. Regarding local production of essential medicines, it is significant that the TRIPS Agreement made technology transfer and socio-economic welfare its overriding objectives while maintaining a proper balance of rights and obligations.⁶⁸³

Given that the agreements covered by the WTO form a single, integrated legal system,⁶⁸⁴ the objectives and principles of the TRIPS Agreement need to be considered in relation to this particular objective.⁶⁸⁵ More significantly, the TRIPS Agreement allows Ghana and other WTO Members to formulate or amend their laws and regulations to adopt measures necessary to protect public health and promote the public interest in vital sectors,⁶⁸⁶ such as the pharmaceutical industry,⁶⁸⁷ and to adopt TRIPS consistent measures, such as compulsory licensing under Article 31, to prevent the abuse of patent rights,⁶⁸⁸ which the Paris Convention as incorporated into TRIPS cites as an example of abuse.⁶⁸⁹

Notably, Paragraph 4 of the Declaration did not repeat the phrase “adopt measures necessary to protect public health” as used in Article 8(1) of TRIPS but has the same practical

⁶⁸² “Japan - Taxes on Alcoholic Beverages” (n 246) 44, Section E.

⁶⁸³ Article 7 of TRIPS. See Correa (n 179) 92. Yu (n 309) 1007, observing that Article 7 can be interpreted in a way to restore the balance of the international intellectual property system.

⁶⁸⁴ Panel Report - United States-Section 110(5) of the U.S. Copyright Act (WT/DS160/R, Jun. 15, 2000) para. 6.185.

⁶⁸⁵ “Resource Book on TRIPS” (n 16) 130, interpreting that ‘The objectives and principles of TRIPS must be considered in relation to the objectives of the WTO Agreement, which is reflected in its preamble’. Henning Grosse Ruse-Khan, Proportionality and Balancing Within the Objectives for Intellectual Property Protection. In: INTELLECTUAL PROPERTY AND HUMAN RIGHTS, Paul Torremans (ed.), ((Alphen, aan den Regin, Kluwer Law International, 2008) 162, analysing the role of a proportional balancing of interests within intellectual property protection as part of international economic regulation.

⁶⁸⁶ “Resource Book on TRIPS” (n 16) 127, observing that the TRIPS Agreement does not offer any definition of the relevant sectors. sectors of vital importance may vary from country to country and region to region. See Correa (n 179) 104.

⁶⁸⁷ Article 8(1) of TRIPS.

⁶⁸⁸ Article 8(2) of TRIPS.

⁶⁸⁹ Article 5(A)(2) of the Paris Convention.

understanding.⁶⁹⁰ Offering the correct interpretation of the TRIPS Agreement in relation to public health, the WTO Members stressed the need for the TRIPS Agreement to be part of the wider national and international action to address the public health problems afflicting Ghana and other WTO Members.⁶⁹¹ They settled that the TRIPS Agreement does not and should not prevent Ghana and other WTO Members from taking measures to protect public health and, in particular, to promote access to medicines for all.⁶⁹²

Put differently, the WTO agreed that Ghana and other WTO Members have the right to interpret and implement the TRIPS Agreement in a way that supports public health goals such as the promotion of affordable medicines.⁶⁹³ In this connection, they reaffirmed the right of Ghana and other WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility⁶⁹⁴ for the purpose of securing better domestic access to necessary medicines for all diseases including HIV/AIDS, Tuberculosis and Malaria.⁶⁹⁵

It is important to note that apart from the compulsory licensing instrument the TRIPS Agreement embodies other flexibilities, which can be used to promote affordable medicines. For example, in relation to the notion of patentable subject matter under Article 27, three criteria for patentability (novelty, inventive step and industrial application) are not defined under TRIPS. Each Member is free to interpret their meanings, which can determine what is patented in the pharmaceutical sector.

In addition, governments can refuse to grant patents for the following reasons that may relate to public health, including inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health (Article 27(2)); diagnostic, therapeutic and surgical methods for treating humans or animals (Article 27(3)(a)). Other flexibilities include exhaustion of rights (parallel importation) under Article 6; research and experimental use exception (Article 30); regulatory (bolar) exception (Article 30); public, non-commercial use

⁶⁹⁰ “TRIPS Resource Book” (n 13) 131, stating that the operative language of Paragraph 4 is in the form of agreement and this may be interpreted as a “decision” of the members under Article IX. 1 of the WTO Agreement.

⁶⁹¹ “Doha Declaration” (n 6) para. 2.

⁶⁹² *ibid.* para. 4.

⁶⁹³ *id.*

⁶⁹⁴ *id.*

⁶⁹⁵ *ibid.* paras. 1, 5(c). See Anderson (n 40) 97.

(government use) (Article 31); scope of pharmaceutical test data protection (Article 39(3)); competition law (Article 40) and transition periods (Articles 65(2); 65(4); and 66(1)).⁶⁹⁶

Importantly, the WTO Members recognised that these flexibilities include the right of Ghana and each WTO Member to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.⁶⁹⁷ Additionally, they committed the WTO to creating flexibility for the its Members unable to manufacture pharmaceuticals domestically.⁶⁹⁸ Paragraph 6 of the Declaration in part reads: ‘We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement’. The Members then instructed the Council for TRIPS to act promptly to find a solution to the problem faced by Ghana and other WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector in making effective use of compulsory licensing under TRIPS.⁶⁹⁹

Although, Paragraph 5(b) of the Doha Declaration confirmed the right of each WTO Member to grant compulsory licences and the freedom to determine the grounds on which such licences are founded, it is important to distinguish between the granting of a compulsory licence to address deficiencies with the patent including a failure to meet the reasonable requirements of the public, the inaccessibility of the patented invention at a reasonably affordable price to the public, or the non-working of the patented invention locally, and a compulsory licence aimed at tackling a national emergency and other circumstances of extreme urgency.

To the extent necessary, the complex conditions and the formal procedural requirements developed by the Doha Solution are only relevant to real situations of national emergency and other circumstances of extreme urgency but immaterial to the use of a compulsory licence aimed at addressing local working shortcomings. Therefore, the Doha Solution is unique in the sense that it authorises a WTO Member to issue a compulsory licence for the manufacture and export of patented pharmaceutical products to any country with an inadequate or non-existent

⁶⁹⁶ UNAIDS. Doha+10 TRIPS Flexibilities and Access to Antiretroviral Therapy: Lessons from the Past, Opportunities for the Future (UNAIDS Technical Brief, Joint United Nations Programme on HIV/AIDS. JC2260E, Nov. 2011) 8-11. See also Ellen ‘t Hoen, Jacquelyn Veraldi, Brigit Toebesc and Hans Hogerzeil, ‘Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016’ (2018) 96 *Bull World Health Organisation* 3, 185.

⁶⁹⁷ “Doha Declaration” (n 6) para. 5(b).

⁶⁹⁸ *ibid.* para. 6.

⁶⁹⁹ *id.*

manufacturing capacity to meet public non-commercial demand or solve a genuine national emergency and other circumstances of extreme urgency.

5.7. 2003 Waiver Decision and the Amendment of Article 31 of TRIPS to Allow Ghana and other WTO to Grant Compulsory Licences

Two years later, on 30 August 2003, the WTO General Council announced a solution to the problem identified under Paragraph 6 of the Doha Declaration, which was dubbed: “The Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”.⁷⁰⁰ The solution took the form of an interim waiver for any LDC Member or Member that compares closely with Ghana, with insufficient or pharmaceutical manufacturing capacity to make use of the Decision to import any pharmaceutical product needed to address public health problems.⁷⁰¹

In short, this Decision waived the obligations set out in Paragraphs (f) and (h) of Article 31 of TRIPS with respect to pharmaceutical products so that Ghana and other WTO Members can expeditiously use the compulsory licensing instrument to promote affordable medicines. This Decision was adopted via the Chairman’s statement of the Council for TRIPS, which sets out several key shared understandings of WTO Members on how the Decision would be interpreted and implemented,⁷⁰² and was designed to appease those who feared that the Decision might be abused and used to undermine patent protection.⁷⁰³

Importantly, if Ghana and other WTO Members were to grant a compulsory licence WTO Members shall not challenge any of such measures taken in conformity with the provisions of the waivers,⁷⁰⁴ except that the Decision was intended only to be an interim measure and the TRIPS Council was mandated to find a more permanent solution.⁷⁰⁵ In the end, the WTO Members focused their efforts on amending the source of the problem, Article 31(f) itself. On December 6, 2005, the waiver became the first-ever amendment to TRIPS.⁷⁰⁶

⁷⁰⁰ “Implementation of Paragraph 6 of the Doha Declaration” (n 47).

⁷⁰¹ *ibid.* paras. 1(a)-(b).

⁷⁰² See “WTO Doc. JOB(03)/177” (n 48).

⁷⁰³ WTO General Council, Minutes of Meeting (WTO Doc. WT/GC/M/82, held on Aug. 25, 26 & 30, 2003) para. 29.

⁷⁰⁴ “Implementation of Paragraph 6 of the Doha Declaration” (n 47) para. 10.

⁷⁰⁵ *ibid.* para. 11.

⁷⁰⁶ “Amendment of the TRIPS Agreement” (n 49).

Designated as Article 31 *bis*, the amendment was formally built into the TRIPS Agreement after acceptance of the “Protocol Amending the TRIPS Agreement” by two thirds of the WTO’s members.⁷⁰⁷ The amendment will be attached to the TRIPS Agreement following Article 31, which will make permanent the Decision on patents and public health.⁷⁰⁸ The amendment took effect on 23 January 2017 and replaced the 2003 waiver for Members who have accepted the amendment. Members like Ghana who are yet to accept the amendment had until 31 December 2019 to do so.⁷⁰⁹ However, for Ghana and other WTO yet to accept the amendment, the waiver will continue to apply until they accept the amendment and it takes effect. The permanent amendment was intended to give legal certainty that would make is easier for Ghana and other WTO Members to use compulsory licences or in the context of Ghana the Section 84 model to obtain affordable medicines for distribution.⁷¹⁰

5.8. The Doha Declaration and the Right to Health

To start with, the legal difficulties encountered by Ghana and other WTO Members in an attempt to obtain affordable medicines regarding the implications of the TRIPS Agreement and public health were reflected in the adoption of the Doha Declaration. The Doha Declaration recognised the “gravity” of the public health problems afflicting Ghana and other WTO Members, especially – but not limited to – those resulting from HIV/AIDS, Tuberculosis, Malaria and other epidemics.⁷¹¹ Importantly, the Declaration reflects the concern regarding the implications of the TRIPS Agreement for public health in general, and particularly concerns about the resulting effects on the prices of essential medicines that Ghana and other WTO Members face.⁷¹² A major concern was that while the WHO had introduced essential medicines lists and national medicine policy concepts, access to essential medicines was challenging.⁷¹³

⁷⁰⁷ *id.*

⁷⁰⁸ Abbott and Reichman (n 460) 984.

⁷⁰⁹ Amendment of the TRIPS Agreement. Sixth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement (Ministerial Conference Decision of Nov. 30, 2017, WTO Doc. WT/L/1024, Dec. 1, 2017).

⁷¹⁰ Anderson (n 50) 168, stating that the amendment was created to provide flexibility and better access to medicines.

⁷¹¹ “Doha Declaration” (n 6) para. 1.

⁷¹² Correa (n 661) 27-28.

⁷¹³ “WHO Medicines Strategy: 2000–2003” (n 659) 1-2, observing at the time that 160 countries had national essential drugs lists, while over 100 countries had national drug policies, access to medicines were still challenging.

The Declaration is significant to Ghana and other WTO Members for several reasons. First, it represents the first time that international health and development was discussed at every level of WTO governance.⁷¹⁴ Second, the Declaration recognises that public health issues can take precedence over IP rights, which the TRIPS Agreement recognises as private rights.⁷¹⁵ As examined already, Paragraph 4 affirms the principle that protecting public health and promoting access to medicines is a valid basis for Ghana and other WTO Members to use the flexibilities under TRIPS.⁷¹⁶ It stipulates that the TRIPS Agreement does not and should not prevent Ghana and other WTO Members from taking measures to protect public health, and affirms that the provisions of the Agreement can and should be interpreted and implemented in a manner supportive of Ghana and other WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In fact, human rights norms present a major means for Ghana and other WTO Members to interpret TRIPS consistent with public health objectives, as the WTO recognises under the Doha Declaration that there is a convincing justification that access to medicines should be available for all.⁷¹⁷ The background to making access to medicines a shared norm backed by the law at the international level follows a useful framework underpinning the basic principles of the overriding objective of public health protection.⁷¹⁸ This concept first emerged in the WHO Constitution, which states that 'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition'.⁷¹⁹

The premise that access to essential medicines is a prerequisite for realising the right to health in Ghana and other WTO Members was reiterated in the 1978 Declaration of Alma Ata.⁷²⁰ As

⁷¹⁴ Bryan Mercurio, 'TRIPS, Patents and Access to Life-Saving Drugs in the Developing World' (2004) 8 *Marquette Intellectual Property Law Review* 2, 212.

⁷¹⁵ Preamble to the TRIPS Agreement. See Bryan Mercurio, 'Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines' (2006) 5 *Northwestern Journal of International Human Rights* 1, para. 8.

⁷¹⁶ *ibid.* para. 10.

⁷¹⁷ "Doha Declaration" (n 6) para. 4.

⁷¹⁸ Shared Responsibilities for Health: A Coherent Global Framework for Health Financing (Final Report of the Centre on Global Health Security Working Group on Health Financing, Chatham House, the Royal Institute of International Affairs, 2014) 7.

⁷¹⁹ Preamble to the Constitution of WHO. Adopted by the International Health Conference, Jun. 19-22, 1946; signed on Jul. 22, 1946. Official Records of WHO, No. 2, p. 100, entered force on Apr. 7, 1948.

⁷²⁰ Health for All: Alma Ata Declaration. Almaty, Kazakhstan, International Conference on Primary Health Care, WHO 1978) Declaration I. Available: <<http://apps.who.int/medicinedocs/documents/s21369en/s21369en.pdf>> [Accessed Feb. 26, 2017].

indicated earlier, per the WHO concept, essential medicines are those that ‘satisfy the priority health care needs of the population’ and ‘are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford’.⁷²¹ Importantly, the Universal Declaration of Human Rights (UDHRs) provided the inherent significance of the right to health into the core obligations which states are bound to respect. The UDHRs asserts that everyone, equally, has the inalienable right to ‘a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.’⁷²²

Therefore, in considering the need for essential medicines in Ghana and other WTO Members, the UN Development Group defines “access” in this context as ‘having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population’.⁷²³ The WHO’s strategic policy document for 2000-2003, which Ghana adopted considered better access to essential medicines a priority health issue.⁷²⁴ Significantly, in 2008, Ghana and other WHO Members reaffirmed their commitment to promoting access to essential medicines with the adoption of a resolution on the “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property” (GSPA-PHI).⁷²⁵

One of the UN’s Sustainable Development Goals (SDGs), which Ghana and other WTO Members have accepted in principle, is to ensure ‘access to safe, effective, quality and affordable essential medicines and vaccines for all’.⁷²⁶ Relative to the SDGs and the notion of “medicines for all”, it is significant that under Paragraph 4 of the Doha Declaration, the WTO was supportive of the Members’ right to protect public health and, in particular, to promote access to medicines for all.

⁷²¹ See “WHO’s Essential Medicines Concept” (n 6).

⁷²² Article 25(1) the Universal Declaration on Human Rights (n 32).

⁷²³ “Millennium Development Goal 8” (n 36) 35.

⁷²⁴ Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000-2003 (Geneva, WHO/EDM/2000, WHO, 2000).

⁷²⁵ World Health Assembly Resolution WHA61.21 (Eighth Plenary Meeting, Agenda Item 11.6, A61/VR/8, WHO, May 24, 2008).

⁷²⁶ Transforming Our World: The 2030 Agenda for Sustainable Development (UN Res. A/RES/70/1, Seventieth Session, Agenda Items 15 and 116, Sept. 25, 2015) Goal 3 Targets.

Within the UN human rights norms and practices the reasoned position is that access to medicines is a human rights subject matter, as several international⁷²⁷ and regional human rights instruments, which Ghana remains a signatory to have widely recognised the right to health.⁷²⁸ The domains of the right to health norm have been transposed into some national constitutional provisions including Ghana.⁷²⁹ As stated already, Article 25(1) of the UDHR reads: ‘Everyone has the right to a standard of living adequate for the health of himself and of his family, including medical care’.⁷³⁰ The right to health was later expanded and included in Article 12 of the International Covenant on Economic, Social and Cultural Rights (1966).⁷³¹

Consistently, several resolutions and declarations at the international level, including those under the UN and its constituent agencies, which Ghana has accepted have placed access to medicines as a significant component of the right to health.⁷³² In 2000, the UN Committee on Economic, Social and Cultural Rights, in General Comment No. 14, upheld the special relationship between the right to a standard of living adequate for health and access to medicines as a human rights matter.⁷³³ This followed several political declarations by the UN

⁷²⁷ Articles 11(1)(f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women [GA res. 34/180, 34 UN GAOR Supp. (No. 46) 193, UN Doc. A/34/46; 1249 UNTS 13; 19 ILM 33 (1980)]. Article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination [660 UNTS 195; G.A. res. 2106 (XX), Annex, 20 U.N. GAOR Supp. (No. 14) at 47, U.N. Doc. A/6014 (1966)]. Article 24 of the Convention on the Rights of the Child [GA res. 44/25, annex, 44 UN GAOR Supp. (No. 49) 167, U.N. Doc. A/44/49 (1989); 1577 UNTS 3; 28 ILM 1456 (1989)].

⁷²⁸ Article 11 of the European Social Charter, European Social Charter (Revised), May 3, 1996, ETS 163, entry into force Jul. 1, 1999, Council of Europe. Strasbourg. Article 16 of the African [Banjul] Charter on Human and Peoples’ Rights, adopted June 27, 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force Oct. 21, 1986. Article 10 of the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, OAS Treaty Series No. 69; 28 ILM 156 (1989).

⁷²⁹ Under Section 27(1) of the Constitution of the Republic of South Africa 1996, “Everyone has the right to have access to – (a) Health care services, including reproductive health care”. Paragraph (2) of Section 27, imposes an obligation on the state to take steps to put in place a legal framework that facilitates access to health care services. See Eleanor Kinney and Brian Alexander Clark, ‘Provisions for Health and Health Care in the Constitutions of the Countries of the World’ (2004) 37 *Cornell International Law Journal* 2, 346. According to the South African Constitutional Court’s decision in *Minister of Health and Others v Treatment Action Campaign and Others* (No 2) (CCT8/02) [2002] ZACC 15; 2002 (5) SA 721; 2002 (10) BCLR 1033 (Jul. 5, 2002) para. 135(3), access to health care services includes access to medicines. See also Chapter 5 of the Constitution of Ghana 1992. Article 41 of the Constitution of the Azerbaijan 1995. Article 50 of the Constitution of Cuba 1992, as amended in 1978, 1992 and in 2002. For a global view of medicines-related rights in national constitutions, see Katrina Pehudof, Brigit Toebes, and Hans Hogerzeil, ‘Essential Medicines in National Constitutions: Progress Since 2008’ (2016) 18 *Health and Human Rights Journal* 1, 146, Table 1.

⁷³⁰ “Universal Declaration on Human Rights” (n 32).

⁷³¹ “ICESCRs” (n 32).

⁷³² World Health Assembly Resolution WHA62.16 (Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Eighth Plenary Meeting, Agenda Item 12.8., A62/VR/8, May 22, 2009. Resolution on Access to Health and Needed Medicines in Africa. African Commission on Human and Peoples’ Rights. OAU Doc. ACHPR/Res.141 (XXXIII)08, 24 November 2008). The Declaration of Commitment on HIV/AIDS (UN General Assembly Res. GA. Res. S-26/2, Eighth Plenary Meeting, Twenty-Sixth Special Session, Agenda Item 8, Jun. 27, 2001) Annex.

⁷³³ “General Comment No. 14” (n 33) para. 12.

reaffirming⁷³⁴ the obligation on Ghana and other WTO Members to enhance access to affordable essential medicines, as defined by the “WHO Action Programme on Essential Drugs”.⁷³⁵

In this context, the UN has affirmed that a central principle underpinning the framework of access to medicines as a human rights matter includes Ghana’s right to offer a broader interpretation of the right to treatment.⁷³⁶ Within this purview, a rights-based approach can help mitigate the lack of essential medicines in Ghana, as Article 2(2) of the Covenant imposes on WHO Members two immediate obligations: firstly, a duty imposed on Ghana to guarantee that the right to health will be exercised without discrimination of any kind; and, secondly, a duty on Ghana to take deliberate, concrete and targeted steps, as provided in Article 2(1), towards the full realisation of Article 12.⁷³⁷

Importantly, in relation to the need for essential medicines in Ghana and other WTO Members, the UN Commission on Human Rights adopted a Resolution in 2001, in which it recognised that “access to medication” is a fundamental element for progressively achieving the full realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.⁷³⁸ Among a list of measures, it called on Ghana and other WTO Members ‘to refrain from taking measures which would deny or limit equal access for all person’s’, clearly with IP in mind.⁷³⁹ In furtherance of this, the Office of the High Commissioner prepared a report in 2001 on the impact of the TRIPS Agreement on human rights,⁷⁴⁰ and the Sub-Commission on the Promotion and Protection of Human Rights took this up in its Resolution in the same year, pursuant to “Intellectual Property Rights and Human Rights”.

⁷³⁴ Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of non-communicable Diseases (UN General Assembly Res. A/RES/66/2, Third Plenary Meeting, Sixty-Sixth Session, Agenda Item 117, Jan. 24, 2012) para. 5.

⁷³⁵ WHO Action Programme on Essential Drugs (WHA Res. WHA31.32, Twelfth Plenary Meeting, May 23, 1978 (Committee A, Third Report).

⁷³⁶ Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, including the Right to Development (UNHRC Res. A/HRC/RES/12/24, Thirty-Second Meeting, Twelfth Session, Agenda Item 3, Oct. 2, 2009) para. 7.

⁷³⁷ Hans Hogerzeil, ‘Essential Medicines and Human Rights: What Can They Learn From Each Other?’ (2006) 84 *Bulleting of the World Health Organisation* 5, 372.

⁷³⁸ “Commission on Human Rights Resolution” (n 36).

⁷³⁹ *ibid.* para. 3(a).

⁷⁴⁰ The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights (UN Doc. E/CN.4/Sub.2/2001/13, Jun. 27, 2001).

The Resolution, adopted by consensus, referred to the actual or potential conflict between the implementation of the TRIPS Agreement in WTO Members that compare closely with Ghana, and international human rights law, pursuant to the realisation of economic, social and cultural rights, and reminded Ghana and all WTO Members of the primacy of human rights obligations over economic policies and agreements.⁷⁴¹ The 2016 Resolution by the UN Human Rights Council confirmed the same proposition, stressing the responsibility of Ghana and other WTO Members to ensure access for all to affordable, safe, efficacious and quality essential medicines.⁷⁴²

Moreover, Article 73 of TRIPS enables Ghana and other WTO Members to pursue any actions that they consider necessary for the protection of their essential security interests, and to fulfil their obligations under the UN Charter. With this provision in mind, it is submitted that Ghana has the right to determine what constitutes its national security interests, and if, public health protection in relation to the high costs and shortages of essential medicines pose a fundamental threat to the security of its people then the country is free from adopting and implementing the Indian model in Section 84 to promote local production of affordable medicines.

Notably, Article 103 of the UN Charter hints that a rule of international law may also be superior to other rules by virtue of a treaty provision. It says that: ‘In the event of a conflict between the obligations of the Members of the United Nations under the ... Charter and their obligations under any other international agreement, their obligations under the ... Charter shall prevail’. Specifically, the need to protect public health in Ghana and other WTO Members is addressed in Article 1(3) of the UN Charter, which provides that one of the purposes of the UN is: ‘to achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights’.⁷⁴³

It is also recognised that the UN Charter enjoys special character owing to the fundamental nature of some of its norms, particularly its principles, purposes and universal acceptance.⁷⁴⁴

⁷⁴¹ Intellectual Property Rights and Human Rights (UN Human Rights Sub-Commission on the Promotion and Protection of Human Rights Res. 2001/21, UN Doc. E/CN.4/SUB.2/RES/2001/21, Aug. 16, 2001) para. 2 & 3.

⁷⁴² Promoting the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health through Enhancing Capacity-Building in Public Health (Human Rights Council, Thirty-Second Session, Agenda Item 3, A/HRC/32/L.24/Rev.1, Jun. 30, 2016) para. 2.

⁷⁴³ United Nations, Charter of the United Nations. 1 UNTS XVI, Oct. 24, 1945.

⁷⁴⁴ *ibid.* Article 2(6).

The scope of Article 103 extends not only to the articles of the Charter but also to binding decisions made by UN organs. Given the strength of the constitutional character of the UN Charter and the established practice of the Members as well as UN organs, the Charter obligations may also prevail over any inconsistent international law.⁷⁴⁵ This view is based on the presumption that as far as essential medicines in Ghana is concerned the primacy of a human right in international law enjoys a special status given its normative superiority and the collective scope of its applicability.⁷⁴⁶

It is important to note that the SDGs carry a UN mandate,⁷⁴⁷ which recognises medicines as essential commodities for the fulfilment of the right to health in Ghana and other WTO Members.⁷⁴⁸ Therefore, taking this into account, it is significant that Paragraph 2 of the Doha Declaration adopted a language in part reflecting the foregoing provision under UN Charter. The WTO Members stressed the need for the WTO TRIPS Agreement to be part of the wider national and international action to address the gravity of the public health problems afflicting

⁷⁴⁵ Howse and Mutua (n 672) 65-66, observing that the Text of the GATT does not, however, explicitly list human rights as grounds for the exclusion of products. It does, however, contain provisions that permit states to protect and promote human rights through trade by taking certain measures against states that violate human rights. The pivotal provision in this respect is Article XX which provides a wide array of exceptions under which a WTO Member can promote and protect human rights without being in violation of the GATT.

⁷⁴⁶ Javid Rehman, *International Human Rights Law* (Harlow, UK: Pearson, 2nd edn. 2010) 3.

⁷⁴⁷ "Sustainable Development Goals" (n 712) Goal 3 Targets.

⁷⁴⁸ Experts remain divided about whether human rights norms fit well within the interpretation of WTO rules. The following scholars are convinced that the world trade regime has a mutual basis with human rights. See Howse and Mutua (n 672) 56, arguing that trade and human rights regimes need not be in conflict, so long as the trade regime is applied and evolved in a manner that respects the hierarchy of norms in international law, human rights, to the extent they are obligations *erga omnes*, or have the status of customs, or of general principles, will normally prevail over specific, conflicting provisions of treaties such as trade agreements. The WTO laws and processes must be interpreted in a way that advances human rights. Thus, human rights and trade are fundamentally linked and must be seen as complementary, not oppositional. Ernst-Ulrich Petersmann, *Human Rights and International Trade law: Defining and Connecting the Two Fields*. In: HUMAN RIGHTS AND INTERNATIONAL TRADE (eds.) Thomas Cottier, Joost Pauwelyn and Elisabeth Burgi (Oxford, Oxford University Press, 2005) 29, proving the consistency of both norm by explaining how the values informing human rights and the general principles of international trade regime are similar. Robert Anderson and Hannu Wager, 'Human Rights, Development and the WTO: The Cases of Intellectual Property and Competition Policy' (2006) 9 *Journal of International Economic Law* 3, 708, arguing that rules of multilateral trading system are a necessary response to the dilemmas of globalisation and remain instruments for the advancement of human rights. However, note that the following scholars see no potential in the interpretation of both norms in harmony. Tatjana Eres, 'The Limits of GATT Article XX: A Back Door for Human Rights?' (2004) 35 *Georgetown Journal of International Law* 597, 631, explaining that most unilateral trade restrictive measures designed to promote human rights are grossly ineffective. Sarah Cleveland, 'Human Rights Sanctions and International Trade: A Theory of Compatibility' (2002) 5 *Journal of International Economic Law* 133, 145, explaining that a directed human rights measure will come up against some challenges, as it might be difficult to measure the effectiveness of human rights measures in international trade regime. Pengcheng Gao, 'Rethinking the Relationship Between the WTO and International Human Rights' (2009) 8 *Richmond Journal of Global Law and Business* 3, 401, arguing that despite the value of non-discrimination underlies both regimes, strictly speaking, the WTO does not incorporate genuinely classic human rights, as scholars commonly interpret. Jenny Schultz and Rachel Ball, 'Trade as a Weapon? The WTO and Human Rights-Based Trade Measures' (2007) 12 *Deakin Law Review* 1, 71 explaining that trade rules restrict the ability of WTO Member States to promote and protect international human rights through trade measures.

Ghana and other WTO Members by further affirming the commitment of developed-country members to provide incentives to Ghana and other WTO Members' enterprises and institutions to promote and encourage technology transfer to promote essential affordable medicines including local manufacture.⁷⁴⁹

From this viewpoint, if the Section 84 model that is consistent with TRIPS and allows for the granting of a compulsory licence provided that the patented invention has not been worked can be implemented in a manner supportive of the right to protect public health in Ghana, and in particular to promote local manufacture of affordable medicines for all, this will be legal. The Doha Declaration provided the same interpretation, which emphasised that the TRIPS Agreement does not and should not prevent Ghana and other WTO Members from taking measure to protect public health.⁷⁵⁰

While the Doha Declaration was considered by many as a breakthrough in the efforts to improve access to medicines for Ghana and other WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector,⁷⁵¹ because it gave an interpretation that recognised the primacy of public health over private IP rights and clarified Ghana and other WTO Members' rights to use the TRIPS safeguards.⁷⁵² Nevertheless, Ghana and other WTO

⁷⁴⁹ "Doha Declaration" (n 6) para. 7.

⁷⁵⁰ *ibid.* para. 4.

⁷⁵¹ "Decision Removes Final Patent Obstacle to Cheap Drug Imports" (n 47). According to the then WTO Director-General, Supachai Panitchpakdi:

This is a historic agreement for the WTO. The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people. It proves once and for all that the organization can handle humanitarian as well as trade concerns. This particular question has been specially difficult. The fact that WTO members have managed to find a compromise in such a complex issue bears testimony to their goodwill. This is a historic agreement for the WTO. The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people. It proves once and for all that the organization can handle humanitarian as well as trade concerns. This particular question has been specially difficult. The fact that WTO members have managed to find a compromise in such a complex issue bears testimony to their goodwill.

For example, Mike Moore, the then WTO Director-General observed that, 'The settlement shows that the WTO's Agreements, such as TRIPS, contain the necessary flexibility to meet the health needs of developing countries and can be used as a basis for resolving difficult issues concerning access to essential drugs'. See Mike Moore, 'Moore Welcomes News of Settlement of South Africa Drug Lawsuit' (World Trade Organisation, Apr. 19, 2001). Available at: <http://www.wto.org/english/news_e/spmm_e/spmm58_e.htm> [Accessed Jun. 11, 2017]. See also James Thuo Gathii, Approaches to Assessing Essential Medicines and the TRIPS Agreement. In: INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE, Peter Yu (ed.), (Westport Connecticut: Praeger, Volume 4, 2007) 400.

⁷⁵² 't Hoen (n 566) 28.

Members that are in need of affordable medicines the most have not been able to utilise the Doha Solution to promote affordable medicine.

5.9. Procedural Restrictions Imposed by the Doha Solution the Use of Compulsory Licences

When considering the right of Ghana and other WTO Members to obtain affordable medicines, the main purpose of Article 31*bis* is to waive the domestic supply requirement under Article 31(f) to enable importing Members to use the Doha system expeditiously.⁷⁵³ Article 31*bis* accomplishes this objective in two ways. First, it would allow Ghana and other WTO Members to grant compulsory licences for their own local manufacturers to produce generic medicines, and even export some of the medicines to other WTO Members in need.⁷⁵⁴ Second, it would allow WTO Members like Ghana lacking sufficient domestic manufacturing capacity as identified in Paragraph 6 of the Doha Declaration to obtain cheaper generic medicines from other WTO Members such as India with adequate manufacturing capacity to export generic medicines.⁷⁵⁵

Still, some serious hurdles remain. Despite several WTO Members adopting the amendment or creating domestic laws to comply with it, and even more articulating support for it, to date,⁷⁵⁶ only two sets of WTO Members have chosen to make use of Article 31*bis*.⁷⁵⁷ The Doha Paragraph 6 Programme appears to have placed further restrictions on the extent to which Ghana and other WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector can make effective use of compulsory licensing under the TRIPS Agreement as identified in Paragraph 6 of the Doha Declaration.⁷⁵⁸ These include firstly, a

⁷⁵³ “Amendment of the TRIPS Agreement” (n 49) see Chapeau.

⁷⁵⁴ “Implementation of Paragraph 6 of the Doha Declaration” (n 47) para. 1(a). See Anderson (n 50) 172.

⁷⁵⁵ *id.* para. 2. “Amendment of the TRIPS Agreement” (n 49) para. 1. See Brook Baker, ‘Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’ (2004) 14 *Indiana International and Comparative Law Review* 3, 677, stating that LDCs will also be permitted to use the August 30 Paragraph 6 Implementation Agreement without not necessarily a need to immediately adopt legislation permitting compulsory licences.

⁷⁵⁶ See the list of members. <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> [Accessed Sept. 12, 2017].

⁷⁵⁷ See Ho (n 589) 217.

⁷⁵⁸ Anderson (n 40) 173-174. Note on the other hand that while the Doha Solution is overly complex in nature for Ghana and other WTO Members to use, evidence also suggests that generally the flexibilities under the TRIPS Agreement have been used more frequently by WTO Members than is commonly assumed and have proven effective for procuring generic versions of essential medicines, particularly for treating HIV infection. See Ellen ‘t Hoen, *et al* (n 696) 190. *ibid.* at 186, finding that between 2011 and 2016 there were 144 use of TRIPS flexibility measures: of which 100 involved compulsory or public non-commercial use licences by 89 countries. Of the 100 instances of compulsory licensing, 81 were implemented, but 19 were not because: (i) the patent holder offered a

condition on importing countries (LDCs excluded) who must notify the TRIPS Council of their eligibility and desire to use compulsory licensing under the Article 31*bis* scheme.⁷⁵⁹

That is, for a country like Ghana to import patented medicines, they must first be an “eligible importing Member”, which is defined as any LDC Member, or a Member that has notified the TRIPS Council of its intention to use the system as an importer.⁷⁶⁰ Secondly, in determining the eligibility of a country to import a specific medicine, the importing country must either be an LDC or decide in accordance with the Appendix to Article 31*bis* that the country lacks the manufacturing capacity for that specific medicine,⁷⁶¹ or make a convincing case that it has insufficient or no manufacturing capacity for the product it seeks.⁷⁶²

Moreover, an importing Member that intends to issue a compulsory licence can only do so, where a pharmaceutical product under consideration is patented in its territory.⁷⁶³ Additionally, importing countries must also notify the TRIPS Council, specifying the name of the products and the expected quantities to be imported.⁷⁶⁴ Furthermore, exporting countries must also issue a compulsory licence.⁷⁶⁵ Also, eligible importing Members shall take reasonable measures to prevent trade diversion or the re-exportation of the products that have been imported into their territories.⁷⁶⁶ This also includes an obligation to make available effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets.⁷⁶⁷

Although the Decision adopts a solution, the numerous safeguards ensuring that no abuses and trade diversions are possible make the process of implementing a compulsory licence disproportionately cumbersome for Ghana and other WTO Members facing a serious health crisis.⁷⁶⁸ Moreover, it contains a requirement on the part of the exporting Member to clearly identify products as generic versions under this exception, including distinguishing the

price reduction or donation (6 instances). *ibid.* 189, finding that there is publicity when there are harsh responses from the US and the EU when a country decides to use compulsory licensing.

⁷⁵⁹ Article 31*bis* (n 47) Annex to the TRIPS Agreement, para. 1(b). See also paras. 2 & 2(c).

⁷⁶⁰ Ho (n 645) 1492.

⁷⁶¹ Article 31*bis* (n 42) Annex to the TRIPS Agreement, para. 2(a)(ii).

⁷⁶² *ibid.* para. 2(a)(ii).

⁷⁶³ *ibid.* para. 2(a)(iii).

⁷⁶⁴ *ibid.* 2(a)(i).

⁷⁶⁵ *ibid.* 2(b).

⁷⁶⁶ *ibid.* para. 4.

⁷⁶⁷ *ibid.* para. 5.

⁷⁶⁸ Thapa (n 48) 473.

products through special packaging, colouring, and/or shaping,⁷⁶⁹ before shipment begins, as well as posting on a website the quantities being supplied to each destination and the distinguishing features of the generic product.⁷⁷⁰ At its end, an importing Member must specify the names and expected quantities of the product and, if the desired medicine is patented in its territory, confirm that it has issued a compulsory licence.⁷⁷¹

For example, under this scheme, Ghana might avoid double compensation, as the obligation in Article 31(h) is waived in the importing country provided that adequate remuneration was paid in the exporting country.⁷⁷² However, the Decision specifies that the remuneration to be paid to the right holder in the country of export must take into account the economic value to the importing country of the use that was authorised in the exporting country.⁷⁷³ No clarification is provided on the application of this standard,⁷⁷⁴ and besides, there is little incentive for exporting countries to participate in the new compulsory licensing scheme.⁷⁷⁵

This requirement presents further practical problems for Ghana and other WTO Members. In order to facilitate access to essential medicines to those living in developing countries, applying an approach that limits the amount of royalties paid to the patentee will help to reduce the costs to the generic manufacturer, create transparency and provide an incentive to generic manufacturers to produce low-cost generics under a compulsory licence, but this is not what the system stipulates.⁷⁷⁶ Furthermore, if some WTO Members are reluctant to issue compulsory licences for the benefit of their own people, it is even less likely that they will use this measure to assist WTO Members like Ghana that lacks adequate manufacturing capacity to promote affordable medicines.⁷⁷⁷

Besides, the general instruction for Ghana and other WTO Members to ensure that the products so imported under a compulsory licence will be used for public health purposes is

⁷⁶⁹ Article 31*bis* (n 47) Annex to the TRIPS Agreement, para. 2(b)(ii)

⁷⁷⁰ *ibid.* para. 2(b)(iii).

⁷⁷¹ *ibid.* para. 2(a)(i), (iii).

⁷⁷² *ibid.* para. 3.

⁷⁷³ *ibid.* para. 2. See “Implementation of Paragraph 6 of the Doha Declaration” (n 47) para. 3.

⁷⁷⁴ Frederick Abbott and Rudolf Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of Doha Declaration Paragraph 6 Decision* (Washington DC., World Bank, 2005) 10-11.

⁷⁷⁵ Thapa (n 48) 473.

⁷⁷⁶ Ng and Kohler (n 586) 161.

⁷⁷⁷ Subhasis Saha, ‘Patent Law and TRIPS: Compulsory Licensing of Patents and Pharmaceutical’ (2009) 91 *Journal of the Patent and Trademark Office Society* 5, 364.

unreasonable.⁷⁷⁸ Last but not least, importing countries must take reasonable measures to prevent re-exportation of the medicines so that the medicines are in fact used for public health purposes.⁷⁷⁹ The procedural requirements of Article 31*bis* as outlined above are numerous, and the amendment imposes too many unnecessary obstacles for Ghana and other WTO Members.⁷⁸⁰ This is not a viable solution to increase access to medicines to Ghana and several other WTO Members.⁷⁸¹ The procedures outlined in Article 31*bis* remain too complex, especially for developing countries that compare closely with Ghana to understand,⁷⁸² as the amendment has made permanent a burdensome drug-by-drug, country-by-country decision-making process'.⁷⁸³

In this context, it is therefore argued that the process of both the exporting and importing countries obtaining compulsory licences increases transaction costs and the possibility of delay.⁷⁸⁴ The public notification provision in Article 31*bis*, which requires the showing of a country's intent to use a compulsory licensing scheme, is unreasonable and unnecessary.⁷⁸⁵ The provision requiring general notification to the TRIPS Council serves no purpose other than to publicly broadcast the desire to use compulsory licensing along and erect political barriers limiting the usefulness of Article 31*bis*.⁷⁸⁶ It is obvious that the conditions established in both the text of the Decision and the statement in regard to allowing exports of patented medicines are hardly compatible with the idea of an "expeditious solution", as identified under Paragraph 6 of the Doha Declaration.⁷⁸⁷

⁷⁷⁸ Fanni Weitsman, 'TRIPS, Access to Medicines and the "North-South" Conflict After Doha: The End or the Beginning' (2006) 67 *Asper Review of International Business and Trade Law* 6, 18-19.

⁷⁷⁹ Article 31*bis* (n 47) Annex to the TRIPS Agreement, para. 3.

⁷⁸⁰ Abbott and Reichman (n 460) 932.

⁷⁸¹ James Tsai, Note, 'Not Tripping over the Pebbles: Focusing on Overlooked TRIPS Article 66 for Technology Transfer to Solve Africa's AIDS Crisis' (2007) 11 *Michigan State University College Journal of Medicine and Law* 2, 458, citing Medecins San Frontieres concern and arguing that the procedural requirements for both importing and exporting countries as overly burdensome and bureaucratic and held that these requirements are a main reason why Article 31*bis* will not increase access to medicines.

⁷⁸² Dutfield (n 568) 123.

⁷⁸³ Members Strike Deal on TRIPS and Public Health: Civil Society Unimpressed (Geneva, Bridges Weekly Trade News Digest, 7 December 2005) 3, citing scepticism raised by Doctors without Borders.

⁷⁸⁴ Mark Lang, Note, 'What a Long, Strange "TRIPS" It's Been: Compulsory Licensing from the Adoption of TRIPS to the Agreement on Implementation of the Doha Declaration' (2004) *John Marshall Review of Intellectual Property Law* 2, 343.

⁷⁸⁵ Anderson (n 50) 174.

⁷⁸⁶ Abbott and Reichman (n 460) 939.

⁷⁸⁷ Medecins Sans Frontieres, Neither Expeditious, Nor A Solution: The WTO August 30th Decision is Unworkable: An Illustration through Canada's Jean Chretien Pledge to Africa (Geneva, Campaign for Access to Essential Medicines, 2006). Available at: <<https://www.msfaccess.org/content/neither-expeditious-nor-solution-wto-august-30th-decision-unworkable>> [Accessed Sept. 14, 2017].

For example, the long protracted process delayed Rwanda's ability to receive necessary medicines.⁷⁸⁸ Rwanda submitted its original notice of intent in July 2007, but its first shipment of medicines from Canada was not sent until September 2008, almost fifteen months later.⁷⁸⁹ When people are dying from diseases that are treatable with medicines, these delays are inexcusable.⁷⁹⁰ For example, in early 2008, Nepal applied for an import-licence under Article 31*bis*. Indian drug manufacturer Natco responded and applied for a compulsory licence to produce generic versions of two anti-cancer medicines. Natco proposed to manufacturer 45,000 doses of the medicine, and subject to Article 31(h), remunerate the patent-holders a five percent royalty.⁷⁹¹

While the Indian government was considering the matter, at the end of 2008, the initiative was indefinitely postponed as one of the patent right holders, Roche, had applied for the right to attend the hearing to approve the compulsory licence. When the Indian court permitted Roche to attend the hearing, Natco postponed the hearing. Roche then sued Natco for patent infringement. Two years later, the compulsory licence application was still pending.⁷⁹² This example shows that the Doha Paragraph 6 Programme has created serious hurdles that can delay the Decision being used for its intended purpose and therefore, it will be unreasonable for Ghana to rely on such a slow system to promote access to timely medicines.⁷⁹³ For example, the Canadian company that exported the medicines to Rwanda is believed to have publicly stated that it would not be willing to do so again because the procedure was too cumbersome.⁷⁹⁴ Nevertheless, there are suggestions that Canada's Bill C-9 had some legislative flaws that prevented Apotex to speed up manufacturing and shipment of medicines to Rwanda.⁷⁹⁵

⁷⁸⁸ Anderson (n 50) 180.

⁷⁸⁹ *ibid.* 180-181.

⁷⁹⁰ Ng and Kohler (n 586) 172.

⁷⁹¹ Thapa (n 48) 473.

⁷⁹² *id.*

⁷⁹³ Ng and Kohler (n 586) 143. Harris (n 85) 390. Anderson (n 40) 104-105.

⁷⁹⁴ Apotex Inc. Press Release, CAMR Federal Law Needs to be Fixed if Life-saving Drugs for Children are to be Developed (May 14, 2009). Available at: <<http://www.apotex.com/global/about/press/20090514.asp>> [Accessed Sept. 14, 2017]. See Ho (n 576) 217.

⁷⁹⁵ See Duncan Matthews, 'From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries?' (2006) 2006 *Intellectual Property Quarterly* 2, 117-118, assessing the complexities and weaknesses in the Canadian Bill C-9. Goldis Chami, Samuel Wasswa-Kintu, 'Compulsory Licensing of Generic Drugs Remains Mired in Quagmires' (2011) 183 *Canadian Medical Association Journal* 11, E705. See also Joel Lexchin, 'Canada and Access to Medicines in Developing Countries: Intellectual Property Rights First' (2013) 9 *Globalization and Health* 42, 3, identifying the flaws in the legislation that made the act largely unworkable as including: the limited list of pharmaceutical products that were eligible for export, limitations on what countries a drug could be exported to, a short duration for a compulsory licence authorising the export of a generic, significant administrative roadblocks, a compulsory licence could only be issued after advance disclosure to the patent-holder of the name of the proposed recipient

The system is so complicated that it will remain virtually unused by Ghana and other WTO Members. This means that both Article 31 of TRIPS and the Doha Solution cannot be relied upon to ensure access to medicines in Ghana. Consequently, Section 84, which is consistent with TRIPS, and allows the granting of a compulsory licence provided that the patented invention has not been worked, would provide a feasible option to mitigate the unnecessarily complex and burdensome procedure that has been created.

5.10. Conclusion

Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is consistent with Article 5(A) of the Paris Convention. The TRIPS Agreement builds upon the provisions of Article 5(A) of the Paris Convention, and incorporates Article 5(A) of the Paris Convention provision under Article 2, thereby establishing the consistency of local working with TRIPS on condition that a compulsory licence may not be applied for on the grounds of failure to work or insufficient working before four years from the date of filing of the patent application or three years from the date of granting of the patent, whichever period expires last.

The TRIPS Agreement however does not limit the grounds or underlying reasons that Ghana and other WTO Members might be used to justify the granting of compulsory licences; it therefore recognises the right of Ghana and each WTO Member to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted subject to the conditions and procedural requirements under Article 31 of TRIPS. The Doha Declaration affirmed this interpretation.⁷⁹⁶ Even though Paragraph 6 of the Doha Declaration recognised that Ghana and WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector face difficulties in making effective use of compulsory licensing under TRIPS, the so-called “expeditious” solution offered by the Doha mechanism, which later culminated with the permanent amendment of Article 31 of TRIPS entails complex procedural requirements.

country, a fixed “maximum quantity” of the product to be exported in generic form and the fact that a generic manufacturer had to file a separate application for every drug, for every amount produced and for every country to which it wanted to export a drug.

⁷⁹⁶ “Doha Declaration” (n 6) para.5(b).

This is evident in the fact that the Doha Solution has only been used once, partly due to the cumbersome formal procedures put in place.⁷⁹⁷ The examples of the administrative hurdles in Canada-Rwanda and India-Nepal illustrate the practical obstacles to be faced by Ghana and other WTO Members in using the scheme.⁷⁹⁸ The discussions in this chapter have shown that Article 31 of TRIPS allows Ghana and other WTO Members the right to grant compulsory licences on any grounds including non-working. However, the conditions and procedural requirements that Ghana and other WTO Members must satisfy when granting compulsory licences are too complex. Additionally, the procedural requirements developed in the Doha mechanism compound the problem by complicating the procedural requirements and adding more restrictions.⁷⁹⁹

Put together, the requirements are too burdensome to follow, as they make it extremely difficult for Ghana and other WTO Members to effectively adopt measures to protect public health and, in particular, to promote access to affordable medicines pointless.⁸⁰⁰ Since compulsory licensing is infrequently used, TRIPS has not effectively reduced the price of medicines on a broad scale, which is essential to increase access to medicines in Ghana and other WTO Members.⁸⁰¹ The argument therefore is that, in view of the multiple conditions and the complex procedural requirements for the granting of compulsory licensing, such a complex and

⁷⁹⁷ Ho (n 632) 1488, observing that despite the long list of procedural requirements compliance with these requirements has not generally been an issue.

⁷⁹⁸ Ng and Kohler (n 573) 171.

⁷⁹⁹ Roger Kampf, *Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation* (World Trade Organization Economic Research and Statistics Division, Staff Working Paper ERSD-2015-07, Jul. 31, 2015) (iv), providing some of the pre-grant conditions many WTO Members require the applicant for a compulsory licence to submit at least details with respect to some or all of the following elements: the product concerned, including, where available, the generic name that identifies a pharmaceutical substance or an active pharmaceutical ingredient (the International Non-Proprietary Name. See the Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances (WHO/PHAM S/NOM 1570, 1997), relevant patents or supplementary protection certificates and the name of the patentee(s), the quantity suggested for production, compulsory licences filed in other countries for the same product, intended duration of the compulsory licence, the name of the importing country(ies) and its/their notification to the TRIPS Council or, in the case of non-WTO Members, to the competent national authority in accordance with para. 2(a) of the 2003 Decision, the patent status in the importing country and, where applicable, the grant of a compulsory licence there, the identity of the purchaser, as well as distinguishing features to be applied to the generic product and the website address where the licensee makes relevant information available. In addition, some legislation specifically requires the granting authorities to provide the patent owner and, in some cases, also any other interested person, with an opportunity to be heard before a compulsory licence is granted. *id.* citing Botswana; Burundi; China; Iceland; Korea; Oman; Samoa; Chinese Taipei. For example, India requires the applicant for a compulsory licence to set out the interest in obtaining such a licence and the terms and conditions that are acceptable. See also Matthews (n 795) 130, concluding that further uncertainties lie ahead, including the prospect that some WTO Members may be prepared to engage in dispute settlement proceedings with respect to perceived or alleged breaches of the right and obligations to the amendment of the TRIPS Agreement.

⁸⁰⁰ "Doha Declaration" (n 6) para. 4.

⁸⁰¹ Tina Bhatt, Note, 'Amending TRIPS: A New Hope for Increased Access to Essential Medicines' (2008) 33 *Brooklyn Journal of International Law* 2, 600.

burdensome system is largely symbolic and is unlikely to lead to any significant outcome in terms of promoting access to affordable medicines in Ghana and other WTO Members.⁸⁰²

The conclusion is that Section 84, which is consistent with TRIPS, and allows the granting of a compulsory licence provided that the patented invention has not been worked, would provide a feasible option for Ghana to mitigate the unnecessarily complex and burdensome procedures that have been created. The next chapter questions whether the implementation of Section 84 model in Ghana will threaten the attainment of socio-economic objectives resulting from the loss of inward FDI opportunities, risks of retaliatory action and their potential frustration owing to impact of FTAs.

⁸⁰² Gary Sampson, *The WTO and Sustainable Development* (Hong Kong, United Nations University Press, 1st edn., 2005) 159.

Chapter Six

6.0. Would Implementation of the Section 84 Model Threatens the Attainment of Socio-Economic Objectives in Ghana?

6.1. Aim of the Chapter

This chapter examines whether Ghana's implementation of the Section 84 model to promote affordable medicines will threaten the attainment of socio-economic objectives, due to the loss of inward FDI opportunities, retaliatory action and their potential frustration owing to the impact of FTAs. The chapter argues that no FTA provision will directly prohibit Ghana from implementing a Section 84 model to promote affordable medicines. Therefore, if Ghana can withstand the potential political pressure and high litigation costs and mitigate the domestic capacity issues pertaining to local manufacture for distribution, the attainment of socio-economic objectives will not be threatened because there are inadequate linkages between robust IP rights protection and inward FDI opportunities.

6.2. Introduction to the Chapter

As argued so far, Section 84 is consistent with TRIPS, and nothing in the light of the Agreement would, in fact, prevent Ghana from adopting and implementing such a model to obtain affordable medicines. Nevertheless, as far as access to affordable medicines in Ghana is concerned, an important question to consider is whether the implementation of the Section 84 model will threaten the attainment of socio-economic objectives due to the loss of inward FDI opportunities, retaliatory action and their potential frustration owing to the impact of FTAs. Yu has importantly asserted that there is a linkage between IP and investment.⁸⁰³ Notably, some studies have fundamentally shown a presumed linkage between stronger IP rights protection as an essential foundation for inward FDI opportunities and the attainment of long-term socio-economic objectives.⁸⁰⁴

⁸⁰³ Peter Yu, 'The Investment-Related Aspects of Intellectual Property Rights' (2017) 66 *American University Law Review* 3, 837.

⁸⁰⁴ Rod Falvey, Neil Foster and Olga Memedovic, *The Role of Intellectual Property Rights in Technology Transfer and Economic Growth: Theory and Evidence* (Vienna: United Nations Industrial Development Organisation, 2006) 9.

The bottom line is that relatively weak IP rights protection in a developing country like Ghana may lower the probability that multinational firms will invest there.⁸⁰⁵ A study commissioned by the UN found overwhelming evidence that appears to confirm that stronger IP rights protection encourages FDI and leads to increased innovation and socio-economic growth.⁸⁰⁶ In this context, Ghana and other developing countries are cautious in using compulsory licensing to avoid any investment consequences of alienating large pharmaceutical companies from the role that they play in their economies.⁸⁰⁷ Apart from the threat of economic sanctions by key developed countries like the US and the EU, the strength of the pharmaceutical industry's response in South Africa, Thailand and Brazil after the use of compulsory licences may have a discouraging effect on Ghana and other WTO Members that lack the political strength to withstand potential threats of law suits or a withdrawal of investment.⁸⁰⁸

Moreover, some developed countries also bind developing countries to more extensive patent protection through FTAs.⁸⁰⁹ Abbott emphasised the investment aspects that often push the global pharmaceutical industry for stronger patent protection worldwide.⁸¹⁰ This is because the pharmaceutical industry considers patents an essential inducement in the development of new medicines.⁸¹¹ Often these FTAs impose stricter IP standards with a view to limiting the use of TRIPS flexibilities.⁸¹² Notwithstanding this, developing countries agree to FTAs to appease

⁸⁰⁵ Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer* (Washington, D.C. International Finance Corporation Working Paper Series. Discussion Paper, No. IFD 19, The World Bank, 1994) 1.

⁸⁰⁶ Falvey, *et al* (n 804) x.

⁸⁰⁷ Harris (n 85) 391-392.

⁸⁰⁸ Ho (n 29) 448-449. Watson (n 86) 151-153, stating that Brazil, South Africa, and Thailand have all at some point been placed on the 301 Watch-List.

⁸⁰⁹ Halajian (n 625) 1214. Margo Bagley, 'Legal Movements in IP: TRIPS, Unilateral Action, Bilateral Agreements, and HIV/AIDS' (2003) 17 *Emory International Law Review* 2, 792. Hestermeyer (n 331) 261-272, discussing the challenges posed by FTAs and BITs.

⁸¹⁰ Frederick Abbott, *The Cycle of Action and Reaction: Developments and Trends in Intellectual Property and Health*. In: *NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES*, Pedro Roffe, Geoff Tansey and David Vivas-Eugui (eds.) (London: Earthscan, 2006) 36, finding that:

A patent is essentially a financial instrument that entitles its bearer to achieve greater than competitive market rates of return on investment. The Pharma companies are market-oriented enterprises that seek to maximize shareholder returns on investment. Pharma treats potential intrusion on the security of the patent and related regulatory support as a threat to return on investment. Pharma justifies its rent seeking as necessary to the funding of research and development for new medicines....The Pharma companies demand rules and enforcement that will protect their income streams, justifying a high return on investment as necessary to drug development.

⁸¹¹ Iain Cockburn and Genia Long, 'The Importance of Patents to Innovation: Updated Cross-industry Comparisons with Biopharmaceuticals' (2015) 25 *Expert Opinion on Therapeutic Patents* 7, 739.

⁸¹² Susan Sell, 'TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TTP' (2011) 18 *Journal of Intellectual Property Law* 2, 488. See Hestermeyer (n 631) 289. Harris (n 85) 393-394.

and build a relationship with developed countries, in the hope of gaining benefits in other trade areas.⁸¹³

While policymakers in developed countries were obsessed with the protection of the investments made by their exporting IP industries,⁸¹⁴ their developing country counterparts were likewise preoccupied with international compliance and the acquisition of foreign investments.⁸¹⁵ According to Yu, ‘Through bilateral, regional, and plurilateral trade and investment agreements, new norms are being developed to address the investment-related aspects of IP rights’.⁸¹⁶ He maintains that policymakers on both sides focused so much on investments that they ignored a primary justification for IP protection, that is, to provide inducements for creativity and innovation. Such a focus is dangerous from a public interest standpoint for countries like Ghana.⁸¹⁷ He further asserts that, ‘Such a shift could take away the traditional limitations, safeguards, and flexibilities that have been built into the international IP regime’.⁸¹⁸

Ghana has signed FTAs with some developed countries with the objective of taking advantage of opportunities offered in key strategic markets, fostering business cooperation and technology transfer and encouraging FDI.⁸¹⁹ Therefore, in the context of Ghana, the foregoing view expressed by Yu is important given that while a country such as India, with a relatively large economy and advanced pharmaceutical industry with the capacity to manufacture

⁸¹³ Bhatt (n 801) 618. Bagley (n 792) 792-792.

⁸¹⁴ Yu (n 803) 841-842.

⁸¹⁵ Deere (n 450) 242, mentioning that implementation of the TRIPS Agreement in the OAPI (African Intellectual Property Organization) countries was shaped by a pro-IP and “compliance-plus”-oriented political environment. See also Maskus and Reichman (n 518) 18, expressing concern that many developing countries are “compliance oriented”.

⁸¹⁶ Yu (n 803) 831.

⁸¹⁷ Peter Yu, *The Non-Multilateral Approach to International Intellectual Property Normsetting*. In: *INTERNATIONAL INTELLECTUAL PROPERTY: A HANDBOOK OF CONTEMPORARY RESEARCH*, Daniel Gervais (ed.) (Cheltenham: Elgar Edward, 2015) 112, observing that:

When policymakers and trade negotiators focus on the protection of intellectual property investments by their own nationals, they will likely be less interested in evaluating the economic efficiency of the intellectual property system and the welfare gains that system produces. Instead, they will push for the development of a system that protects foreign investors often at the expense of the public interest . . . , the local innovative environment and the country’s social-economic conditions.

⁸¹⁸ Peter Yu, ‘Currents and Crosscurrents in the International Intellectual Property Regime’ (2004) 38 *Loyola Los Angeles Law Review* 1, 392–400, examining the growing use of bilateral and regional trade agreements to push for higher intellectual property standards. Yu (n 804) 835. Yu (n 217) 863, discussing Articles 7 and 8 of TRIPS, 869-879, examining Article 31*bis* and the Doha Declaration.

⁸¹⁹ For key FTAs signed by Ghana-US see (n 87). See also Trade Policy Review Report by Ghana (WTO Trade Policy Review Body, WT/TPR/G/298, 2014) 8, para.3.10.

affordable medicines, could easily implement Section 84 without the fear of losing significant FDIs, the opposite conclusion can be drawn about Ghana, a country that relies heavily on FDIs for the attainment of its socio-economic objectives.⁸²⁰ For example, investments recorded for the fiscal year ending 31 December 2017 hit US\$ 6.19 billion with FDI component reaching US\$ 4.91 billion (i.e. approximately 98.2 per cent of the original target for the country).⁸²¹ The investments recorded have exciting prospects of generating a minimum of 22,570 jobs. Added to this, FDIs channelled through the Ghana Free Zones Board, Minerals Commission and the Petroleum Commission also reached an unprecedented US\$4.98 billion.⁸²²

6.3. The Relationship Between TRIPS and FTAs

FTAs are reciprocal preferential trade agreements between two or more partners.⁸²³ There has been a growing concern about an ongoing shift of IP norm-setting activities from the trade regime to the investment regime,⁸²⁴ as many industries and their supportive governments have already viewed IP protection through an investment lens.⁸²⁵ Advocates often suggest that FTAs remain consequential to the socio-economic needs of developing countries like Ghana⁸²⁶ except that they mostly include either investment protection clauses or chapters addressing IP rights protection.⁸²⁷ The trend in FTAs is indicative of the long history of international IP

⁸²⁰ *ibid.* 12, para. 6.12.

⁸²¹ Investment in the Fourth Quarter. Ghana Investment Promotion Centre. (2017) 13 *Quarterly Investment Report* 4, 1.

⁸²² *id.*

⁸²³ Preferential trade arrangements in the WTO are unilateral trade preferences. They include a Generalized System of Preferences schemes (under which developed countries grant preferential tariffs to imports from developing countries), as well as other non-reciprocal preferential schemes granted a waiver by the General Council. See <https://www.wto.org/english/tratop_e/region_e/rta_pta_e.htm> [Accessed Sept. 12, 2017]. See Rorden Wilkinson, *Multilateralism and the World Trade Organisation: The Architecture and Extension of International Trade Regulation* (London and New York: Routledge, 2000) 80.

⁸²⁴ Rochelle Dreyfuss and Susy Frankel, 'From Incentive to Commodity to Asset: How International Law is Reconceptualising Intellectual Property' (2015) 36 *Michigan Journal of International Law* 4, 566 observing that while TRIPS laid the platform for commodification, much of the current regime shifting is reconceptualising IP as an asset and progressively detaching it from its grounding in incentive-based principles.

⁸²⁵ Yu (n 803) 909.

⁸²⁶ The European Union Explained: Trade - Free Trade is a Source of Economic Growth (Luxembourg: Publications Office of the European Union, 2013) 5, noting that free trade is more important than ever for economic growth and job creation. Shujiro Urata, 'Globalization and the Growth in Free Trade Agreements' (2002) 9 *Asia-Pacific Review* 1, 25, observing that access to markets and the expansion of export opportunities are particularly important for companies from smaller countries. *ibid.* at 26, noting that internal factors include economic growth from increased efficiency due to greater competition as a result of the markets being opened.

⁸²⁷ Frederick Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) 99 *The American Journal of International Law* 2, 349.

protection, whose development has primarily been a one-way route towards ever increasing levels of protection.⁸²⁸

The pharmaceutical industry stands strongly behind these efforts.⁸²⁹ While the IP chapters of these agreements vary in their specific terms, their common objective is to deter developing countries from using the TRIPS flexibilities, such as by limiting the grounds on which compulsory licences may be granted.⁸³⁰ This confirms Yu's position that if the IP standards in FTAs are set too high, they will erode global competitiveness and jeopardise access to essential medicines to countries like Ghana.⁸³¹ That is, FTAs with dominant economies like the EU and the US, if contain restrictive provisions would most likely threaten the implementation of the Section 84 model in Ghana.⁸³²

The relationship between the TRIPS Agreement and FTAs lies in the general most favoured nation treatment, a principle, which was part of the GATT 1947⁸³³ and is found in Article I of

⁸²⁸ Henning Grosse Ruse-Khan, 'The International Law Relation Between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?' (2011) 18 *Journal of Intellectual Property Law* 2, 329.

⁸²⁹ See Free Trade Agreements - Challenges and Opportunities (PhRMA "Special 301" Submission to USTR, 2004) Appendix B, observing that FTA negotiations are a "second best" to multilateral agreements, but that 'deliberations in the TRIPS Council call into question the current value of the WTO as a venue for improving the worldwide protection of intellectual property'. See also PhRMA Statement on 2016 "Special 301 Report (Submission to USTR, 2016) 15 & 22 - Section B, finding that PhRMA members encourage USTR and other federal agencies to continue to promote and support effective patent enforcement abroad, including in bilateral forums.

⁸³⁰ Article 17.9(7) of the United States-Australia Free Trade Agreement (Jan. 1, 2005, 43 I.L.M. 1248). Article 16.7(6) of the United States-Singapore Free Trade Agreement (May 6, 2003, 42 I.L.M. 1026). Peter Drahos, 'BITS and BIPs: Bilateralism in Intellectual Property' (2001) 4 *The Journal of World Intellectual Property* 6, 791, 804. Sell (n 812) 488. Xavier Seuba, Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit (Geneva: ICTSD Programme on IPRs and Sustainable Development Working Paper, June 2009) v.

⁸³¹ Peter Yu, 'The RCEP and Trans-Pacific Intellectual Property Norms' (2017) 50 *Vanderbilt Journal of Transnational Law* 3, 740.

⁸³² See World Trade Organisation, Regional Trade Agreements Gateway. Available at: https://www.wto.org/english/tratop_e/region_e/region_e.htm [Accessed Sep. 16, 2017]. Carlos Correa, 'Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines' (2004) 36 *Case Western Reserve Journal of International Law* 1, 79, observing that shortly after the conclusion of the Uruguay Round, the EU and the US continued to use various means to put pressure on developing countries not only to implement the TRIPS Agreement, but also to obtain "TRIPS-plus" protection, that is, levels of protection beyond the minimum standards required by the TRIPS Agreement. Ruth Okediji, 'Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection' (2004) 1 *University of Ottawa Law & Technology Journal* 1-2, 140, stating that despite the hope that the TRIPS Agreement would diminish the use of bilateralism to secure international protection for IP, post-TRIPS bilateralism remains the dominant policy of the US. Peter Drahos, Expanding Intellectual Property's Empire: The Role of FTAs (Regulatory Institutions Network, Research School of Social Sciences, Australian National University, 2003) 7, explaining that the US was the principal architect of the global regulatory ratchet for IP, with the EU to a lesser extent also making use of it. Keith Maskus, 'Intellectual Property Rights and Economic Development' (2000) 32 *Case Western Journal of International Law* 3, 493, stating that the main beneficiary of BTAs is the US, with a net inflow of some US\$ 5.8 billion per year.

⁸³³ Part 1, Article 1 of the General Agreement on Tariffs and Trade 1947 (GATT 1947), 55 U.N.T.S. 194.

the GATT 1994.⁸³⁴ This non-discrimination norm underpins a specific requirement that in a situation where for example, Ghana extends or grants any “advantage, favour, privilege or immunity” to the nationals of another WTO Member then the same concession must be accorded to the nationals of other Members “immediately and unconditionally”.⁸³⁵ Although some principles contained in the GATT had a bearing on IP measures taken on imports or exports, for example Article XX(d) of the GATT 1947, which specifically referred to IP rights,⁸³⁶ the most favoured nation principle was not traditionally incorporated into IP rights related conventions.⁸³⁷

It was assumed that the Members would not grant IP rights protection to foreign nationals more extensively than the protection granted to local nationals.⁸³⁸ As bilateral pressure mounted in the late 1980s to standardise IP rights protection, the Uruguay Round negotiators became concerned that some countries were indeed granting IP rights privileges to foreign nationals more extensively than they were granting rights to their own nationals.⁸³⁹ This focused attention on incorporating a most favoured nation principle into TRIPS, so that all Members would obtain an equivalent level of protection when more extensive protection was granted to foreigners.⁸⁴⁰ Article 4 of the TRIPS Agreement provides that any advantage, favour, privilege

⁸³⁴ Article 1(1) of the General Agreement on Tariffs and Trade (GATT 1994) 1867 U.N.T.S. 187; 33 I.L.M. 1153 provides for WTO members to extend most favoured treatment to like products of other WTO members regarding tariffs, regulations on exports and imports, internal taxes and charges, and internal regulations. In other words, “like” products from all WTO members must be given the same treatment as the most advantageous treatment accorded the products of any state.

⁸³⁵ William Dave, *Non-discrimination in the World Trade Organization: The Rules and Exceptions* (The Hague, Hague Academy of International Law, 2012) 110.

⁸³⁶ Now Article XX(d) of GATT 1994. Under this provision, measures that would otherwise be inconsistent with the General Agreement could be taken (subject to certain conditions) to secure compliance with laws or regulations, which constitute a means of arbitrary or unjustifiable discrimination between countries or a disguised restriction on international trade, relating, among other things, to IP rights. Note that this clause is not applicable to international agreements related to the protection of IP that entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against a national of other members. Notifications of Laws and Regulations Relating to Articles 3, 4 and 5 of the TRIPS Agreement: Format for One Option (Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/9, Mar. 12, 1997) para. 2. See Peter-Tobias Stoll, Jan Busche, Katrin Arend (eds.), *WTO: Trade-Related Aspects of Intellectual Property Rights*, (Leiden: Max Planck Commentary of World Trade Law, Martinus Nijhoff, 2009) 166. Susy Frankel and Daniel Gervais, *Advanced Introduction to International Intellectual Property* (Cheltenham: Elgar Edwards, 2016) 55.

⁸³⁷ Note that Article 2(1) of the Paris Convention requires that state parties provide the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with.

⁸³⁸ “Resource Book on TRIPS” (n 16) 63, para. 1.2.

⁸³⁹ *id.*

⁸⁴⁰ *id.* See also Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (MTN.GNG/NG11/W/26, July 1988) III.D.6.

or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.⁸⁴¹

According to the Appellate Body in the US – Section 211 Omnibus Appropriations Act of 1998, the most favoured nation principle is a cornerstone of the WTO system and must be accorded the same significance with respect to IP rights under the TRIPS Agreement that it has long been accorded with respect to trade in goods under the GATT.⁸⁴² Added to the foregoing principle is Article 1(1) of TRIPS, which provides that Members may implement more extensive protection than that set out by the Agreement, provided that such protection does not contravene the provisions of the Agreement.⁸⁴³ The basic assumption by that reference is that the TRIPS Agreement only sets the minimum standards for IP protection and, therefore, Members are free to implement standards that are more extensive.⁸⁴⁴

FTAs are however exceptions to the general rule of most favoured nation.⁸⁴⁵ The legal basis of this exception finds its roots under the GATT 1947 in Article XXIV, and it was subsequently adopted by the WTO in 1994.⁸⁴⁶ Accordingly, Article XXIV:4 of the GATT 1947 stipulates that: ‘The contracting parties recognise the desirability of increasing freedom of trade by the development, through voluntary agreements, of closer integration between the economies of the countries parties to such agreements’.⁸⁴⁷ More importantly, a major qualification is found in Article XXIV:5 of the GATT, which reiterates that the GATT ‘shall not prevent, as between the territories of contracting parties, the formation of a customs union or of a free-trade area or the adoption of an interim agreement necessary for the formation of a customs union or of a free-trade area’.⁸⁴⁸

⁸⁴¹ “Resource Book on TRIPS” (n 16) 61.

⁸⁴² Report of the Appellate Body in United States – Section 211 Omnibus Appropriations Act of 1998 (WT/DS176/AB/R, Jan. 2, 2002) para. 297.

⁸⁴³ Peter Drahos, ‘Four Lessons for Developing Countries from the Trade Negotiations Over Access to Medicines’ (2007) 28 *Liverpool Law Review* 1, 14.

⁸⁴⁴ Reichman (n 66) 351.

⁸⁴⁵ Mohammed El Said, ‘Public Health related TRIPS-plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the Eastern Mediterranean Region’ (Cairo, Egypt: World Health Organisation and International Centre for Trade and Sustainable Development 2010) 40.

⁸⁴⁶ The GATT (1994) (n 834).

⁸⁴⁷ Peter Gillies and Gabriel Moens, *International Trade & Business Law & Policy* (London: Cavendish Publishing, 2000) 519,

⁸⁴⁸ Report of the Panel in Turkey - Restrictions on Imports of Textile and tioducts, Report of the Panel (WT/DS34/R, May 31, 19991) para. 104.

This creates an exception for FTAs and customs unions for trade in goods. These pertinent conditions first provide that Members of the FTAs must substantially remove all barriers to trade across all sectors with no partial preferences or exclusion of certain sectors. Secondly, trade barriers against non-members of the FTAs should not be more restrictive than before the agreement came into effect. Finally, there should be a schedule that ensures that the formation of a FTA will be complete within a reasonable amount of time.⁸⁴⁹ Relative to the relationship between TRIPS and FTAs, Article 30 of the VCLT concerning the application of successive treaties (TRIPS) related to the same subject matter (IP protection) is relevant to the validity of FTAs.

On this basis, it has been argued that any agreement (FTA) created subsequent to the WTO treaty (TRIPS) is relevant and can potentially interact with certain obligations and the enjoyment of rights attached to the latter.⁸⁵⁰ The approach to consistent interpretation is primarily set out in the general rule of Article 31(1) of the VCLT. Article 31(3)(c) VCLT basically covers all relationships between TRIPS and subsequent FTAs. This provision provides for the interpreter to aim for as much as possible a coherent and mutually consistent interpretation of the different treaty rules in consideration of subsequent agreements between the parties.⁸⁵¹ This provision would require Ghana to interpret TRIPS and its FTA provisions as a single set of compatible treaty obligations, since almost all FTAs have been agreed to amongst states that are also Members of the WTO.

From this distinction, it follows that an obligation in any FTA signed by Ghana may conflict with an optional TRIPS provision and limit Ghana's ability to exercise a right or flexibility that TRIPS provides, such as the implementation of the Section 84 to promote affordable medicines.⁸⁵² In the relation between the FTA parties, these conflict clauses are *lex specialis*⁸⁵³

⁸⁴⁹ Article XXIV(a), (b) &(c) of the GATT. Rafael Leal-Arcas, 'Proliferation of Regional Trade Agreements: Complementing or Supplanting Multilateralism?' (2011) 11 *Chicago Journal of International Law* 2, 604. For further discussion of Article XXIV of GATT see Mitsuo Matsushita, Legal Aspects of Free Trade Agreements in the Context of Article XXIV of the GATT 1994: WTO and East Asia: New Perspectives. In: WTO AND EAST ASIA: NEW PERSPECTIVES, Mitsuo Matsushita and Dukgeun Ahn (eds), (London: Cameron May, 2004) ch. 19, 497-514.

⁸⁵⁰ Pauwelyn (n 675) 541 & 544.

⁸⁵¹ Article 31(3)(a) of the VCLT (n 119).

⁸⁵² Ruse-Khan (n 828) 328.

⁸⁵³ Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to other Rules of International Law* (New York: Cambridge University Press, 2003) 412, explaining *lex specialis* that when two norms apply to the same subject matter, that which is more specific should prevail and be given priority over the more general rule.

to the general rule in Article 1(1) of TRIPS.⁸⁵⁴ That is, if Ghana were to decide to waive rights (by not exercising certain TRIPS flexibilities), then any FTA provision that undermines the use of such a flexibility would arguably be deemed valid.⁸⁵⁵ For example, the US-Australia FTA limits the grounds on which compulsory licences may be granted to situations where the grant of such licences is necessary in order to remedy a practice determined after judicial or administrative process to be anticompetitive, as well as to “cases of public non-commercial use”, or of “national emergency, or other circumstances of extreme urgency” if further conditions are satisfied.⁸⁵⁶

However, such a far-reaching provision if applies to any of the FTAs signed by Ghana then then such a provision may weaken the country’s right to effectively use implement the Section 84 model or compulsory licensing as set out in the Doha Declaration, which affirmed that Ghana and other WTO Members may use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.⁸⁵⁷ However, if FTA provisions do safeguard TRIPS flexibilities, such a provision will arguably prevail.⁸⁵⁸ For example, the FTAs concluded by Japan contain a clause that says that ‘in the event of any inconsistency between this Agreement and the WTO Agreement, the WTO Agreement shall prevail to the extent of the inconsistency’.⁸⁵⁹ In such cases, the application of TRIPS flexibilities would prevail over FTA rules.⁸⁶⁰

6.4. Implementation of Section 84: Assessing the Potential Impediments and Threats

Although India’s use of Section 84 demonstrates that if used, compulsory licensing can be an effective tool to provide access to essential medicines, numerous legal and political barriers have been erected by developed countries to further minimise, if not eliminate, the use of

⁸⁵⁴ Article 1(1) of TRIPS in part provides that:

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.

⁸⁵⁵ Ruse-Khan (n 838) 337 & 352.

⁸⁵⁶ Article 17.9.7(b)(i)-(iii) of the US-Australia FTA (n. 813).

⁸⁵⁷ “Doha Declaration” (n 6) para. 4.

⁸⁵⁸ Ruse-Khan (n 828) 325.

⁸⁵⁹ See Article 12 of the Japan-Indonesia Economic Partnership Agreement (Aug. 20, 2007), Article 11 of the Japan-Thailand Economic Partnership Agreement (Apr. 3, 2007), Article 11 of the Japan-Philippines Economic Partnership Agreement (Sept. 9, 2006), Article 11 of the Japan-Malaysia Economic Partnership Agreement (Dec. 13, 2005) and Article 9 of the Japan-Vietnam Economic Partnership Agreement (Dec. 12, 2008).

⁸⁶⁰ Article 197:1 of the EU-Colombia-Peru Free Trade Agreement (Mar. 24, 2011).

TRIPS flexibilities. Retaliatory action, be it a legal challenge, political pressure or economic sanctions, could hinder the effectiveness of the implementation of Section 84 in Ghana by making such a measure legally, administratively, and politically challenging. More importantly, Ghana has since the 1960s, depended heavily on foreign aid and development assistance to fund its development programmes in spite of the country's wealth in natural resources - cocoa, gold, timber, oil and gas, bauxite and manganese, among others.⁸⁶¹

Therefore, given that the pharmaceutical industry considers patents an essential inducement in the development of new medicines, the threat of a lawsuit poses an impediment to the implementation of Section 84 in Ghana, as has been evidenced by the case of South Africa.⁸⁶² For example, after Thailand issued a compulsory license for Abbott's HIV medicine, Kaletra, Abbott stated that it would not sell certain medicines in Thailand and withdrew seven new medicines applications from the country.⁸⁶³ Some pharmaceutical companies also threatened to move investments away from Brazil after the country attempted to use compulsory licensing on non-working grounds.⁸⁶⁴

It has been reported that Novartis abandoned plans to set up R&D centres in India, after its petition challenging the country's patent law was thrown out by the High Court in Chennai.⁸⁶⁵ In addition to retaliation by pharmaceutical companies, there is a possibility that trade sanctions will be imposed by developed countries or the US will place Ghana on the "Special 301 Watch-List" if Section 84 is implemented.⁸⁶⁶ For example, following India's use of Section 84,

⁸⁶¹ Sule Jotie, *Ghana Beyond Aid - President Akufo-Addo Charts the Path*, 61 *One Years After Independence* (Government of Ghana Official Portal, May 2018). Available at: <<http://www.ghana.gov.gh/index.php/media-center/features/4437-ghana-beyond-aid-61-one-years-after-independence>> [Accessed May 5, 2018]. Note that Ghana received foreign aid to the tune of \$1,324 billion in 2016. See *Development Aid at a Glance Statistics by Region: AFRICA*. 2018 Edition (Committee of the Organisation for Economic Co-operation and Development (Paris, OECD, Apr. 9, 2018) 7, Table 2.2.7.

⁸⁶² Watson (n 86) 152.

⁸⁶³ Ho (n 29) 444.

⁸⁶⁴ *Brazil Issues Compulsory Licence for AIDS Drug* (International Centre for Trade and Sustainable Development Report, *Bridges Weekly Trade News Digest*, Vol. 11, No. 16, May 9, 2007) 1, stating that Merck responded by saying that it is "profoundly disappointed" by the outcome, with the US-Brazil Business Council calling it "a major step backward" that will discourage investment in Brazil.

⁸⁶⁵ Victoria Gill, *Novartis withdraws investment from India* (London: Chemistry World Published by the Royal Society of Chemistry, Oct. 1, 2007). Available at: <<https://www.chemistryworld.com/news/novartis-withdraws-investment-from-india/3003000.article>> [Accessed Oct. 12, 2017].

⁸⁶⁶ Watson (n 86) 151-153, examining that Brazil, South Africa, and Thailand have all at some point been placed on the 301 Watch-List.

evidence suggests that the country has come under intense pressure from the pharmaceutical industry, the US and the EU.⁸⁶⁷

Evidence suggests that on 13 March 2013, during a hearing at the House of Representatives' Committee on Ways and Means' Subcommittee on "US-India Trade Relations: Opportunities and Challenges",⁸⁶⁸ it was stated that India had abused compulsory licences, as they are intended to be used in national emergencies and situations of extreme urgency.⁸⁶⁹ The US subsequently put India on the "Section 301 Watch List".⁸⁷⁰ Although India has defended its use of Section 84 as consistent with TRIPS,⁸⁷¹ it appears that the country has been unable to resist the increasing bilateral pressure.⁸⁷²

Accordingly, the US-India Business Council submission to the US Trade Representative shows that the US-India Joint Business Council obtained verbal assurance for the non-use of a compulsory licence from the Government of India.⁸⁷³ India remains under the 2017 Special

⁸⁶⁷ Peter Roderick and Allyson Pollock, 'India's Patent Laws under Pressure' (2012) 380 *The Lancet* 9846, e2. 'A Timeline of US Attacks on India's Patent Law & Generic Competition' (Access Campaign/Medecins sans Frontieres). <https://www.msfacecess.org/sites/default/files/MSF_assets/IP/Docs/IP_factsheet_TimelineUSPressu reIndia_ENG_2014.pdf> [Accessed Jun. 14, 2017].

⁸⁶⁸ Written Testimony of Roy Waldron, Chief Intellectual Property Counsel Pfizer Inc. Before the House Committee on Ways and Means Subcommittee on Trade Hearing. On U.S.-India Trade Relations: Opportunities and Challenges (Mar. 13, 2013) 4, stating that despite being a member of the WTO and an important global trading partner, India has systematically failed to interpret and apply its intellectual property laws in a manner consistent with recognised global standards.

⁸⁶⁹ *ibid.* 7.

⁸⁷⁰ "The Special 301 Report, 2014". Available at: <<https://ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FIN AL.pdf>> [Accessed Aug. 2, 2017] 37.

⁸⁷¹ Trade Minister "Anand Sharma" Accuses US of Protectionism Ahead of Visit (The Economic Times, 5 March 2014). Available at: <http://articles.economictimes.indiatimes.com/2014-03-05/news/47895347_1_anand-sharma-compulsory-licence-intellectual-property-rights> [Accessed Jul. 1, 2017]. Indian Finance Minister (Mr. P. Chidambaram) Defends Compulsory Licensing during at the Leadership Summit of the US-India Business Council (USIBC) in Washington. See Chidanand Raighattal, Don't Let Rhetoric Trump Reason, Chidambaram tells US (The Times of India, Jul. 12, 2013). Available at: <<http://timesofindia.indiatimes.com/business/india-business/Dont-let-rhetoric-trump-reason-Chidambaram-tells-US/articleshow/21043653.cms>> [Accessed Jul. 2, 2017]. 'Department of Intellectual Property and Promotion, Ministry of Commerce. Statement on Bilateral Mechanism for Discussing IPR Issues with USA' (Press Information Bureau, Government of India, Ministry of Commerce & Industry, Oct. 3, 2014). <<http://pib.nic.in/newsite/PrintRelease.aspx?relid=110288>> [Accessed Aug. 1, 2017]. 'India Ready to Take on US over Patents at World Trade Organisation' (The Times of India, Feb. 25, 2014). Available at: <<http://timesofindia.indiatimes.com/business/india-business/India-ready-to-take-on-US-over-patents-at-World-TradeOrganization/articleshow/30967967.cms>> [Accessed Sept. 1, 2017].

⁸⁷² Patralekha Chatterjee, Special Report: India Rocked by Report of Secret Assurance to US Industry on IP (Intellectual Property Watch, Mar. 22, 2016). Available at: <<http://www.ip-watch.org/2016/03/22/india-rocked-by-report-of-secret-assurance-to-us-industry-on-ip/>> [Accessed Jul. 19, 2017].

⁸⁷³ Zeba Siddique, U.S. Industry Body says India Agreed to not Issue 'Compulsory' Drug Licences (Reuters, Mar. 9, 2016). Available at: <<http://uk.reuters.com/article/india-patents-usa-idUKKCN0WA18Q>> [Accessed Sept. 12, 2017]. Amit Sengupta, India Assures the US it Will Not Issue Compulsory Licences on Medicines (The Wire, Mar. 12, 2016). Available at: <<https://thewire.in/24621/india-assures-the-us-it-will-not-issue-compulsory-licences-on-medicines/>> [Accessed Oct. 24, 2017].

301 Report.⁸⁷⁴ Moreover, in 2014, the EC consistently reiterated its concerns that some countries have tended to engage in aggressive policies that seek to appropriate foreign technology in sectors considered strategic, e.g. through “forced technology transfer”.⁸⁷⁵

Subsequently, the EU listed India as one of the high priority countries over a large number of locally produced IP rights infringing goods, notably medicines and related products.⁸⁷⁶ Moreover, it has been reported that in 2015, Switzerland, which is currently assisting Ghana to develop its IP policy,⁸⁷⁷ put bilateral pressure on Colombia’s Ministry of Health and Social Protection to deny the grant of a compulsory licence for Imatinib, a leukaemia medicine owned by Novartis.⁸⁷⁸ Therefore, Ghana must be aware of the risks that powerful governments pose, as the risk of retaliation is high where the country has signed some FTAs with some developed countries.

6.4.1. Potential Frustration Owing to Impacts of FTAs Signed by Ghana

6.4.1.1. Ghana-US AGOA Initiative and TIFA

Ghana enjoys preferential trade arrangements with special access to the US market under the AGOA initiative, whereby over six thousand products from the beneficiary countries enter the US market duty-free and quota-free.⁸⁷⁹ Section 104 of the AGOA *inter alia* authorises the US President to designate an African country as a beneficiary of trade concessions if the President determines that such a country has established or is making progress towards establishing

⁸⁷⁴ Available at: <<https://ustr.gov/sites/default/files/301/2017%20Special%20301%20Report%20FINAL.PDF>> [Accessed Feb. 8, 2018] 42.

⁸⁷⁵ Trade, Growth and Intellectual Property - Strategy for the Protection and Enforcement of Intellectual Property Rights in Third Countries (Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, {SWD(2014) 204 final} 1.7.2014 COM(2014) 389 final) 8, para. 2.2.5.

⁸⁷⁶ Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries (Commission Staff Working Document, Brussels, 1.7.2015 SWD(2015) 132 final, Aug. 1, 2015) 11.

⁸⁷⁷ Swiss-Ghanaian Intellectual Property Project, Phase II (SGIP II). (Council for TRIPS, IP/C/W/632/Add.5, Oct. 6, 2017) para. 2.3. Available at: <https://www.ige.ch/fileadmin/user_upload/recht/entwicklungszusammenarbeit/factsheet_ghana.pdf> [Accessed Jul. 28, 2017]. Rebecca Duho, ‘National Intellectual Property Policy Launched’ (Graphic News Online, Jan. 21, 2016). <<http://www.graphic.com.gh/news/general-news/national-intellectual-property-policy-launched.html>> [Accessed Oct. 20, 2017].

⁸⁷⁸ Ambassador Livia Leu, the Swiss Head of Bilateral Economic Relations and Delegate of the Federal Council for Trade Agreements. In a Letter dated 26 May 2015. Available at: <<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/patent-of-Imatinib-glive-closing-arguments.pdf>> [Accessed Aug. 19, 2017].

⁸⁷⁹ Sections 111 & 112 Title 1 of the Trade and Development Act 2000. 19 USC 3701. Public Law 106-200. 114 Stat. 251. See “Trade Policy Review - Ghana” (n 819) 9, para. 3.11. John Rothgeb, *US Trade Policy: Balancing Economic Dreams and Political Realities* (Washington DC. CQ Press, 2001) 243.

national treatment and measures to create an environment conducive to domestic and foreign investment, and the protection of IP.⁸⁸⁰

Moreover, Section 111 of the AGOA, which is a direct reflection of Section 506(A) of the GSP Act,⁸⁸¹ stipulates the strengthening of IP protection for US firms in accordance with Section 502.5(C) of the Trade Act 1974 as a fundamental requirement for designating countries as beneficiaries.⁸⁸² Where this is the case, it seems that the implementation of Section 84 may, in the light of Ghana's obligations towards the AGOA, erect barriers to US trade and investment interests pursuant to Section 104(c) of the AGOA. With this in mind, Drahos contends that the preferential trading arrangements as found in the AGOA initiative could effectively operate as external or bilateral pressure against the imposition of compulsory licensing.⁸⁸³

The implementation of Section 84 could breach Section 104(c)(i) of the AGOA, which stresses the need to create an environment conducive to IP rights protection specifically for US corporations.⁸⁸⁴ In addition, Ghana has a TIFA with the US.⁸⁸⁵ Paragraph 4 of the Ghana-US-TIFA recognises the importance of fostering an open and predictable environment for international trade and investment.⁸⁸⁶ Recital 11 recognises the importance of providing adequate and effective protection and the enforcement of IP rights. These provisions could operate to limit the extent to which Ghana can implement a Section 84 model.

⁸⁸⁰ Section 104 (a)(1)(C)(ii) of AGOA.

⁸⁸¹ Title V of the Trade and Tariff Act of 1984 (Pub. L. 98-573) subject to periodic renewal by Congress (the so-called Generalised System of Preferences Renewal Act) conditioning GSP; *inter alia*, on protection of IP rights in order to maintain the US' preferential trading status. This Act clarified the conditions under which unfair trade cases under Section 301 of the Trade Act of 1974 can be pursued. See also the Reauthorisation Act of 1996 (19 USC 2101. Pub. L. 104-188, Title I, subtitle J. 110 STAT 1917), which now requires the President to "take into account the extent to which such country is providing adequate and effective protection of intellectual property rights". (Last renewed on Jul. 31, 2013, through Pub. L. 112-40.) For further review of the US GSP. See Amy Mason, 'The Degeneralization of the Generalized System of Preferences (GSP): Questioning the Legitimacy of the US GSP' (2004) 54 *Duke Law Journal* 2-5, 524, criticising the US-GSP as primarily employing negative conditionality that falls generally under its overarching economic interests.

⁸⁸² AGOA authorises the President to designate a country listed in Section 107 of the AGOA (19 USC 3706) as a beneficiary if the President determines that the country meets the eligibility requirements set forth in Section 104 of the AGOA (19 USC 3703), as well as, the eligibility criteria set forth in Section 502 of the Trade Act, 1974 (19 USC 2462)

⁸⁸³ Drahos (n 830) 801.

⁸⁸⁴ See Section 104(c)(ii) of AGOA.

⁸⁸⁵ "Ghana - US TIFA" (n 87)

⁸⁸⁶ *ibid.* para. 8 recognises that FDI confers positive benefits.

6.4.1.2. Ghana-EU-EPA and National Indication Programme

The EU is Ghana's most important trading partner.⁸⁸⁷ Ghana's trade with the EU amounts to €5.5 billion.⁸⁸⁸ The EU is Ghana's main market for its agri-business products and supplies a large part of the equipment that contributes to economic growth.⁸⁸⁹ The EU also supports Ghana's competitiveness through dedicated institutional development programmes.⁸⁹⁰ It is Ghana's largest export market, with annual exports worth approximately EUR 3 billion or 42.9 percent of Ghana's total exports.⁸⁹¹ For example, in 2016 Ghana imported about €113 worth of pharmaceutical products from the EU, and this represents a growth of 2.9 per cent from 2013.⁸⁹² Ghana is a signatory Member to the EU-EPA.⁸⁹³

The EPA aims at reducing and eventually eradicating poverty, consistent with the objectives of sustainable development and the gradual integration of Ghana into the world economy.⁸⁹⁴ Under this FTA, Ghana is to benefit from the enhanced duty- and quota-free market access for all Ghanaian exports to the EU.⁸⁹⁵ Under the Global Europe Strategy,⁸⁹⁶ the EU adopted a communication on the revised "Strategy for the Protection and Enforcement of Intellectual Property Rights in Third Countries".⁸⁹⁷ In this connection, the EU believes that its 'BTAs

⁸⁸⁷ EU-Ghana Indicative Programme 2014-2020 (11th European Development Fun. Ref. Ares(2014)2070433 - 24/06/2014) 7. Available at: <https://ec.europa.eu/europeaid/sites/devco/files/nip-ghana-20140619_en.pdf> [Accessed Oct. 13, 2017].

⁸⁸⁸ Interim Economic Partnership Agreement between Ghana and the European Union – Factsheet, Feb. 16, 2017. Available at: <http://trade.ec.europa.eu/doclib/docs/2017/february/tradoc_155314.pdf> [Accessed Feb. 1, 2018].

⁸⁸⁹ id.

⁸⁹⁰ id.

⁸⁹¹ id.

⁸⁹² European Union, Trade in Goods with Ghana (Directorate-General for Trade, European Commission, November 2017) 4, Page Units A4 / G2. Available at: <http://trade.ec.europa.eu/doclib/docs/2006/september/tradoc_122461.pdf> [Accessed Feb. 8, 2018].

⁸⁹³ Stepping Stone Economic Partnership Agreement between Ghana, of the one part, and the European Community and its Member States, of the other part (OJ L 287/3, 21.10.2016) 3–319.

⁸⁹⁴ *ibid.* Article 2.

⁸⁹⁵ *ibid.* Articles 2 & 12.

⁸⁹⁶ Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions - Global Europe: Competing in the World A Contribution to the EU's Growth and Jobs Strategy ({SEC(2006) 1228} {SEC(2006) 1229} {SEC(2006) 1230}/COM/2006/0567 final/, 4.10.2006) paras. 4.2(ii), FTAs and 3.2(iii), IPRs.

⁸⁹⁷ Revised Strategy for the Protection and Enforcement of Intellectual Property Rights in Third Countries'. COM/2014/0389 final. 01.07.2014. See also 'The EU Strategy for the Enforcement of Intellectual Property Rights in Third Countries' (O. J. C. 129. 2005/C/129/03. 26.5.2005). Strategy for the Enforcement of Intellectual Property Rights in Third Countries (European Commission Directorate General for Trade, TRADE-2004-00480-00-00-EN-REV-00 (EN)). Available at: <http://trade.ec.europa.eu/doclib/docs/2005/april/tradoc_122636.pdf> [Accessed Sept. 10, 2017]. Evaluation of the Intellectual Property Rights Enforcement Strategy in Third Countries (European Commission, Final Report, Vol. I – Main Report, November 2010) 17, Figure 2.2, "EQ 6: Intervention Logic: Objectives Diagram".

should include stronger provisions for IPRs and competition, including provisions on enforcement of IP rights along the lines of the EU Enforcement Directive'.⁸⁹⁸

Under Article 46 of the EPA, the parties will cooperate to facilitate all of the necessary measures on IP. Within this frame, the EU intended to use its so-called “Trade Barriers Regulation” more vigorously against countries that contravened IP rights belonging to EU companies.⁸⁹⁹ A 2015 motion passed by the European Parliament ‘Supports the Commission’s pledge to give priority to promoting better IPR protection, and enforcement thereof, in the WTO and in any other international arenas, thereby opening up new markets for European exporters and improving existing market access’.⁹⁰⁰ At the heart of the Indicative Programme lies Article 44 of the EPA, which refers to investment protection and IP. The protection of IP is further reflected under Article 68(v) of the EPA, which provides that:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between the Parties where like conditions prevail, or a disguised restriction on trade in goods, services or establishment, nothing in this Agreement shall be construed to prevent the adoption or enforcement by the Parties of measures for the protection of intellectual property.⁹⁰¹

Within the EPA lies a National Indicative Programme, under the 10th European Development Fund,⁹⁰² which the EU has established as a further platform for cooperation to administer EU aid in favour of Ghana.⁹⁰³ This initiative has been drawn up in accordance with Article 4 of the Ghana-EU-EPA pursuant to finance cooperation.⁹⁰⁴ Under this financial cooperation, the EU

⁸⁹⁸ Directive 2004/48/EC of the European Parliament and of the Council on the Enforcement of Intellectual Property Rights (O. J. L. 157. 30.4.2004). See Thomas Jaeger, *The EU Approach to IP Protection in Partnership Agreements* (Munich: Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper No. 10-01, 2010) 28, mentioning that the aim of the EU is apparently to establish coherence between its domestic high levels of IP enforcement and the enforcement levels abroad.

⁸⁹⁹ Note that the EU Trade Barriers Regulation is found in the Council Regulation ((EC) No 3286/94. O. J. L. 349, 31.12.1994) 71-78, laying down Community procedures in the field of common commercial policy in order to ensure the exercise of the Community’s rights under international trade rules, in particular, those established under the auspices of the WTO. See The (Revised Regulation) Council Regulation on Measures to Prohibit the Release for Free Circulation, Export, Re-export or entry for a Suspensive Procedure of Counterfeit and Pirated goods ((EC) No. 3295/94, O. J. L. 341, 30.12.1994) 8-13.

⁹⁰⁰ Article 37 of the Resolution on Strategy for the Protection and Enforcement of Intellectual Property Rights in Third Countries (Motion of the European Parliament, (2014/2206(INI), May 13, 2015).

⁹⁰¹ “Stepping Stone Economic Partnership Agreement between Ghana and the EU” (n 893).

⁹⁰² Council Regulation (EU) 2015/322 of 2 March 2015 on the Implementation of the 11th European Development Fund (OJ L 58, 3.3.2015) p. 1.

⁹⁰³ See Ghana-EU National Indicative Programme: 2014-2020 (Decision C(2014)3660 of 12.06.2014, Jun. 19, 2014). Available at: <http://eeas.europa.eu/development-cooperation/docs/national-indicative-programme_2014-2020/2014-2020_national-indicative-programme_ghana_en.pdf> [Accessed Jul. 28, 2017].

⁹⁰⁴ Articles 2 & 4 of Annex IV to the Cotonou Agreement and Multiannual Financial Framework 2014–2020 (Revised in Ouagadougou, Jun. 22, 2010. OJ L 287, 4.11.2010).

intends to make available to Ghana for the period 2014 – 2020 an amount of EUR 323 million, which is also referred to in Article 3(2)(a) of Annex IV of the ACP-EU EPAs, 2010.⁹⁰⁵

Moreover, Ghana stands to benefit from the European Investment Bank financial facility in accordance with Articles 2(c) and 3 of the 11th EDF multi-annual financial framework⁹⁰⁶ for the period 2014-2020.⁹⁰⁷ In addition to this, the EU has committed itself to aligning its current and future assistance to Ghana with the priorities and objectives identified in the overall country strategy, named: “Compact 2012-2022 - Leveraging Partnerships for Shared Growth and Development”.⁹⁰⁸ The “Compact” sets out a four-fold medium to long term strategy to contribute to accelerated and inclusive economic growth and sustained poverty reduction, to strengthen Ghana’s Lower-Middle-Income Country status in a transition phase, during which the country will strive to become less aid dependent by focusing its policies on key development priorities, to be supported by the EU.⁹⁰⁹

Furthermore, Ghana has been selected to participate in a pilot Joint Programming launched between 2012-2016 and the country is expected to benefit from a fully-fledged Joint Programming for the period 2017-2020.⁹¹⁰ This external assistance programming is fully coherent with Ghana’s overall development strategy.⁹¹¹ The overall financial package for the

⁹⁰⁵ *ibid.* para. 2.

⁹⁰⁶ Council Regulation (EU) 2015/323 on the Financial Regulation Applicable to the 11th European Development Fund (OJ L 58, 3.3.2015).

⁹⁰⁷ “EU-Ghana Indicative Programme” (n 887) para. 6

⁹⁰⁸ Compact 2012-2022 - Leveraging Partnerships for Shared Growth and Development (Signed on Jun. 21, 2012). Available at: <<http://www.epd.eu/wp-content/uploads/2014/10/Leveraging-Partnership-for-Shared-Growth-and-Development-2012-2014.pdf>> [Accessed Sept. 19, 2017]. See OECD Development Co-operation Peer Reviews (Denmark, OECD, 2016) 111.

⁹⁰⁹ *ibid.* 9, para. 15. See EU-Ghana: Four Decades of Development Cooperation (2nd Edition) 1, stating that in total, it will be an EU support of EUR 1.5 billion provided to Ghana for the period 2013-2016 alone. Available at: <http://www.eeas.europa.eu/archives/delegations/ghana/documents/more_info/general.pdf> [Accessed Oct. 12, 2017].

⁹¹⁰ EU-Ghana Cooperation: EU Joint Programming Phase II 2017-2020 (signed Jun. 21, 2012). See “OECD Development Co-operation Peer Reviews” (n 908) 111. Note that including the Czech Republic, Denmark, France, Germany, Italy, Netherlands, Spain, United Kingdom and the EU itself, the European Investment Bank (EIB) has expressed its willingness to be included in the EU Joint Programming effort. See ACP-EU Cooperation After 2020: Towards A New Partnership? (The Hague: Advisory Council on International Affairs, Report No. 93, March 2015) 22, footnote 35, stating that the European Investment Bank plays a role in supporting development activities in ACP countries; through a combination of a European Development Fund and the bank’s own funds it provides various forms of loans and an investment facility.

⁹¹¹ Note that Ghana’s socio-economic development strategy operates under seven (7) thematic areas: International Trade, Import-Export Regime; Trade Facilitation Enhancing Production Capacity; Domestic Trade and Distribution; Consumer Protection and Fair Trade; and Intellectual Property Rights. See Trade Policy Review - Ghana (n 819) 9, para. 4.1-2. Objectives are grouped into four main components:

- (1) Production and Distribution: To ensure that adequate local agro-based industrial raw materials, mineral deposits and competitively priced imported inputs are available for local manufacturing.
- (2) Technology and Innovation: To encourage

period of this Joint Co-operation Strategy (2017–2020) is approximately €1.25 billion.⁹¹² Out of this total contribution, the EU has decided to focus on supporting two of the five goals of Ghana’s Long-Term Development Plan as follows: firstly, Goal 1: Build an industrialised, inclusive and resilient economy; secondly, Goal 4: Build effective, efficient and dynamic institutions.⁹¹³

Recent evidence suggests that Ghana and the EU are actively engaged in the process of starting new negotiations to extend the current EPAs beyond 2020.⁹¹⁴ With this in mind, Ghana may not have the will to implement Section 84, as it may lose all of these benefits, given that if not the letter, then the spirit of the FTAs it has with key development partners could undermine the implementation of a Section 84 model in Ghana.

6.4.1.3. Implementing Section 84: Can Ghana Afford to Lose Foreign Development Assistance?

An important question worth considering is whether Ghana will have the practical political will to implement a Section 84 model, and the risk of being deprived a substantial part of the foreign development assistance (FDA), which the country relies heavily upon to fund its key socio-economic development programmes.⁹¹⁵ Nevertheless, from a rhetoric stance, it appears that Ghana is prepared to manage the country’s natural resources in a manner that will allow the country’s development agenda to be financed without recourse to external development

the adoption and dissemination of modern technology in industry. (3) Incentives and Regulations: To create a conducive, transparent and predictable regulatory environment to attract the requisite investment into the industrial sector. (4) Crosscutting Issues: To encourage greater participation of the under-privileged, empowerment of women and a fight against communicable diseases such as HIV/AIDS that hamper development in the sector.

ibid. 10-11, paras. 4.11.

⁹¹² European Partners Working Together in Ghana: Joint Co-operation Strategy 2017-2020 (European Union Delegation in Ghana, 2017). Available at: https://ec.europa.eu/sites/ecas/files/european_partners_working_together_in_ghana_2017-2020_final_26_09_2017.pdf [Accessed May 2, 2018] 17 & 34.

⁹¹³ ibid. Annex I: Indicative contributions per European Partners in Ghana. Table 3. p. 38.

⁹¹⁴ Recommendation for a Council Decision Authorising the Opening of Negotiations on a Partnership Agreement between the European Union and countries of the African, Caribbean and Pacific Group of States (Strasbourg, COM(2017) 763 final, Dec. 12, 2017). Available: <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52017PC0763> [Accessed Fe. 9, 2018].

⁹¹⁵ “OECD Development Co-operation Peer Reviews” (n 908) 7, Table 2.2.7, stating that Ghana received foreign aid to the tune of \$ 1,324 billion in 2016.

assistance - an agenda the Ghanaian President refers to as building “Ghana Beyond Aid”.⁹¹⁶ The IMF⁹¹⁷ and the EU support the “Ghana Beyond Aid” agenda.⁹¹⁸

This agenda aims at weaning the country off any FDAs from its development partners, and to be replaced with the use of local and foreign resources on commercial terms through foreign trade and investment.⁹¹⁹ The agenda is based on the numerous research findings that have tended to show that FDAs have had no positive consequences on the development of African countries.⁹²⁰ In terms of Ghana, most independent research suggests that FDAs have had unintended and unwanted side effects with no significant impact on economic growth of the country.⁹²¹ The issue is that FDA often exerts disproportionate pressure on Ghana to continue its dependence on IMF and World Bank initiatives, and this has affected the country’s capacity to legitimately utilise the so-called FDAs effectively to promote homegrown policies towards sustainable economic growth.⁹²²

Addressing the 72nd Session of the UN General Assembly on 21 September 2017, the President of the Republic of Ghana, Nana Addo Dankwa Akufo-Addo stated that, ‘We do not want to be a scar on anybody's conscience. We want to build an economy that is not dependent on charity and handouts. Long and bitter experience has taught us no matter how generous the

⁹¹⁶ Office of the President of Ghana. Sustainable Development Goals Advisory Unit. Accra International Conference Centre (Office of the President, Nov. 30, 2017). Available at: > <http://gh.one.un.org/content/dam/unct/ghana/docs/Speeches/UNCT-GH-Multi-stakeholder-conference-SDGs-Speech-President-Akufo-Addo-2017.pdf>> [Accessed May 3, 2017] 6 under Second.

⁹¹⁷ Ghana: Country Report No. 18/113 (Washington D.C., International Monetary Fund, May 2018) 9, para. 12; p. 36, Appendix I. Attachment I, para. 2, p. 38.

⁹¹⁸ “European Partners Working Together in Ghana: Joint Co-operation Strategy 2017-2020” (n 912) 5 & 7.

⁹¹⁹ id.

⁹²⁰ Kin-Boon Tang and Diya Bundhoo, ‘Foreign Aid and Economic Growth in Developing Countries: Evidence from Sub-Saharan Africa’ (2017) 7 *Theoretical Economics Letters* 5, 1488, finding that aid by itself is not effective on the economic performance of the recipient country. Dambisa Moyo, *Dead Aid: Why Aid is Not Working and How There is Another Way for Africa* (Penguin; Reprint Edition, 2010) 29. Maurice Phiri, ‘The Impact of Aid on the Economic Growth of Developing Countries (LDCs) in Sub-Saharan Africa’ (2017) 10 *Gettysburg Economic Review* 1/4, 42, finding that a percentage increase in net official development assistances reduces real GDP by about 0.03%. Thus, this goes to show that aid was ineffective towards achieving high levels of economic growth.

⁹²¹ Samuel Adams and Francis Atsu, ‘Aid Dependence and Economic Growth in Ghana’ (2014) 44 *Journal of Economic Analysis and Policy* 2, 233. See also Stephen Brown, ‘Foreign Aid and National Ownership in Mali and Ghana’ (2017) 44 *Journal of Forum for Development Studies* 3, 352.

⁹²² Nathan Andrews, ‘Foreign Official Development Assistance (ODA) and Ghana’s Development: The Case for “Bringing Culture Back In” to the Analysis’ (2010) 2 *International Journal of Sociology and Anthropology* 5, 102, reiterating the need for Ghana to own its development - a process that foreign aid can only support, not determine. See also Jiyoung Kim, ‘Aid and State Transition in Ghana and South Korea’ (2015) 36 *Third World Quarterly* 7, 1341.

charity, we would remain poor'.⁹²³ It continues: We are not disclaiming aid, but we do want to discard a mind-set of dependency and living on handouts; we want to build a Ghana Beyond Aid.⁹²⁴

Moreover, during a roundtable meeting with selected Chief Executive Officers (CEOs) of leading African and international companies on the 5th Edition of the Africa CEOs forum in Switzerland, the President reaffirmed the “Ghana Beyond Aid” agenda by stating that:

We want to build a Ghana beyond aid; a Ghana which looks to the use of its own resources. We want to build an economy that is not dependent on charity and handouts, but an economy that will look at the proper management of its resources as the way to engineer social and economic growth in our country.⁹²⁵

While this is a long-term initiative, it seems that Ghana is not concerned about losing any FDAs now. This is evident as the President informed the French President, Emmanuel Macron while on a visit in Ghana that the country does not need aid to develop, and this was a clear rejection of FDA.⁹²⁶ Nevertheless, it is doubtful whether the country will be prepared to implement a Section 84 model. In fact, evidence suggests that the use of TRIPS flexibilities has decreased because voluntary licensing had become more common. For example, it has been concluded that the use of compulsory licences for essential medicines resulted in prices that were generally higher than the prices achieved by countries that obtained the medicines through the Global Fund and other international procurement channels.⁹²⁷ This is as a result of Unitaid and Medicines Patent Pool activities aimed at negotiating voluntary licences that enabled the production and supply of generic medicines and, consequently, countries within the territorial scope of Medicines Patent Pool licences might no longer need to invoke TRIPS flexibilities to promote affordable medicines.⁹²⁸

Importantly, Ghana continues to benefit from international financing schemes to secure essential medicines. For example, under the Global Fund’s funding model, Ghana was

⁹²³ Address Delivered by the President of the Republic of Ghana, Nana Addo Dankwa Akufo-Addo, at the 72nd Session of the United Nations General Assembly (New York, Thursday, Sept. 21, 2017). Available at: <<http://accra.sites.uniconnetwork.org/files/2017/09/Ghana-E-Address.pdf>> [Accessed May 4, 2018] 3.

⁹²⁴ *ibid.* 4.

⁹²⁵ Shaping the future of Africa. 5th Edition of the Africa CEO Forum (Geneva, Mar. 20, 2017).

⁹²⁶ Ama Lorenz, Ghana’s President surprised Macron with a Clear Rejection of Development Aid (EURACTIV, Germany, 5 Dec. 2017). Available at: <<https://www.euractiv.com/section/development-policy/news/ghanas-president-surprised-macron-with-a-clear-rejection-of-development-aid/>> [Accessed May 4, 2018].

⁹²⁷ Reed Beall, Randall Kuhn and Amir Attaran, ‘Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement’ (2015) 34 *Health Affairs* 3, 494.

⁹²⁸ Medicines Patent Pool. <<https://medicinespatentpool.org/>> [Assessed Mar. 10, 2019].

allocated a total of US\$ 300 million for the 2015-2017 cycle for HIV/AIDS, including US\$ 24 million for Malaria in “incentive funding”, a reserve designed to reward high-impact and well-performing programmes. Moreover, the Global Fund has earmarked \$194 million for Ghana to fight HIV/AIDS, Malaria and Tuberculosis between 2018 and 2020. There is also a separate \$12 million out of the funds to be used to build a resilient and sustainable health delivery system in the country. This reinforces the notion that Ghana might not have the practical political will to implement the Section 84 model.

6.5. Is There a Risk of Political Pressure Against the Implementation of Section 84 Model in Ghana?

The question arises whether the implementation of Section 84 in Ghana would be undermined by any potential political pressure emanating from key developed countries. In fact, EU Member States are not expected to adopt any aggressive approach against the implementation of Section 84 in Ghana. In fact, EC is committed to supporting countries to fully integrate the Doha Declaration in their policies and practices.⁹²⁹ This is important as Article 36 of the EPA provides that the parties reaffirm their rights and obligations under the WTO Agreements. This is supported by Article 68, dubbed the “General Exception Clause”, which stipulates that ‘nothing in this Agreement shall be construed to prevent the adoption or enforcement by the Parties of measures that: (b) are necessary to protect human, animal or plant life or health’. Importantly, the EU has adopted a regulation allowing for the granting of compulsory licences; this policy response demonstrates an understanding and acknowledgement that compulsory licensing is still permissible under TRIPS.⁹³⁰

Moreover, nothing in the light of AGOA or US-Ghana TIFA would directly undermine an attempt by Ghana to implement a Section 84 model. Moreover, further examples of clauses upholding specific TRIPS flexibilities can be found in US FTAs in relation to the prohibition of expropriation.⁹³¹ Importantly, Paragraph 3 of the US-Ghana TIFA states that:

⁹²⁹ Communication from the EC to the TRIPS Council on the implementation of the Doha Declaration on the TRIPs Agreement and Public health (Ref. 282/03 Rev1, Brussels, Jun. 2, 2003) para. 20.

⁹³⁰ Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems (EC) No 816/2006 (European Parliament and the Council (OJEU. L 157/1, May 14, 2006).

⁹³¹ Articles 10.6:5 and 10.8:3(b)(i) of United States-Morocco Free Trade Agreement (Jun. 15, 2004, 44 I.L.M. 544), Articles 15.6:5, 15.8:3(b)(i) of the US-Singapore FTA (n 830). Articles 10.7:5 and 10.9:3(b)(i) of the United States- Dominican Republic-Central America-Free Trade Agreement (Aug. 5, 2004, 43 I.L.M. 514). Note that according to Article 6(5) of the US Model Bilateral Investment Treaty 2012, the standards on expropriation do ‘not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance

Taking into account the participation of both countries in the World Trade Organisation (WTO), and noting that this Agreement is without prejudice to the rights and obligations of the Parties under the Marrakesh Agreement Establishing the World Trade Organisation and the agreements, understandings, and other instruments relating thereto or concluded under the auspices of the WTO.⁹³²

Under Section 129(2) of AGOA the US recognises that the HIV/AIDS crisis has reached epidemic proportions in sub-Saharan Africa, where more than 21,000,000 men, women, and children are infected with HIV, and thus supports the need to prevent and reduce the incidence of HIV/AIDS through the establishment of an HIV/AIDS Response Fund.⁹³³ For example, the US was the largest donor to HIV efforts in 2016, providing \$4.9 billion.⁹³⁴ The US recognises the importance of access to medicines and public health protection in needy countries,⁹³⁵ and the country is committed to strengthening healthcare systems and helping to fight the diseases affecting African countries.⁹³⁶

It is important to note that all countries including the US through the UN reaffirmed their commitment to end the AIDS epidemic by 2030.⁹³⁷ Since Congress' recognition that the restrictive conditions in FTAs may impede pharmaceutical policies that governments may elect to pursue,⁹³⁸ some FTAs concluded by the US have referred to the Doha Declaration and

with the TRIPS Agreement'. Under recent BITs, this type of safeguard clause extends further to cover not only compulsory licences, but also 'the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with the TRIPS Agreement'. Articles 6(5) of the United States-Uruguay Bilateral Investment Treaty (Nov. 4, 2005) and the United States-Rwanda Bilateral Investment Treaty (Feb. 19, 2008).

⁹³² See also Article 7, which provides that 'This Agreement will be without prejudice to the rights of either Party under its domestic law or under any other instrument to which either country is a party'.

⁹³³ Section 128.

⁹³⁴ Donor Government Funding for HIV in Low- and Middle-Income Countries in 2016 (UNAIDS and The Henry Kaiser Family Foundation, July 2017) 4. Note that the US President's Emergency Plan for AIDS Relief (PEPFAR) is the largest commitment by any nation towards a single disease. Note that since 2003, PEPFAR has spent US\$ 70 billion on programmes globally to combat HIV and AIDS, tuberculosis, malaria and other opportunistic infections. Since its inception in 2003, PEPFAR has received strong bipartisan support in Congress and through administrations. Available at: <https://www.pepfar.gov/documents/organization/251737.pdf> [Accessed Oct. 23, 2017].

⁹³⁵ Statement of US Trade Representative Robert Zoellick on TRIPS and Access to Medicines (Aug. 30, 2003). At: https://ustr.gov/archive/Document_Library/Press_Releases/2003/August/Statement_of_US_Trade_Representative_Robert_B_Zoellick_on_TRIPS_access_to_medicines.html [Accessed Oct. 23, 2017].

⁹³⁶ Section 127(b)(3)(B) of AGOA.

⁹³⁷ Political Declaration on HIV and AIDS: On the Fast Track to Accelerating the Fight against HIV and to Ending the AIDS Epidemic by 2030 (Seventieth session Agenda item 11, 97th plenary meeting. United Nations General Assembly Resolution: A/RES/70/266, Jun. 8, 2016) para. 1.

⁹³⁸ Opposing the Inclusion in Future Free Trade Agreements of Provisions That Would Have the Effect of Restricting, Undermining, or Discouraging the Enactment or Implementation of Legislation Authorizing the Importation of Prescription Drugs, and for Other Purposes, H.R. 758, 108th Cong. (2004); House Resolution Opposes Future FTAs Against Drug Importation (World Trade Online, Sept. 14, 2004). Available at: <https://insidetrade.com/> [Accessed Oct. 23, 2017]. See Abbott (n 827) 354. Drahos (n 832) 13.

provided that ‘a Party may take measures to protect public health in accordance with ... the Declaration on the TRIPS Agreement and Public Health’.⁹³⁹ Therefore, the US would not adopt any aggressive political pressure against Ghana if the country were to implement a Section 84 model to promote affordable medicines.

In fact, there is already a WTO Panel decision criticising the US for past use of the Section 301 listings for TRIPS-related matters, and that decision expressly warned that sanctions would be likely to be authorised if such violations continued in the future.⁹⁴⁰ The US government will avoid unilateral retaliatory action such as sanctions or political pressure.⁹⁴¹ This is significant, as on the 10 May 2000 President Clinton signed an Executive Order prohibiting the US Government from taking action pursuant to Section 301(b) of the Trade Act of 1974 with respect to any law or policy, such as compulsory licensing, as it had done with South Africa.⁹⁴²

The US recognises that it stands to be isolated if the country adopts any aggressive political pressure against the implementation of Section 84 in Ghana. During the negotiation of the Doha Declaration, the US was isolated,⁹⁴³ which puts it in the diplomatically uncomfortable position of being the sole obstacle to a solution to the Doha Paragraph 6 problem.⁹⁴⁴ The US was concerned by the level of isolation from its allies,⁹⁴⁵ as it did not enjoy broad developed country support for its preferred hard-line approach to the Doha Decision.⁹⁴⁶

⁹³⁹ Article 16.10:2(e) of the US-Colombia Trade Promotion Agreement (Nov. 22, 2006), Article 16.10: 2 (e) of the United States-Peru Trade Promotion Agreement (Apr. 12, 2006), Article 18.g:3 of the United States-Korea Free Trade Agreement (Jun. 30, 2007).

⁹⁴⁰ Panel Report in United States – Sections 301–310 of the Trade Act of 1974 (WT/DS152/R, Dec. 22, 1999) paras. 5.227- 5.228 regarding India’s argument; para. 8.1. See Abbott and Reichman (n 460) 980–981.

⁹⁴¹ Jerome Reichman, ‘Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options’ (2009) 37 *Journal of Law and Medical Ethics* 2, 263.

⁹⁴² The US Executive Order No. 13155, (May 12, 2000) 65 *Federal Register* 93, paras. 30521-30523. Section 3 of this Executive Order also required sub-Saharan African countries to provide adequate and effective intellectual property protection as a precondition for increasing access to HIV/AIDS drugs. Section 1(9) maintains, “individual countries should have the ability to take measures to address the HIV/AIDS epidemic, provided that such measures are consistent with their international obligations” In Feb. 2001, Joseph Papovich, The US Trade Representative for Intellectual Property Rights; stated that President Bush was ‘not considering a change in the present “flexible policy” on compulsory licensing of drugs by AIDS- stricken countries’. See Graeme Dinwoodie, William Hennessey, Shira Perlmutter, and Graeme Austin, *International Intellectual Property Law and Policy* (New York, Matthew Bender: LexisNexis, 1st edn. 2001) 436.

⁹⁴³ Drahos (n 832) 19, stating that the Doha Declaration was about the weak networking networks that surrounded and eventually isolated the US and in the final instance its pharmaceutical industry.

⁹⁴⁴ Abbott (n 827) 332.

⁹⁴⁵ *ibid.* 343, stating that the Europeans distanced themselves from the Americans on subject matter the latter considered important.

⁹⁴⁶ *ibid.* 354.

6.5.1. Unlikely Political Pressure: Consistency of Section 84 with United States Statutory Law

While the US Patent law does not contain a general compulsory licensing section, the country has numerous statutory provisions that can be invoked to grant compulsory licences to protect the public interest.⁹⁴⁷ These include an authorisation of compulsory licensing for public health purposes⁹⁴⁸ and government use.⁹⁴⁹ In addition, the US government can issue compulsory licences under the antitrust laws to remedy anticompetitive practices.⁹⁵⁰ For example, 28 USC Section 1498 gives the federal government the power to grant a compulsory licence to use or produce a patented invention or authorise third parties to use patents for virtually any public use in certain situations without negotiation.⁹⁵¹

⁹⁴⁷ Title 7 USC Section 2404 (2000) (plant variety protection certificates necessary for the nation's fiber, food, or feed supply (Chapter 57. (Pub. L. 91-557, title II, Section 44, Dec. 24, 1970) 84 Stat. 1547 (amended) Pub. L. 103-349, Section 13(f), Oct. 6, 1994. 108, Stat. 3143); Title 28 USC Section 1498 (2000) (government use of patents. (June 25, 1948, ch. 646. 62 Stat. 941. May 24, 1949 (as amended and last) Pub. L. 105-304, title V, Section 503(d), Oct. 28, 1998. 112 Stat. 2917); Title 35 USC Section 203 (2000) (patents developed through the use of government research funding under the (The Bayh–Dole Act or Patent and Trademark Law Amendments Act (Pub. L. 96-517, Dec. 12, 1980) 94 Stat. 3015); and 42 USC Section 2183 (2000) (atomic energy).

⁹⁴⁸ See March-in Rights, Title 35 USC Section 203(a)(2)(2001), allowing the government to license patents for inventions funded by the government and invented by a small business or nonprofit organisation in circumstances where the patent holder could not reasonably satisfy public health or safety needs.

⁹⁴⁹ See Title 28 USC Section 1498(a) (2001), entitling patent holders the right to sue and claim compensation for the federal government's unauthorised use of a patent, or the government's licensing of a patent to third parties acting by or for the government. Other grounds on which the government can grant compulsory licences are: For "pollution" see Clean Air Act of 1988, Title 42 USC Section 7608 (2001), requiring mandatory licensing of patents by the government to ensure compliance with the requirements of the Clean Air Act. For "atomic energy" see Atomic Energy Act of 1988, 42 USC Section 2183 (2001), permitting the government to use or licence a patent in connection with the production of nuclear materials or atomic energy, if doing so would advance the public interest. (Aug. 5, 1954, ch. 658, Section 1. 68 Stat. 674. Pub. L. 93-222 (amended) Pub. L. 96-88, title V, Section 509(b), Oct. 17, 1979. 93 Stat. 695) For "national security" see Title 35 USC "Patents" [Jul. 19, 1952], ch. 950, 66 Stat. 803; Pub. L. 97-164 (as amended). Section 181 (2001), granting government agencies the authority to withhold patents for inventions that may endanger national security.

⁹⁵⁰ See Antitrust Procedures and Penalties Act, Title 15 USC Sections 16(b)-(h) (2001) (describing the procedural requirements for obtaining consent judgments in antitrust proceedings (Section 16. Pub. L. 93–528, Dec. 21, 1974. 88 Stat. 1708); see also e.g., *United States v. 3D Systems Corp. & DTM Corp.*, No. CIV.1:01CV01237(GK), 2001 WL 964343, at 34 (D.D.C. Aug. 16, 2001) (ordering 3 D Systems Corp. to license 178 of its patents in the United States, Canada, and Mexico, to a third party). The US Department of Justice initiated the suit against 3D Systems Corp. to prevent a prospective acquisition of DTM Corp. by 3D Systems Corp., which would give the merged company a monopoly on rapid prototyping technologies in the US market. See James Love and Michael Palmedo, *Examples of Compulsory Licensing of Intellectual Property in the United States*. Available at: <<http://www.cptech.org/ip/health/cl/us-at.html>> [Accessed Sept. 27, 2017] ch. 3.

⁹⁵¹ Title 28 USC Part IV, Chapter 91. Pub. L. 114-38. *Zoltek Corp. v. United States*, 442 F.3d 1350 (Fed. Cir. 2006), held that patents are not property protected by the Fifth Amendment therefore the government cannot be sued for patent infringement. For further analysis, see Joshua Miller, '28 USC Section 1498(A) and the Unconstitutional Taking of Patents' (2011) 13 *Yale Journal of Law and Technology* 1, 3-4. See also Love (n 285) 12.

The law only mandates that the government to pay reasonable compensation whenever an invention covered by a patent is used or manufactured by, or for, the US government.⁹⁵² Pursuant to this viewpoint, a US Court confirmed that 28 USC Section 1498 ‘is essentially an Act to authorise the eminent domain taking of a patent licence, and to provide just compensation for the patentee’.⁹⁵³ Under the theory of “eminent domain”, the government has the right to use the patented invention to meet the reasonable requirements of the public by paying just compensation to avoid violating the “Takings Clause” of the Constitution.⁹⁵⁴

Nevertheless, several US case laws teach us that the use of patents by the government does not even apply to the so-called “Taking Clause” if the satisfaction of the reasonable requirements of the public is at stake.⁹⁵⁵ In *Brunswick Corp. v. US*, the Court reasoned that government’s use of a patent under 28 USC 1498 was not “in strictest sense” a “taking in violation of Fifth Amendment”, since 28 USC Section 1498 ‘grants government absolute power to take a compulsory, non-exclusive licence to a patented invention at will’, and thus ‘the government has a statutory right to use a patented device’.⁹⁵⁶ Importantly, Section 209 of the US patent statute specifies that:

If the Federal Agency finds that the public will be served by the granting of the license, or license is a reasonable and necessary incentive to bring the invention to practical application; or to promote the invention’s utilization by the public; the Federal Agency may grant an exclusive or partially exclusive license on a federally owned invention thereof.⁹⁵⁷

More significantly, while the foregoing provision, which is known as “Licensing Federally Owned Inventions” in the above citation, appears to only allow for the granting of compulsory licences on federally owned inventions, it at least provides adequate scope on the relevance of compulsory licensing as an instrument of government policy or the right of the state, including, consistently, the possibility of it being used to advance the protection of the public interest

⁹⁵² 28 USC Section 1498(a) (2000). See Adam Mossoff, ‘Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause’ (2007) 87 *Boston University Law Review* 3, 694.

⁹⁵³ *Leesona Corp. v. United States*, 599 F.2d 958, 964, 202 U.S.P.Q. (BNA) 424 (Ct. Cl.), cert. denied, 444 U.S. 991 (1979).

⁹⁵⁴ US Constitution: Amendment V: ‘Nor shall private property be taken for public use, without just compensation’.

⁹⁵⁵ *De Graffenried v. United States*, 29 Fed. Cl. 384 (1998), holding that patents are not secured under the “Takings Clause”. See also *Zoltek Corp. v. United States* (n 951) 1352, rejecting claim that patents are secured under the Takings Clause.

⁹⁵⁶ *Brunswick Corp. v. U.S.*, 36 Fed. Cl. 204 (1996).

⁹⁵⁷ Title 35 USC (n 949) [Emphasis added].

against abusive behaviour accordingly. Noting that relevance of local working requirements in the US, Section 204 of the US Patent law stipulates that:

Notwithstanding any other provision of this chapter, no patents shall be granted to any organisation or to any person to enjoy exclusive right to use or sell any subject invention in the US unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially within the US.⁹⁵⁸

Moreover, the claim that patents must be manufactured locally in order to satisfy the public interest has been central to several pieces of scholarship within the US.⁹⁵⁹ In particular, Vaughan says that:

Speaking of the position of patents in America ... it would be a contravention of patents law and economic injustice to the American manufacturer to allow a foreigner to take out a patent in this country merely for the purpose of reserving the United States as a market for his patented product which is manufactured abroad exclusively.⁹⁶⁰

More importantly, the abovementioned Section 204 provision in the US patent regime is TRIPS-compliant. Thus, according to the legislative wisdom of the US, patentees have affirmative obligations under its domestic patent system to manufacture the patented invention locally. All things considered, it is very difficult to envisage from any contrary argument that Section 84 would remain inconsistent with the TRIPS Agreement when, in fact, the US has a similar provision.

6.5.2. Consistency of the Reasonable Requirements of the Public under Section 84 with United States Patent Jurisprudence

Advancing the argument from the preceding discussion, the US, which is often seen as the global IP policy leader, has continuously accepted a series of judicial and policy decisions demanding that the public interest remains the true basis for the granting of patents. It is significant that it was established in the IP Clause of the US Constitution that the primary goal of patent law is to advance the public interest and achieve social progress as efficiently as possible.⁹⁶¹ In fact, several empirical elements support the understanding that granted patents must meet the reasonable requirements of the public locally. In particular, it is notable that

⁹⁵⁸ *id.* [Emphasis added].

⁹⁵⁹ Mercurio and Tyagi (n 76) 281.

⁹⁶⁰ Floyd Vaughan, 'Suppression and Non-Working of Patents with Special Reference to the Dye and Chemical Industries' (1919) 9 *The American Economic Review* 4, 700.

⁹⁶¹ Article I, Section 8, Clause 8 of the US Constitution.

Thomas Jefferson, the chief architect of the original US patent system, espoused this view, conclusively stating that patents are for “the benefit of the public” and plainly rejecting the notion that patentees have natural rights in their patented inventions.⁹⁶²

Another remarkable line of argument consistent with a key US statutory provision stipulates that: ‘A patent by its very nature is affected with a public interest’.⁹⁶³ Remarkably, the US Supreme Court has interpreted the public interest principle under its patent regime by stating that the patent system is designed to promote innovation that satisfies the fundamental interests of the public.⁹⁶⁴

In fact, the US Supreme Court recognised that the power of Congress to adopt any patent system is not an absolute one but rather is subject to the strict constitutional intent of promoting the public interest. It stated that: ‘Congress...may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly system without regard to the...advancement or social benefit gained thereby’.⁹⁶⁵ This reasoning reinforces the idea that patentees must at all times work their patented inventions or apply the processes locally not for their own profit but rather for the benefit of the public. A subsequent US Supreme Court decision found that:

It is undeniably true that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly ... The true policy and ends of the patent laws enacted under this government are disclosed in that article of the Constitution, the source of all these laws, viz., [to promote the progress of science and the useful arts], contemplating and necessarily implying their extension, and increasing adaptation to the uses of society ... By correct induction from these truths, it follows that the inventor who designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public comes not within the policy or objects of the Constitution or acts of Congress.⁹⁶⁶

The US, that is often seen as the global IP policy leader has successively, accepted series of judicial and policy decisions demanding that public interests remain the true basis for the grant

⁹⁶² Andrew Lipscomb and Albert Ellery Burgh (eds.) *Letter from Thomas Jefferson to Isaac McPherson Monticello on Aug. 13, 1813*. In THE WRITINGS OF THOMAS JEFFERSON (Washington DC, The Thomas Jefferson Memorial Association, 1905) 334.

⁹⁶³ Code of Federal Regulations. Title 37 — Patents, Trademarks, and Copyrights. Section 1(56)(a) Duty to Disclose Information Material to Patentability.

⁹⁶⁴ *Graham v John Deere Co. of Kansas City*, 383 U.S. 1 (1966) para. 5.

⁹⁶⁵ *ibid.* at paras. 5–6.

⁹⁶⁶ *Kendall v Winsor*, 62 U.S. (1858) 328.

of patents; thus, patentees are under an affirmative duty to work the patented inventions or apply the processes not for their own profit but rather for the benefit of the public. This is a significant legislative tradition of the IP system and none of the developed countries have departed from this key norm. This ensures that technological innovations flow to the domestic patent granting country's economy. This, according to the popular view of the containment of patent policy, permitting patentees to choose not to work their patented inventions locally would be an affront to the public interest.⁹⁶⁷ Going by this view, it is argued that Ghana and other WTO Members have the right to adopt and implement any local working requirements that follow the Indian Section 84 model, which is consistent with TRIPS.

6.5.3. Section 84: Recent Developments on Local Working in the United States

The US President, Donald Trump has threatened to impose a 20 percent tariff on all EU manufactured light vehicles coming into the US,⁹⁶⁸ stating that auto imports pose a national security threat.⁹⁶⁹ In other words, the US claims imports of automobiles, including SUVs, vans and light trucks, and automotive parts into the US⁹⁷⁰ threaten to impair national security as defined by Section 232 of the Trade Expansion Act of 1962.⁹⁷¹ There is ongoing investigation pursuant to part 705 of the National Security Industrial Base Regulations.⁹⁷² Under Section

⁹⁶⁷ Correa (n 15) 7, noting that patent rights are not absolute and national laws have traditionally identified certain situations in which patents are not to be granted including the protection of public interest.

⁹⁶⁸ US Launches New Trade Probes into Auto Imports, Macron Calls for WTO Reform (International Centre for Trade and Sustainable Development -Bridges, vol. 22, No. 19, May 31, 2018). Available at: <<https://www.ictsd.org/bridges-news/bridges/news/us-launches-new-trade-probes-into-auto-imports-macron-calls-for-wto-reform>> [Accessed Aug. 9, 2018]. See Jenny Leonard and Richard Bravo, 'Trump Tariff Threat on European Cars Escalates Global Trade War' (Bloomberg, Jun. 22, 2018). Available at: <<https://www.bloomberg.com/news/articles/2018-06-22/trump-threatens-to-impose-20-percent-tariff-on-european-cars>> [Accessed Aug. 4, 2018]. See also Sam Fleming, Shawn Donnan and Jim Brunsten, 'Trump Threatens 20% Tariff on EU Car Imports' (Financial Times, Jun. 22, 2018). Available at: <<https://www.ft.com/content/9aba7138-762d-11e8-b326-75a27d27ea5f>> [Accessed Aug. 4, 2018].

⁹⁶⁹ Notice of Request for Public Comments and Public Hearing on Section 232 National Security Investigation of Imports of Automobiles, including Cars, SUVs, Vans and Light Trucks, and Automotive Parts. Federal Register 24735, Document No. 2018-11708, vol. 83, No. 104 pp.24735-24737, May 30, 2018. Available at: <<https://www.gpo.gov/fdsys/pkg/FR-2018-05-30/pdf/2018-11708.pdf>> [Accessed Aug. 16, 2018].

⁹⁷⁰ Note that evidence suggests that Mexico is the top exporter of passenger vehicles and light trucks to the US followed by Japan, Canada, Germany, and South Korea. According to the Commerce Department, imports of motor vehicles into the US have grown 16 percent over the past 20 years. See Department of Commerce. Office of Transportation and Machinery. Automotive Team: Industry Trade Data. Available at: <<https://www.trade.gov/td/otm/autostats.asp>> [Accessed Aug. 12, 2018]. See also Ana Swanson, 'Trump Initiates Trade Inquiry That Could Lead to Tariffs on Foreign Cars' (The New York Times, May 23, 2018).

⁹⁷¹ Pub.L. 87-792, 76 Stat. 872, enacted Oct. 11, 1962, codified at 19 U.S.C. ch. 7 as amended (19 U.S.C. 1862).

⁹⁷² 15 CFR Part 705. Effect of Imported Articles on the National Security. U.S.C. Title 19. Section 1862. Safeguarding National Security (Federal Register, Doc No: 2018-12120, vol. 83, No. 109, Jun. 6, 2018) paras. 26204-26205.

232, the Secretary of Commerce can conduct comprehensive investigations to determine the effects of imported products on US national security.

According to the US, ‘There is evidence suggesting that, for decades, imports from abroad have eroded our domestic auto industry’.⁹⁷³ It continued that, ‘The Department of Commerce will conduct a thorough, fair, and transparent investigation into whether such imports are weakening our internal economy and may impair the national security’.⁹⁷⁴ To determine the effects of imports on national security, the Section 232 investigation will consider criteria under Section 705.4 of the National Security Industrial Base Regulations, in particular, whether there has been a ‘loss of skills or investment, substantial unemployment, and decrease in government revenue’ as well as the ‘impact of foreign competition on specific domestic industries and the impact of displacement of any domestic products by excessive imports’.⁹⁷⁵

In a related development, President Trump claimed that:

⁹⁷³ See Secretary Ross’s letter to Secretary of Defence, James Mattis informing him of the investigation. U.S. Department of Commerce Initiates Section 232 Investigation into Auto Imports (Office of Public Affairs, US Department of Commerce, May 23, 2018). Available at: ><https://www.commerce.gov/news/press-releases/2018/05/us-department-commerce-initiates-section-232-investigation-auto-imports>> [Accessed Aug. 18, 2018].

⁹⁷⁴ id.

⁹⁷⁵ Section 705.4 criteria for determining effect of imports on the national security are:

(a) To determine the effect on the national security of the imports of the article under investigation, the Department shall consider the quantity of the article in question or other circumstances related to its import. With regard for the requirements of national security, the Department shall also consider the following:

- (1) Domestic production needed for projected national defence requirements;
- (2) The capacity of domestic industries to meet projected national defence requirements;
- (3) The existing and anticipated availabilities of human resources, products, raw materials, production equipment and facilities, and other supplies and services essential to the national defence;
- (4) The growth requirements of domestic industries to meet national defence requirements and the supplies and services including the investment, exploration and development necessary to assure such growth; and
- (5) Any other relevant factors.

(b) In recognition of the close relation between the strength of our national economy and the capacity of the United States to meet national security requirements, the Department shall also, with regard for the quantity, availability, character and uses of the imported article under investigation, consider the following:

- (1) The impact of foreign competition on the economic welfare of any domestic industry essential to our national security;
- (2) The displacement of any domestic products causing substantial unemployment, decrease in the revenues of government, loss of investment or specialized skills and productive capacity, or other serious effects; and
- (3) Any other relevant factors that are causing or will cause a weakening of our national economy.

See Section 232 Investigations Programme Guide: The Effect of Imports on the National Security (Bureau of Industry and Security, Office of Technology Evaluation, June 2007). Available at: <<https://www.bis.doc.gov/index.php/forms-documents/section-232-investigations/86-section-232-booklet/file>>[Accessed Aug. 10, 2018].

Based on the Tariffs and Trade Barriers long placed on the U.S. and it great companies and workers by the European Union, if these Tariffs and Barriers are not soon broken down and removed, we will be placing a 20% Tariff on all of their cars coming into the U.S. Build them here!⁹⁷⁶

At least the President's assertion that European car manufacturers should "Build them here" is very significant to local working requirements. Although this issue is about cars rather than essential medicines, it will make Section 84, which allows for the granting of a compulsory licence provided that the reasonable requirements of the public with respect to the patented invention have not been satisfied consistent with TRIPS, where for example, failure to work any pharmaceutical patents in the territory of Ghana results in high costs and shortages of essential medicines. In this context, the implementation of Section 84 is highly relevant to Ghana's public health because it will allow the government to potentially intervene to promote affordable medicines.

6.6. Potential Risks of FDI Retribution Effects

Some scholars argue that stronger IP protection is a major stimulus to inward FDI, technology transfer, industrial skills enhancement, access to the international market and ultimately economic growth in developing countries.⁹⁷⁷ A study by Lee and Mansfield found that reasonable firms consider IP rights in FDI decisions,⁹⁷⁸ and therefore countries with strong IP regimes stand to benefit from inward FDI.⁹⁷⁹ Likewise, Javorcik found that weak protection of IP rights impacts the composition of FDI inflows, deterring investment in IP right-sensitive sectors and encouraging distribution rather than local production.⁹⁸⁰ That is, relatively weak IP

⁹⁷⁶ Trump wrote on Twitter, Friday Jun. 22, 2018. Available at: <<https://twitter.com/realdonaldtrump/status/1010320166486454272?lang=en>> [Accessed Aug. 18, 2018]. See also Richard Partington, 'Trump Threatens Car Tariffs after EU sets up £2.5bn of Levies on US' (The Guardian, Jun. 22, 2018). Available at: <<https://www.theguardian.com/business/2018/jun/22/bourbon-levis-prices-rise-eu-enforces-tariffs-us>> [Accessed Aug. 18, 2018].

⁹⁷⁷ Michael Wallerstein, Mary Ellen Moge, and Roberta Schoen, *Global Dimensions of Intellectual Property Rights in Science and Technology* (Washington D.C.: Office of International Affairs, Policy and Global Affairs, National Research Council National Academy Press, 1993) 111. Falvey, *et al* (n 804) x. Foreign Direct Investment for Development: Maximising Benefits, Minimising Costs (Organisation for Economic Cooperation and Development, 2002) 9, discussing the actual influence of FDI on economic growth and claiming that FDI raises total factor productivity in the recipient country.

⁹⁷⁸ Jeong-Yeon Lee and Edwin Mansfield, 'Intellectual Property Protection and U.S. Foreign Direct Investment' (1996) 78 *The Review of Economics and Statistics* 2, 181-186.

⁹⁷⁹ *ibid.* 185-186.

⁹⁸⁰ Beata Smarzynska Javorcik, 'The Composition of Foreign Direct Investment and Protection of Intellectual Property Rights: Evidence from Transition Economies' (2004) 48 *European Economic Review* 2004, 40.

rights protection in a developing country may lower the probability that multinational firms will invest there.⁹⁸¹

Simply put, the exposure of a patent to an uncertain legal environment such as, in the case Ghana implements a Section 84 model can cause questions to arise concerning whether or not the target Ghana's economy will be a breeding ground for investment protection.⁹⁸² This understanding explains why Ghana and other WTO Members may have unilaterally strengthened their IP rights laws and enforcement regimes, and could also explain the universal acceptance of the TRIPS Agreement.⁹⁸³ A significant school of thought, along this line of thinking holds that the pharmaceutical industry, which finds the security of IP rights lacking for example, in Ghana may cancel or reduce planned investments,⁹⁸⁴ or decline to bring new products to the country in question,⁹⁸⁵ as was threatened in South Africa,⁹⁸⁶ Thailand⁹⁸⁷ and India.⁹⁸⁸ In another background example, Egypt's compulsory licensing for Pfizer's Viagra is believed to have had a ripple effect on FDI to the country.⁹⁸⁹

Importantly, FDI is welcomed and, indeed, actively sought by Ghana, and evidence suggests that Ghana has gained immensely from inward FDI.⁹⁹⁰ The country's policy of encouraging

⁹⁸¹ Mansfield (n 805) 1.

⁹⁸² *id.* suggesting that MNEs often are interested in the following questions: (1) Is there an adequate legal infrastructure in the country? (2) Can the country's laws protect their technology? (3) Do the relevant government agencies in the country enforce the laws and provide prompt and equitable treatment to foreign firms?

⁹⁸³ Keith Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer* (Brussels: prepared for the Conference "Public-Private Initiatives After TRIPS: Designing a Global Agenda", July 1997) 19.

⁹⁸⁴ Robert Bird and Daniel Cahoy, 'The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach' (2008) 45 *American Business Law Journal* 2, 309, citing the Case of Pfizer with respect to Viagra in Egypt. Keith Maskus, 'The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer' (1998) 9 *Duke Journal of Comparative and International Law* 1, 130-131, defending a link between stronger IP protection and FDI. Reichman (n 924) 252-254.

⁹⁸⁵ Abbott and Reichman (n 460) 952-953. Kristina Lybeck and Elisabeth Fowler, 'Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules' (2009) 37 *Journal of Law, Medicine and Ethics* 2, 233, asserting that the impact on innovative pharmaceutical companies' decisions to launch new products in Thailand was felt more immediately after the issuance of compulsory licensing. For example, in March 2007, Abbott Laboratories responded by electing not to launch any new products in Thailand, saying "Thailand has chosen to break patents on numerous medicines, ignoring the patent system."

⁹⁸⁶ Reichman (n 941) 256

⁹⁸⁷ *id.*

⁹⁸⁸ Abbott and Reichman (n 460) 959. After the Decision, the Chairman of Novartis announced that the company would redirect its research and development program away from India to more receptive environments. See Andrew Jack, "Novartis to move Indian R&D", (FT.com, Aug. 22, 2007 edn.).

⁹⁸⁹ Richard Castellano, 'Note, Patent Law for New Medical Uses of Known Compounds and Pfizer's Viagra Patent' (2006) 46 *IDEA: The Intellectual Property Law Review* 2, 289, asserting that the compulsory licensing measure led Pfizer to "slam the brakes" on a state of the art production facility in Egypt.

⁹⁹⁰ Ghana is ranked 3rd among top five recipient of FDI into Africa. See World Investment Report (UNCTAD/WIR/2017). Available at: <http://unctad.org/en/PublicationsLibrary/wir2017_en.pdf> [Accessed Oct.

foreign investment is demonstrated in many ways, particularly by a principal law, the Investment Promotion Centre Act 2013, which aimed to create an enhanced, transparent and responsive environment for investment into the Ghanaian economy.⁹⁹¹ This law provides guarantees including prohibition against discrimination and expropriation to FDIs.⁹⁹² This is in line with Ghana government's vision of creating an industrialised economy that creates jobs, a modernised agricultural sector that emphasises value addition and an integrated business infrastructure that truly builds up the private sector as the engine of growth.⁹⁹³

Therefore, based on the theory that links robust IP rights protection and inward FDI opportunities, it can be suggested that the implementation of a Section 84 model in Ghana would, all things being equal, weaken IP rights significantly,⁹⁹⁴ and eventually Ghana would risk losing inward FDI. Nevertheless, while the above standpoints appear to be a common philosophical version it is also the case that some scholars may generally find it more difficult to endorse the wholesale assumption that robust IP rights protection is a definitive incentive for inward FDI and socio-economic growth.

6.6.1. Would Implementation of the Section 84 Threaten Inward FDI Opportunities and Socio-Economic Growth in Ghana?

Given that the relationship between IP rights, inward FDI and socio-economic growth remains complex and dependent on certain circumstances,⁹⁹⁵ the question is whether the

29, 2017] 47, finding that FDI inflows to Ghana increased by 9 per cent to \$3.5 billion. See also George Owusu-Antwi, 'Foreign Direct Investment: A Journey to Economic Growth in Ghana – Empirical Evidence' (2013) 12 *International Business and Economic Research Journal* 5, 573. Samuel Antwi and Xicang Zhao, 'Impact of Foreign Direct Investment and Economic Growth in Ghana: A Cointegration Analysis' (2013) 3 *International Journal of Business and Social Research* 1, 64.

⁹⁹¹ Act 865 of 2013.

⁹⁹² Part II. Article 28(1):

(a) no enterprise shall be nationalized or expropriated by Government; and (b) no person who owns, whether wholly or in part, the capital of any enterprise shall be compelled by law to cede his interest in the capital to any other person. (2) There shall not be any acquisition of an enterprise to which this Act applies by the State unless the acquisition is in the national interest for a public purpose and under a law which makes provision for - (a) payment of fair and adequate compensation.

⁹⁹³ "Trade Policy Review – Ghana" (n 819) 10, para.4.9. The key development objectives of the Industrial Policy are: i. To expand productive employment in the manufacturing sector ii. To expand technological capacity in the manufacturing sector iii. To promote agro-based industrial development iv. To promote spatial distribution of industries in order to achieve a reduction in poverty and income inequalities.

⁹⁹⁴ Bird and Cahoy (n 984) 284.

⁹⁹⁵ Keith Maskus, *Intellectual Property Rights in the Global Economy* (Washington D.C.: Institute for International Economics, 2000) 169. Primo Braga, Carlos Alberto and Carsten Fink, 'The Relationship Between Intellectual Property Rights and Foreign Direct Investment' (1998) 9 *Duke Journal of Comparative and*

implementation of Section 84 would truly result in a reduction in FDI incentives and threaten socio-economic growth in Ghana. A paper by Abbott and Reichman questions whether such a measure would result in a palpable reduction in FDI given the pragmatic nature of most companies.⁹⁹⁶ However, they conclude that this is an unrealistic proposition.⁹⁹⁷ A comprehensive review of the extent of FDI inflow to Ghana, pursuant to the sectorial distribution, is needed, to quantify the potential effect on FDI if a Section 84 model were to be implemented. A study on the trends and sectorial distribution of FDI inflows into the country has revealed that FDI in Ghana continues to be concentrated in the mining and oil and gas sectors.⁹⁹⁸

The inward FDI towards the pharmaceutical sector has been minimal if not non-existent. The fact is that Ghana does not derive any benefits from FDI into its pharmaceutical sector.⁹⁹⁹ Ghana's economy is relatively small, and open to primary commodity producers, which have not been lucrative enough for investment from the pharmaceutical industry.¹⁰⁰⁰ In other words, there is not a single mainstream pharmaceutical company that has a manufacturing plant or research facility in Ghana, as they prefer not to build manufacturing plants; rather, they simply resort to the importation of essential medicines to Ghana, thereby keeping investments as limited as possible even though Ghana has a very strong patent law.

Therefore, a more direct impact on FDI to the pharmaceutical sector cannot be sketched on a general presumption that the implementation of Section 84 would affect inward FDI, and hence the attainment of socio-economic objectives. In fact, the implementation of Section 84 could possibly encourage the generic pharmaceutical industry to invest in the Ghanaian local market. Importantly, Mansfield found that US firms may be quite willing to invest considerable amounts in sales and distribution outlets and in rudimentary production and assembly facilities

International Law 1, 172, explaining that the net effect of higher levels of IPR protection on FDI is theoretically ambiguous.

⁹⁹⁶ Abbott and Reichman (n 460) 938-939.

⁹⁹⁷ *id.*

⁹⁹⁸ Thomas Akabzaa, and Charles Ayamdo, 'Towards a Fair and Equitable Taxation for Sustainable Development Financing in Africa: A Study on Trends and Nature of Taxation in Ghana's Extractive Sector' (Integrated Social Development Centre, 2009) 7, observing that in Ghana mining companies pay the minimum rate tax of 3 per cent. Daniel Boakye, Sebastien Dessus, Yusuf Foday and Felix Oppong, *Investing the Mineral Wealth in Development Assets: Ghana, Liberia and Sierra Leone* (Washington, DC: World Bank, Apr. 2012) 12, para. 25, stating that even though Ghana has simplified its tax regime for mining companies they pay 3 per cent of the royalty rate and most of these are depleted through tax evasion.

⁹⁹⁹ Quarterly Investment Report is available at: <<http://www.gipcghana.com/press-and-media/downloads/reports.html>> [Accessed Feb. 6, 2018].

¹⁰⁰⁰ *id.*

in countries with weak protection.¹⁰⁰¹ It is difficult, therefore, to make a case that robust IP rights protection would, by itself, lead to a significant surge in FDI, or that the implementation of Section 84 would cause a loss in FDI incentives.¹⁰⁰²

Notably, the implementation of Section 84 in India and an attempt to impose compulsory licensing on the grounds of non-working in Brazil did not appear to come at the price of any loss in FDI.¹⁰⁰³ Along the same lines, it is contended that the implementation of a Section 84 model would not substantially reduce FDI to Ghana's economy. There is little empirical evidence to support the responsiveness of stronger IP rights protection and inward FDI opportunities and socio-economic growth despite the widespread and growing acceptance linking them.¹⁰⁰⁴ Ghana does not need to look far to dismantle this misconception.

The fact that the country continues to have a strong IP regime, yet the pharmaceutical industry has failed to invest in the country and even continues to cite commercial reasons as the real cause for neglecting innovation in regard to tropical diseases, provides a sufficient presumption to argue that a country like Ghana that pursues a systematic policy orientation to enforce robust IP standards as a means of attracting FDIs may be misleading itself.¹⁰⁰⁵ Thus, any wholesale association of the impact of Section 84 relative to FDI incentives and socio-economic growth is controversial and ambiguous.¹⁰⁰⁶

¹⁰⁰¹ Mansfield (n 805) 17, finding however that their decision to invest in R&D facilities or in facilities to manufacture components or complete products may be more likely to go to countries with stronger protection systems.

¹⁰⁰² Sanjaya Lall and Manuel Albaladejo, *Indicators of the Relative Importance of IPRs in Developing Countries* (Geneva, UNCTAD, and International Centre for Trade and Sustainable Development Issue Paper No. 3, 2003) 12.

¹⁰⁰³ Nagesh Kumar, *Intellectual Property Rights, Technology, and Economic Development: Experiences of Asian Countries* (London, Commission on Intellectual Property Rights Study Paper 1b, 2002) 37, finding that despite loose IP protection, many foreign pharmaceutical companies, including Abbot Laboratories, Smith Kline, and Astra-Zeneca, have set up research and development centres across India. Walter Park, Douglas Lippoldt, *Technology Transfer and the Economic Implications of the Strengthening of Intellectual Property Rights in Developing Countries* (Paris: OECD Trade Policy Working Papers, No. 62, TAD/TC/WP(2007)19/FINAL, 2008) 27, para. 95.

¹⁰⁰⁴ Maskus (n 983) 19.

¹⁰⁰⁵ *id.* observing that a poor country hoping to attract inward FDI would be better advised to improve its overall investment climate and business infrastructure than to strengthen its patent regime sharply, an action that would have little effect on its own. See Maskus (n 984) 128-129, noting that if stronger IP protection always led to more FDI, recent FDI flows to developing economies would have gone largely to sub-Saharan Africa and Eastern Europe rather than China, Brazil, and other high-growth, large-market developing economies with weak IPRs. See also Abbott (n 827) 325, noting that there is reason to doubt that the pharmaceutical companies are underfunded from lack of patent rents from developing countries

¹⁰⁰⁶ Peter Yu, *Intellectual Property, Economic Development, and the China Puzzle*. In: *INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA*, Daniel Gervais (ed.), (Oxford: Oxford University Press, 2007) 173–174 & 176–180.

As Maskus puts it in the FDI context, IPRs are an important component of the general regulatory system, including taxation, investment regulations, production incentives, trade policies and competition rules.¹⁰⁰⁷ The joint implementation of an overall pro-competitive business environment matters most for FDI.¹⁰⁰⁸ In addition, Frischtak states that a country's overall investment climate is often more influential on decisions regarding FDI than the strength of the IP protection it offers.¹⁰⁰⁹ More specifically, what matters ultimately to the firm is the likelihood that an investment will raise its expected profits.¹⁰¹⁰ In this context, Fink and Maskus observed that a poor country hoping to attract inward FDI would be better advised to improve its overall investment climate and business infrastructure than to strengthen its patent regime sharply, an action that would have little effect on its own.¹⁰¹¹

6.6.2. Lack of Linkages Between Robust IP Protection, Inward FDI Opportunities and Socio-Economic Growth

Maskus, Braga, Alberto and Fink have shown that IP rights protection is more likely to attract FDI if two additional conditions are met.¹⁰¹² Most pronounced is the difference between countries at different income and investment attraction levels, meaning that FDI incentives do not hinge solely on patent protection of pharmaceuticals but depend on a series of other factors.¹⁰¹³ First, the country in question needs to have a robust capability to copy foreign patented products and technologies. If domestic competitors are incapable of copying these patented products and technologies, the commercial interests of foreign firms' patent owners are unlikely to be threatened, and IP protection will be needless.¹⁰¹⁴

¹⁰⁰⁷ Maskus (n 984) 129.

¹⁰⁰⁸ *id.*

¹⁰⁰⁹ Claudio Frischtak, Harmonization Versus Differentiation in Intellectual Property Rights Regime. In: GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY Mitchel Wallerstein, Mary Ellen Mogee and Roberta Schoen (eds.), (Washington, DC: National Academy Press, 1993) 99–100.

¹⁰¹⁰ Maskus (n 983) 13, para. 2c.

¹⁰¹¹ Carsten Fink and Keith Maskus, Why We Study Intellectual Property Rights and What We Have Learned. In: INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH, Carsten Fink and Keith Maskus (eds.), (Washington, DC: A co-publication of the World Bank and Oxford University Press, 2005) 7.

¹⁰¹² Maskus (n 984) 130-131. Braga, *et al* (n 995) 164.

¹⁰¹³ *id.*

¹⁰¹⁴ *id.*

Second, the country needs to have a large market to enable foreign firms to capture economies of scale. That is, while the robustness or weakness of IP rights protection will affect a firm's evaluation in regard to internalising or externalising its intellectual assets, it is only one of the many location advantages that influence such a decision.¹⁰¹⁵ Therefore, in a country that lacks such a market, foreign firms are unlikely to find it beneficial to move their manufacturing facilities abroad.¹⁰¹⁶ This means that while strong IP protection is a main consideration for marketing decisions, a decision to relocate production facilities is likely to be based on location advantages, market size and growth, local demand patterns, transport costs and distance from markets, low wage costs in relation to labour productivity, abundant natural resources, and trade protection that could encourage "tariff-jumping" investments'.¹⁰¹⁷

Simply put, whether or not a country will be able to attract FDI depends on the size of the market, and the larger the market, the greater the incentive for private corporations to enter through FDI in order to take advantage of the market.¹⁰¹⁸ What appears to weaken the assessment linking the relative inadequacy of stronger patents and FDIs further is the confirmation that China continues to attract more FDI than many developed countries even though it is indisputable that IP matters in China may not be as strong as those standards prevailing in key industrialised countries.¹⁰¹⁹

Several scholars support the foregoing contention including Maskus.¹⁰²⁰ For example, Outterson believes that it is poorly reasoned that compulsory licensing will have any impact on innovation and this position has prevented the wider use of the compulsory licensing mechanism in developing countries.¹⁰²¹ Chon argues that the so-called innovation-driven growth created primarily through FDIs and accompanying technology transfer may be an

¹⁰¹⁵ *ibid.* 171. See Yu (n 1006) 124, stating that because of China's multiple location advantages, industrial base and its huge market the country continues to attract FDIs despite not having a robust IP regime.

¹⁰¹⁶ *id.* See Paul Heald, 'Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game' (2003) 99 *Minnesota Law Review* 2, 266.

¹⁰¹⁷ Maskus (n 983) 123.

¹⁰¹⁸ David Wheeler and Ashoka Mody, 'International Investment Location Decisions: The Case of U.S. Firms' (1992) 33 *Journal of International Economic* 1&2, 59-60.

¹⁰¹⁹ Yu (n 1006) 124, stating that despite China being a major infringer of alleged IP rights this has not deterred substantial FDI inflow to the country. See Foreign Direct Investment in Figures (OECD, Apr. 27, 2017). Available at: <<http://www.oecd.org/corporate/FDI-in-Figures-April-2017.pdf>> [Accessed Oct. 13, 2017] 2.

¹⁰²⁰ Maskus (n 984) 129, stating that if stronger IP protection always led to more FDI, recent FDI flows to developing economies would have gone largely to African countries and Eastern Europe countries rather than China, Brazil, and other high-growth, large-market developing economies with presumably weak IP rights.

¹⁰²¹ Kevin Outterson, 'Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets' (2005) 5 *Yale Journal of Health Policy Law and Ethics* 1, 230, arguing that if patent rents are "supra optimal", compulsory licensing at marginal costs will not reduce innovation.

abstract or perhaps even non-existent benefit for developing countries.¹⁰²² Maskus suggests that several developing countries with little to offer in the way of comparable economic opportunities attract virtually no FDI despite strict patent laws that sometimes afford more protection than that of the US.¹⁰²³ This means that the implementation of Section 84 to promote affordable medicines would have little impact on FDI incentives and socio-economic growth in Ghana.¹⁰²⁴

Moreover, industries differ widely in regard to the extent to which patents are effective,¹⁰²⁵ as firms in most industries, even in advanced countries, do not find patents to be a particularly effective means of appropriating the returns on R&D.¹⁰²⁶ Many economists seem to believe that patent protection tends to be more important to smaller firms than to larger ones.¹⁰²⁷ At the same time, the argument concerning patent rights protection is focused almost exclusively on large, established firms operating within specific industries,¹⁰²⁸ and this is unlikely to be apt for promoting the small, incremental and adaptive innovations that are typical in developing countries.¹⁰²⁹

Empirical evidence affirms that the need for IP rights varies with the level of development. For example, many developed countries used weak IP rights protection in their early stages of industrialisation to develop local technological bases, increasing protection as they approached the leaders.¹⁰³⁰ In other words, IP rights should be less strong in the early developmental stages, or at the very least balanced with limitations and exceptions to encourage public access for the purposes of encouraging downstream innovation and promoting competition.¹⁰³¹ Thus, weak

¹⁰²² Margaret Chon, 'Intellectual Property and the Development Divide' (2006) 27 *Cardozo Law Review* 6, 2855.

¹⁰²³ Maskus (n 984) 129-130, providing empirical facts in the discussion of the role of IP in encouraging FDIs.

¹⁰²⁴ Hestermeyer (n 631) 242.

¹⁰²⁵ Sean Bottomley, *The British Patent System during the Industrial Revolution 1700–1852: From Privilege to Property* (Cambridge: Cambridge University Press, 2014) 11.

¹⁰²⁶ Wesley Cohen and Richard Levin, Empirical Studies of Innovative Activity and Market Structures. In: HANDBOOK OF INDUSTRIAL ORGANISATION, Richard Schmalensee and Robert Willig (eds.), (Amsterdam, Holland: Elsevier, Volume 2, 1989) 1090. Falvey, *et al* (n 804) 20.

¹⁰²⁷ Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32 *Management Science* 2, 175. Duncan Matthews, John Pickering and John Kirkland, A Strategic Approach to Managing Intellectual Property. In: INTELLECTUAL PROPERTY AND INNOVATION MANAGEMENT IN SMALL FIRMS, Robert Blackburn (ed.), (New York: Routledge, 2005) 57. For further discussion of this point, see Edwin Mansfield, Anthony Romeo, Mark Schwartz, David Teece, Samuel Wagner and Peter Brach, *Technology Transfer, Productivity, and Economic Policy* (New York: Norton, 1982).

¹⁰²⁸ Falvey, *et al* (n 804) 17.

¹⁰²⁹ *ibid.* 18

¹⁰³⁰ Lall and Albaladejo (n 1002) 11.

¹⁰³¹ *id.*

patents can help local firms to build their technological capabilities by permitting imitation and reverse engineering.¹⁰³²

It has been argued in the same vein that lax IPRs have not deterred FDI in China or Brazil, or held back technology licensing in Korea and Taiwan, although IP rights protection in these countries is weak relative to key industrialised countries.¹⁰³³ Similarly, the UNCTAD, in conjunction with the International Centre for Trade and Sustainable Development (ICTSD) published a report describing the indicators of the relative importance of loose IP protection in developing countries like Ghana, and affirmed that weak protection helped spark high growth in India's pharmaceutical industry.¹⁰³⁴

6.6.3. Countering Potential FDI-Retributive Effects

Given the economic implications of FDI-related retributive effects, policies that go beyond national borders and take into account the degree to which actors in a region are able to connect to, and benefit from networks are critical. Concerns regarding FDI-related retributive effects and the potential threat of lawsuits by the pharmaceutical industry could be eased if Ghana were to work with its neighbours, as it is not expected that a reasonable pharmaceutical company would sue or withdraw investments from the entire sub-region.

A key policy consideration is whether regional mechanisms could significantly help Ghana to address any potential FDI-retributive related effects and bilateral pressure, harness economies of scale and build technical capacity if it were to implement a Section 84 model. More importantly, if, through a coordinated approach, Ghana and other countries in the sub-region impose a sequence of compulsory licences, one might imagine that the likelihood of any FDI-retribution would be reduced or eliminated, leaving only the economic advantages gained from the granting of such licences.¹⁰³⁵

Moreover, while it may be possible for a multinational corporation to withdraw its investments within a particular country in protest against the granting of a compulsory licence, as in the

¹⁰³² *ibid.* 10, stating that weak IPRs can help local firms in early stages to build technological capabilities by permitting imitation and reverse engineering. This is certainly borne out by the experience of the East Asian 'Tigers' like Korea and Taiwan that developed strong indigenous firms in an array of sophisticated industries.

¹⁰³³ *ibid.* 11.

¹⁰³⁴ *id.*

¹⁰³⁵ Abbott and Reichman (n 460) 973–974.

cases of Abbott in regard to “Kaletra” in Thailand,¹⁰³⁶ and Pfizer’s Viagra in Egypt,¹⁰³⁷ a reasonable private corporation would not be expected to leave the entire sub-region if the approach were a coordinated one. It is obvious that the WTO will not object to the principle behind the adoption of any regional legal infrastructure in order to implement compulsory licences for the manufacture and distribution of affordable medicines for public health protection. This is because the TRIPS General Council Decision of 30 August 2003 provided the need to harness economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.¹⁰³⁸

6.7. Implementation of Section 84: Potential High Litigation Costs

An actual or threatened legal challenge is a threat to the implementation of Section 84 to promote affordable medicines. This was evident in 1997, when about forty pharmaceutical companies sued the South African government in regard to its intention to use the TRIPS flexibilities to promote the manufacture of affordable medicines locally.¹⁰³⁹ As already examined, on 19 December 1997, the EC alleged that Canada’s legislation is not compatible with its obligations under the TRIPS Agreement, because it does not provide for the full protection of patented pharmaceutical inventions for the entire duration of the term of protection envisaged by Articles 27(1), 28 and 33 of the TRIPS Agreement.¹⁰⁴⁰ Brazil’s use of compulsory licensing was criticised by pharmaceutical companies, which claimed that compulsory licensing would negatively affect research into new medicines.¹⁰⁴¹

¹⁰³⁶ Stephanie Skees, ‘Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand’s AIDS Epidemic?’ (2007) 17 *Pace International Law Review* 2, 242, finding that in addition to Aluvia®, Abbott pulled applications for Brufen® (ibuprofen), Abbotec® (clarithromycin), Clivarine® (heparin), Humira® (adalimumab), Tarka® (trandolapril/verapamil HCL ER), and Wemplar® (paricalcitol).

¹⁰³⁷ Castellano (n 989) 289, asserting that the compulsory licensing measure led Pfizer to “slam the brakes” on a state of the art production facility in Egypt.

¹⁰³⁸ “Implementation of Paragraph 6 of the Doha Declaration” (n 47) para. 6.

¹⁰³⁹ Aileen McGill, ‘Compulsory Licensing of Patented Pharmaceuticals: Why A WTO Administrative Body Should Determine What Constitutes a Public Health Crisis Under the Doha Declaration’ (2009) 10 *Wake Forest Intellectual Property Law Journal* 1, 88, observing that the Act attempted to allow generic production of patented antiretroviral HIV drugs. *id.* However, public outcry eventually forced the pharmaceutical companies to withdraw the suit. The US also placed South Africa on its Special 301 Watch List. See Watson (n 86) 152.

¹⁰⁴⁰ “Canada – Patent Protection of Pharmaceutical Products” (n 68).

¹⁰⁴¹ International Centre for Trade and Sustainable Development Report. Brazil Issues Compulsory Licence for AIDS Drug (Bridges Weekly Trade News Digest, Vol. 11, No. 16, May 9, 2007) 1, stating that Merck responded by saying that it is “profoundly disappointed” by the outcome, with the US-Brazil Business Council calling it “a major step backward” that will discourage investment in Brazil.

The US followed this by attempting to challenge the compulsory licensing provisions of the Brazilian Industrial Property Law in a petition to the WTO/DSB.¹⁰⁴² In 2007, when Thailand issued a compulsory licence, including Efavirenz and Kaletra, so as to make treatment affordable, and to ensure more reliable supplies, the US threatened trade sanctions against Thailand, which is the country's biggest export market, and in the end, Thailand had to stop producing a generic version of the HIV medicine, Didanosine.¹⁰⁴³ In this connection, a EU Commissioner is alleged to have written a letter stating that, 'neither the TRIPS Agreement nor the Doha Declaration appear to justify a systematic use of compulsory licence wherever medicine exceeds certain prices'.¹⁰⁴⁴

Moreover, in 2012, Indian generic manufacturers CIPLA and Natco faced separate patent infringement lawsuits in the Delhi High Court by Bayer Pharmaceuticals for its patented cancer drug Nexavar.¹⁰⁴⁵ The predictable negative reaction by pharmaceutical companies poses obvious worries for countries and instils fear into Ghana and other WTO Members that intend to use compulsory licensing to promote affordable medicines.¹⁰⁴⁶ Such challenges could potentially delay access to essential medicines in Ghana and add costs to seeking a compulsory licence.¹⁰⁴⁷ Based on this scepticism, Reichman argued that a country like Ghana that intends implement a Section 84 model must exercise caution because it is reasonable to suggest that companies that fear a growing trend of compulsory licences, such as pharmaceutical companies, may enter into substantial retribution to protect the long-term gains provided by stronger patent standards.¹⁰⁴⁸ Moreover, a study by Abbott and Reichman later confirmed the same proposition.¹⁰⁴⁹ It is on this basis that Ghana and other WTO Members lack the will to use compulsory licensing.¹⁰⁵⁰

6.7.1. The Case of Ghana v GSK

¹⁰⁴² "Notification of Mutually Agreed Solution, Brazil" (n 83). See Halajian (n 625) 1216. Chow and Lee (n 645) 454.

¹⁰⁴³ Josephine Johnston and Angela Wasunna, 'Patents, Biomedical Research, and Treatments: Examining Concerns, Canvassing Solutions' (2007) 37 *Hastings Centre Report* 1, S19.

¹⁰⁴⁴ See (n 554) for EU letter challenging the use of compulsory licensing.

¹⁰⁴⁵ "Bayer Corp. v. Natco Pharma Ltd" (n 181).

¹⁰⁴⁶ t' Hoen (666) 37, stating that the EC policies have closely tracked the pharmaceutical industry's agenda. See Patents versus Patients Five Years after the Doha Declaration (Oxfam Briefing Paper 95, November 2006). Available at: <<https://www.oxfam.org/sites/www.oxfam.org/files/Patents%20vs.%20Patients.pdf>> [Accessed Oct. 22, 2017] 3.

¹⁰⁴⁷ Halajian (n 625) 1216.

¹⁰⁴⁸ Reichman (n 941) 252-254. See also Abbott and Reichman (n 460) 959.

¹⁰⁴⁹ Abbott and Reichman (n 453) 921-987.

¹⁰⁵⁰ Fauver (n 11) 676, explaining that compulsory licenses reduce the inventor's incentive to develop new technology and discourages FDIs.

In 2000, Ghana attempted to import HIV/AIDS medicines, Duovir – a combination copy of Zidovudine+Lamivudine, and a generic version of Combivir from India.¹⁰⁵¹ However, GSK, the patent holder, attempted to block the initiative.¹⁰⁵² In a letter to a pharmaceutical distributor in Ghana (Healthcare Pharmacy) and CIPLA an Indian generic medicines manufacturer, GSK alleged that sales of generic versions of its patented medicines, Combivir, in Ghana would be illegal because they would be violating its patents.¹⁰⁵³

Indeed, Ghana had filed legal documents to challenge GSK's claim, as the country had earlier rejected the three patents that the company claimed it owned in Ghana.¹⁰⁵⁴ Significantly, officials at the African regional patent authority, the African Regional Industrial Property Organisation (ARIPO), which examined the patents in question, explained that they were invalid in Ghana or did not apply: 'Glaxo's actions are wrong', said Christopher Kiige, head patent examiner of the ARIPO. He went on to say: 'If [Glaxo officials] went to court they would lose'.¹⁰⁵⁵ This is because the said patents were issued at a time when Ghana did not provide patent protection for pharmaceuticals, or similarly at that time pharmaceutical inventions were not patentable under the previous Patent law of Ghana.¹⁰⁵⁶

Ghana began allowing pharmaceutical product patents on 1 July 1993 following the adoption of Patent Law No. 305A in 1992, and any product patents registered before that would not apply. Further investigations revealed that these patents were not new, and GSK should not have attempted to apply for protection or they should not have been granted a patent in the first place in view of the fact that the said patents lacked novelty in the ARIPO system.¹⁰⁵⁷ In a similar move, when GSK tried to patent the same formulations, zidovudine+lamivudine (Combivir) in India, the application was opposed.¹⁰⁵⁸

¹⁰⁵¹ Anthony So and Cecila Oh, 'Approaches to Intellectual Property and Innovation that Meet the Public Health Challenge of AIDS' (Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, July 2011) 3.

¹⁰⁵² "Glaxo Blocks Importation of Generic Combivir into Ghana" (n 656). See also Condon (n 656) 101.

¹⁰⁵³ Schoofs (n 5).

¹⁰⁵⁴ *id.*

¹⁰⁵⁵ *id.* citing the then Chief Examiner of the African Regional Industrial Property Organisation.

¹⁰⁵⁶ Patent Law No. 305A of Dec. 30, 1992.

¹⁰⁵⁷ Amar Lulla, Director of CIPLA notes that: 'GlaxoWellcome does not hold the patents in Ghana, as the only patent (AP 300) granted after 1 July also just relates to crystalline lamivudine and we've written to them saying so'. 'They still haven't replied, so as of now, the export will continue'. Sanchita Sharma, "Drug Majors Battle for Ghanaian AIDS Market" (*The Indian Express*, Nov. 18, 2000).

¹⁰⁵⁸ Pre-Grant Representation by Way of Opposition for Patent Application No. 2044/CAL/1997 filed on Oct. 29, 1997 titled "Pharmaceutical Compositions" Under Section 25(1) of the Patents Act 1970 (39 of 1970) and Rule

On 30 March 2006, the Indian Network of People Living with HIV/AIDS and the Manipur Network of Positive People filed their opposition to GSK's patent application for Combivir. They claimed that the drug did not qualify as a true innovation or new invention. They successfully invoked Section 25(1) of the Indian Patent Act and Rule 55(1) of the Rules governing the patent regime, which allows the public to bring evidence for patent rejection to the attention of the Controller.¹⁰⁵⁹

They alleged that GSK's patent under consideration for patent was not an invention under Section 3(d) of the Indian Patent Act because it was merely a "discovery" of a new form of a known substance.¹⁰⁶⁰ Old molecules, which have been slightly modified for a new use, do not comply with Section 3(d) of the Indian patent law.¹⁰⁶¹ Heading for rejection, the company (GSK) later withdrew its patent application in India.¹⁰⁶² Nevertheless, Ghana had to abandon its plans to import affordable medicines from India to avoid high litigation costs.¹⁰⁶³

However, due to GSK's intervention, Ghana experienced shortages of Duovir, and for public health reasons, the then Minister of Health issued a compulsory licence on 26 October 2005 for the importation into Ghana of generic HIV/AIDS medicines after a declaration of a state of emergency consistent with Article 31(b) of TRIPS.¹⁰⁶⁴ The granting of compulsory licensing in Ghana is covered under Section 13 of Ghana's Patents Act 2003 (Act 657). According to the Minister, after considering the TRIPS Agreement and Doha Declaration, a compulsory licence for importation into Ghana of generic HIV/AIDS medicines was approved.¹⁰⁶⁵

55 (1) of the Rules as Amended by the Patents (Amendment) Act, 2005 by the Indian Network of People Living with HIV/AIDS and the Manipur Network of Positive People on Mar. 30, 2006.

¹⁰⁵⁹ *id.*

¹⁰⁶⁰ *id.*

¹⁰⁶¹ *ibid.* p. 3, lines 6-17; and p. 7, lines 13-29.

¹⁰⁶² Note that GSK made a similar attempt to apply for patents in Thailand, which was also withdrawn. "GSK Withdraws Combivir Patent Application from India and Thailand" (Geneva, Third World Network, IP Issues No. Sept06/03: Sept. 12, 2006). See Poku Adusei, *Patenting of Pharmaceuticals and Development in Sub-Saharan Africa: Laws, Institutions, Practices and Politics* (Berlin, Germany: Springer-Verlag, 2013) 150. See also Sridhaya Ragavan, "Patent and Trade Disparities in Developing Countries" (New York, Oxford University Press, 2012) 118-119.

¹⁰⁶³ Schoofs (n 5).

¹⁰⁶⁴ "Notification of Emergency and Issuance of Government Use Licence by Ghana" (n 8). Love (n 8) 16. See also Savoie (n 8) 237.

¹⁰⁶⁵ *id.*

The duration of the government use licence was 3 years, and it was for the importation of Combivir from India (CILPA). The licence was for government use, as the medicine was to be used within the national HIV/AIDS programme to treat people without commercial purpose.¹⁰⁶⁶ According to one study conducted by Correa, the cost of the ARVs dropped by almost 50 per cent from \$495 to \$235 for one year's treatment per patient in Ghana.¹⁰⁶⁷ However, the country abandoned this initiative, and consequently was left with no sustainable supply of lifesaving medicines for its HIV patients.¹⁰⁶⁸

6.7.2. Unlikely Legal Challenge After the Doha Solution Against the Implementation of Section 84

One important purpose of the Doha Declaration was to clear the air of uncertainty that had arisen in Ghana and other WTO Members surrounding the use of the TRIPS flexibilities, due to a lack of experience and administrative know-how in these countries in regard to the regulation of patents.¹⁰⁶⁹ Therefore, after the historic Doha Solution, it is not expected that the pharmaceutical industry will adopt an aggressive approach to challenging the legality of a model like Section 84. Although, some Indian generic manufacturers including CIPLA and Natco have while manufacturing affordable medicines faced patent infringement lawsuits in India.¹⁰⁷⁰

More importantly, Yu has raised some critical concerns regarding the possibility of using investor-state dispute settlement to address international disputes involving IP investments.¹⁰⁷¹ He contends that FTAs 'norms will reinforce the ability of private investors, such as IP rights holders, to sue foreign governments without the support of their home governments'.¹⁰⁷² In fact, several high-profile investment cases have arisen where right holders invoke protections under treaties to challenge measures by host states that affect their IP rights.¹⁰⁷³

¹⁰⁶⁶ *id.*

¹⁰⁶⁷ Carlos Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (Geneva: South Centre Research Papers 41, 2011) 18, Table 4.

¹⁰⁶⁸ Cloatre (n 9) 53.

¹⁰⁶⁹ Drahos (n 832) 17.

¹⁰⁷⁰ "Bayer Corp. v. Natco Pharma Ltd., C.S. (O.S.) No. 1090/2011" (n 181). See also "Bayer Corp. v. CIPLA Pharm: Case No. CS (OS) 523/2010" (n 208).

¹⁰⁷¹ Yu (n 803) 831.

¹⁰⁷² *id.*

¹⁰⁷³ An investment dispute where compliance with IP treaties is challenged concerns the US-based pharmaceutical company Eli Lilly and the revocation of two of its patents in Canada. In November 2012, Eli Lilly initiated International Centre for the Settlement of Investment Disputes proceedings (under Chapter 11 of NAFTA The North American Free Trade Agreement. 32 ILM 289, 605 (1993)) against Canada, following the invalidation of

In the context of Africa, one of such cases is AHS Niger and Menzies Middle East and Africa S.A. v Republic of Niger.¹⁰⁷⁴ In this case, the claimants (Menzies Middle East and Africa SA (MMEA), a Luxembourg-registered company, and its 75 per cent owned Nigerien subsidiary, Aviation Handling Services Niger SA (AHS)), provided airport cargo and ground services at Diori Hamani International Airport, in Niamey, Niger, under a concession agreement concluded with the government. In December 2010, Nigerien authorities terminated the arrangement, seized equipment belonging to the claimants, and requisitioned its airport staff.¹⁰⁷⁵

Citing a grant of jurisdiction arising from the parties' investment agreement with the government of Niger, the claimants brought a suit before the International Centre for Settlement of Investment Disputes in March 2011. In addition to claiming an expropriation, they raised the issue of infringements of their IP rights in the form of trademark and trade names. The claimants alleged that the new personnel employed by the Nigerien authorities after the seizure of its equipment had continued to operate airport services using uniforms showing their IP-protected trademarks and trade names. The tribunal issued an award in July 2013, rejecting the IP-related aspects of the claim.¹⁰⁷⁶

pharmaceutical patents for its drugs Strattera and Zyprexa by Canadian courts, where the Canadian Courts held to be insufficiently supported by evidence in the patent application. Lilly argues, breaches NAFTA's investment chapter since 'Canada has a positive obligation to ensure Canadian law complies with NAFTA and the PCT, consistent with the reasonable investment-backed expectations of the investor.' See *Eli Lilly & Company v Teva Canada Limited*, 2011 FCA 220, affirming the earlier trial court decision (2010 FC 915) and *Eli Lilly Canada v Novopharm Limited*, 2012 FCA 232, again affirming the earlier trial court decision (2011 FC 1288). Moreover, in 2010, 3 Philip Morris (PM) companies filed a request for arbitration under the bilateral investment treaty between Uruguay and Switzerland with the International Centre for the Settlement of Investment Disputes (ICSID). See *(Philip Morris Brand Sàrl (Switzerland), Philip Morris Products S.A. (Switzerland) and Abal Hermanos S.A. (Uruguay) v Oriental Republic of Uruguay*, [2009], ICSID Case No. ARB/10/7. The company alleges that Uruguay's limits on the use of trademarks on tobacco packaging 'have substantially damaged the value of the companies' investments in Uruguay and deprived them of the ability to use their brands and trademarks'. See Todd Weiler, 'Philip Morris vs. Uruguay: An Analysis of Tobacco Control Measures in the Context of International Investment Law' (Report #1 for Physicians for a Smoke Free Canada, Jul. 28, 2010) 26-27. The Tribunal rejected, *inter alia*, the argument that Philip Morris' business of selling tobacco products in Uruguay is not an 'investment' entitled to arbitration under Article 25 of the International Centre for the Settlement of Investment Disputes Convention [1965] 575 UNTS 159. The tribunal argued that for an investment to contribute to the host state's economic development is not a "mandatory legal requirement", but merely pointing to the typical features of an investment. See *Philip Morris v Uruguay*, Decision on Jurisdiction (Jul. 2, 2013) para. 204-210.

¹⁰⁷⁴ AHS Niger and Menzies Middle East and Africa S.A. v Republic of Niger (ICSID Case No ARB/11/ 11). (Award Jul. 15, 2013).

¹⁰⁷⁵ See Henning Grosse Ruse – Khan, 'Challenging Compliance with International Intellectual Property Norms in Investor-State Dispute Settlement' (2016) 19 *Journal of International Economic Law* 1, 241-277.

¹⁰⁷⁶ "AHS Niger and Menzies Middle East and Africa S.A. v Republic of Niger" (n 1074) para.150.

It is important to note that, for example, Article 49 of the EU-EPA provides for the initiation of arbitration procedure where there is a conflict.¹⁰⁷⁷ In this context, investors can initiate proceedings against the Ghanaian government. It therefore follows that large multinational corporations are given the right to challenge decisions and ‘laws they don’t like - not in court, but in front of industry-friendly arbitration panels that sit outside any court system’.¹⁰⁷⁸

To avoid the challenges posed by investor-state dispute settlement countries such as India, Indonesia and South Africa have already started terminating international investment agreements.¹⁰⁷⁹ Remarkably, according to the EU it has been negotiating a FTA with India, but India has refused to include a substantial IP right chapter.¹⁰⁸⁰ It is unclear at this point whether Ghana will have the political will to terminate existing FTAs or refuse to agree to include IP chapters in any subsequent FTAs, as India has done.

Nevertheless, for example, since NGOs draw the attention of the public to issues, which generates news coverage, and political leaders derive their authority from the public, NGOs representing affected groups may play a significant role in resisting pressure to concede the TRIPS flexibilities in the event of legal challenge by the pharmaceutical industry.¹⁰⁸¹ The rise in influence of the Africa Group has been enabled by a partnership with NGOs and civil society actors who help in framing the contest of principles surrounding IP rights and public health in the court of global public opinion.¹⁰⁸²

¹⁰⁷⁷ See Ghana-EU-EPA (n 893) Chapter 3, Section I.

¹⁰⁷⁸ Peter Yu, ‘The Investment-Related Aspects of Intellectual Property Rights’ (2017) 66 *American University Law Review* 3, 832, citing Senator Elizabeth Warren (D–Mass.) in Deirdre Fulton, ‘As Countries Line up to Sign Toxic Deal, Warren Leads Call to Reject TPP’ (Common Dreams, Feb. 3, 2016). Available at: <<https://www.commondreams.org/news/2016/02/03/countries-line-sign-toxic-deal-warren-leads-call-reject-tpp>> [Accessed Feb. 3, 2018].

¹⁰⁷⁹ Yu (n 803) 855, see footnote 119, citing Ben Bland and Shawn Donnan, ‘Indonesia to Terminate More than 60 Bilateral Investment Treaties’ (Financial Times, Mar. 26, 2014), ‘Indonesia is planning to terminate more than 60 bilateral investment treaties that allow disgruntled foreign investors to bypass local courts and seek compensation in international tribunals, amid a growing global backlash against such provisions’. Adam Green, ‘South Africa: BITs in Pieces’ (Financial Times, Oct. 19, 2012), ‘South Africa has terminated a bilateral investment treaty with Belgium and Luxembourg in the first of a series of planned shreadings of post-apartheid-era agreements which are coming up for renewal’. See David Price, ‘Indonesia’s Bold Strategy on Bilateral Investment Treaties: Seeking an Equitable Climate for Investment?’ (2017) 7 *Asian Journal of International Law* 1, 124. Nicholas Peacock and Joseph Nihal, Mixed Messages to Investors as India Quietly Terminates Bilateral Investment Treaties with 58 Countries (Herbert Smith Freehills, Mar. 16, 2017). Available at: <<https://hsfnotes.com/arbitration/2017/03/16/mixed-messages-to-investors-as-india-quietly-terminates-bilateral-investment-treaties-with-58-countries/>> [Accessed Feb. 12, 2018].

¹⁰⁸⁰ “Report on the Protection and Enforcement of Intellectual Property Rights in Third Countries” (n 876) 12.

¹⁰⁸¹ Abbott (n 827) 356.

¹⁰⁸² John Braithwaite and Peter Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000) 575-576.

In other words, NGOs and civil society actors have succeeded in reducing the complexities of patent law and HIV/AIDS to a simple choice that is readily understood by the mass public.¹⁰⁸³ According to Drahos, at Doha, the then USTR Robert Zoellick faced a choice between appearing to be against access to medicines or abandoning the US pharmaceutical industry. Neither were especially palatable alternatives. He chose the latter.¹⁰⁸⁴ No individual, country or organisation could be seen to be deciding the latter,¹⁰⁸⁵ bearing in mind the public relations disaster of the litigation by pharmaceutical multinationals against South Africa.¹⁰⁸⁶

6.8. The Feasibility of Pharmaceutical Manufacturing Capacity to Produce Affordable Medicines for Distribution

While nothing in the light of TRIPS or FTAs would directly operate to prevent Ghana from implementing a Section 84 model, the question is whether Ghana is capable of embarking on any efficient local manufacture of medicines for distribution, like India, which has adequate manufacturing capacity.¹⁰⁸⁷ Producing pharmaceuticals is a complex process that requires a reliable, high quality supply of raw materials, technical expertise and a stable supply of electricity, gas and other utilities, plus sufficient human resource capacity - scientists and expertise in pharmaceutical process and regulation.¹⁰⁸⁸

In this context, the question is whether Ghana has the requisite infrastructure, workforce, supplies, organisational ability, technical know-how, or access to raw materials that would support the local production of patented inventions. That is, an analysis should include the economic reasons why local working might not be beneficial to needy people.¹⁰⁸⁹ This would assist in weighing up all of the options, particularly in regard to whether importation on a large scale would not provide the much needed affordable medicines.¹⁰⁹⁰ There is rich literature,

¹⁰⁸³ Drahos (n 832) 19.

¹⁰⁸⁴ *id.*

¹⁰⁸⁵ *ibid.* 20.

¹⁰⁸⁶ John Odell and Susan Sell, *Reframing the Issue: The WTO Coalition on Intellectual Property and Public Health*, 2001. In: *NEGOTIATING TRADE: DEVELOPING COUNTRIES IN THE WTO AND NAFTA*, John Odell (ed.), (Cambridge: Cambridge University Press, 2006) 98.

¹⁰⁸⁷ Warren Kaplan and Richard Laing, *Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines an Overview of Key Concepts, Issues and Opportunities for Future Research* (Washington, D.C.: HNP Discussion Paper, World Bank, 2005) 29.

¹⁰⁸⁸ *ibid.* 33.

¹⁰⁸⁹ Cottier, *et al* (n 66) 453.

¹⁰⁹⁰ *ibid.* 453. See Kaplan and Laing (n 1087) 7, observing that domestic supply has been met without heavy local investment.

much of it emanating from the World Bank, that deals with barriers to business and industrial concerns in developing countries.¹⁰⁹¹

Most of the barriers are well-known, particularly in the context of Africa.¹⁰⁹² The Brazilian experience of providing universal access to HIV/AIDS treatment demonstrates that it is not, in all cases, economically feasible for a developing country like Ghana with a relatively small market size to embark on local manufacture.¹⁰⁹³ For Ghana and other WTO Members, technical expertise, raw materials, quality standards, and production and laboratory equipment need to be imported, with the result that foreign exchange savings may be small or non-existent.¹⁰⁹⁴

Arguably, the larger transitional and developing countries may be able to concentrate on producing, assured quality, low cost generics as a matter of health policy.¹⁰⁹⁵ Clearly, local pharmaceutical companies in Ghana cannot compete if they produce ineffective or poor quality medicines.¹⁰⁹⁶ The World Bank has suggested that local pharmaceutical manufacturing should only be encouraged in countries that have inadequate capacity to embark on efficient manufacturing.¹⁰⁹⁷

Although governments can play an important role in strengthening local production capacity, in terms of state-controlled local production, the WHO considers this to be ill-informed,¹⁰⁹⁸ as it may have no impact whatsoever on patient access to much needed medicines.¹⁰⁹⁹ The profit

¹⁰⁹¹ Sara Bennett, Jonathan Quick and German Velasquez, *Public Private Roles in the Pharmaceutical Sector*, World Health Organisation (Geneva: WHO Action Programme on Essential Drugs, WHO DAP 97.12: DAP Series No. 5, 1997).

¹⁰⁹² Kaplan and Laing (n 1087) 12, citing a shortage of skilled labour; a weak financial sector (banking/non-banking); diminished flows of foreign direct investment; the fact that smaller firms face more problems than larger firms with financing, taxes and regulation, inflation, corruption and street crime; economies of scale; legal and regulatory systems and enforcement.

¹⁰⁹³ Dirceu Greco and Mariangela Simao, 'Brazilian Policy of Universal Access to AIDS Treatment: Sustainability Challenges and Perspectives' (2007) 21 *AIDS*, suppl. 4, 41, finding that in middle-income countries such as Brazil there were specific challenges to maintaining universal access to treatment policy, especially considering the need to move to more complex ART, which required investment to be made in both public and private Brazilian laboratories to increase local production at fair prices not only of the finished drugs but particularly of the active principal ingredients.

¹⁰⁹⁴ Cottier, *et al* (n 66) 458.

¹⁰⁹⁵ Kaplan and Laing (n 1087) 25.

¹⁰⁹⁶ *ibid.* 30.

¹⁰⁹⁷ Andreas Seiter, *Pharmaceuticals: Local Manufacturing*, Joy de Beyer (ed.), (Washington D.C., World Bank, HNP Brief #3, March 2005) 2.

¹⁰⁹⁸ Bennett, *et al* (n 1091) iv, observing that the government's role is often best fulfilled by creating a stable economic and political environment, an efficient regulatory environment and favourable tax and duty structures.

¹⁰⁹⁹ Kaplan and Laing (n 1087) 33

margins on bulk generic medicines are low, so public production must be as efficient as private manufacturing if losses are to be avoided.

As a general matter, it will be difficult for the local Ghanaian producers to compete with foreign suppliers operating large-scale efficient production facilities because the capital costs, including the cost of borrowing are very high in the African region.¹¹⁰⁰ Therefore, local production may often not be reliable in Ghana and other WTO Members and, even if it is reliable, it does not necessarily mean that medicine prices are reduced for the end user.¹¹⁰¹

Moreover, the Ghanaian government may be limited in terms of the extent to which it can purchase from local producers because of higher prices in the case where a Section 84 model is implemented.¹¹⁰² That is, if Ghana to efficiently adopt the Section 84 model to promote affordable medicines, the result may be less access to medicines, since production facilities in the country may mean forgoing economies of scale.¹¹⁰³ Consequently, it has been suggested by African stakeholders that locally producing medicines already in abundance is not the way forward because it makes little economic sense.¹¹⁰⁴

On this premise, if Ghana does not have the infrastructure required to manufacture patented medicines locally, then the implementation of a Section 84 model may be futile, as the country will not be able to supply its market through domestic production and will have to import medicines anyway.¹¹⁰⁵ Notably, Ghana has a comparatively strong pharmaceutical industry within the sub-region.¹¹⁰⁶

Ghana hosts many generic manufacturers.¹¹⁰⁷ Most of the local manufacturing companies are certified with Good Manufacturing Practice.¹¹⁰⁸ Nevertheless, since the implementation of a Section 84 model in Ghana is expected to benefit the public, such requirements are not

¹¹⁰⁰ Frederick Abbott, *Trends in Local Production of Medicines and Related Technology Transfer* (Paris: Prepared for the WHO Department of Public Health, Innovation and Intellectual Property, 2011) 22, citing the difficulties in meeting price competition of products from India and China.

¹¹⁰¹ *id.*

¹¹⁰² *ibid.* 23.

¹¹⁰³ Kaplan and Laing (n 1087) 34.

¹¹⁰⁴ Abbott (n 1100) 22.

¹¹⁰⁵ Kaplan and Laing (n 1087) 10.

¹¹⁰⁶ Samuel Yaw Akomea, Olav Jull Sorensen, Kweku Amponsah-Efah, 'Export Drivers and Barriers: Evidence from Ghanaian Pharmaceutical Manufacturing Firms' (2014) 8 *Global Journal of Business Research* 2, 84.

¹¹⁰⁷ Harper and Gyansa-Lutterodt (n 127) 42.

¹¹⁰⁸ "Ghana Pharmaceutical Country Profile" (n 99) 12.

measured solely in terms of domestic manufacture;¹¹⁰⁹ they should theoretically factor in the channels for supplying medicines to the needy people.¹¹¹⁰

6.8.1. Building Capacity for Local Pharmaceutical Manufacturing in Ghana

Although, Ghana has effective distribution channels to deliver medicines to the needy people,¹¹¹¹ a major symptom of the constraints that the Ghanaian local industry is facing is the significant underutilisation of manufacturing capacity, often by more than 50 per cent.¹¹¹² This is due to the smallness of the market size, which means that the country is not able to absorb its pharmaceutical production capacity.¹¹¹³ This can lead to high operating costs where local companies are unable to generate economies of scale, compared with a large-scale Indian manufacturer.¹¹¹⁴

Theoretically, Ghana could mitigate the issue of its small market size by deciding to work with its neighbours in the sub-region to enhance economies of scale to generate more incentive for the local manufacture of essential medicines. Another option available to Ghana is the use of south-south initiative to promote collaboration, such as foreign directive investment-driven joint ventures as exemplified by the investment made in Uganda by CIPLA.¹¹¹⁵ The viability of such initiative could be provided by advanced market commitments by the Ghanaian government, as well as the promise of a market across the West African sub-region.¹¹¹⁶

Paragraph 6 of the Doha Implementation Decision in 2003 would help alleviate the problems associated with economies of scale resulting from the small size of the market.¹¹¹⁷ As already

¹¹⁰⁹ Taubman (n 59) 104.

¹¹¹⁰ Katharina Gamharter, *Access to Affordable Medicines: Developing Responses under the TRIPS Agreement and EC Law* (Vienna: Springer 2004) 27-28.

¹¹¹¹ Seiter and Gyansa-Lutterodt (n 91) 11, finding that the private sector is dominant in the supply chain for pharmaceuticals in Ghana. *ibid.* 13, stating that drugs are distributed through a public-sector system and several private sector channels. *ibid.* 16, observing that the Christian Health Association of Ghana runs a network of 144 hospitals and health centres, predominantly located in rural areas and serving an estimated 35-40 per cent of the Ghanaian population.

¹¹¹² Harper and Gyansa-Lutterodt (n 127) 3.

¹¹¹³ *ibid.* 42.

¹¹¹⁴ Warren Kaplan, *Local Production and Access to Medicines in Low- and Middle-Income Countries: A Literature Review and Critical Analysis* (France: WHO Department of Public Health, Innovation and Intellectual Property, World Health Organisation, 2011) 8.

¹¹¹⁵ Obijiofor Aginam, 'Global Health Governance, Intellectual Property and Access to Essential Medicines: Opportunities and Impediments for South-South Cooperation' (2010) 4 *Global Health Governance* 1, 6.

¹¹¹⁶ *ibid.* 7, stating that Ghana and some other African countries have started exploring the feasibility of local production of generic ARV drugs along the lines of the Uganda-Cipla venture.

¹¹¹⁷ "Implementation of Paragraph 6 of the Doha Declaration" (n 47).

stated, in as much as the measures conform to the provisions of Article XXIV of the GATT 1947, as subsequently adopted by the WTO in 1994,¹¹¹⁸ the measures waive certain obligations in order to enable the Members to harness economies of scale for the purpose of enhancing purchasing power for, and facilitating the local production of pharmaceutical products.¹¹¹⁹ This therefore means that local manufacturers in Ghana may have to look beyond the national borders in order to sell their products.¹¹²⁰

Importantly, given that the lack of affordable medicines is a shared concern in the sub-region and an area that deserves cooperation, a regional approach would enable similarly situated countries to address their constraints jointly by drawing on each other's expertise and experience and by pooling and sharing resources and information.¹¹²¹ From an economic and public health standpoint, a regional approach could provide incentives for establishing or developing regional pharmaceutical production and help to expand research capabilities.¹¹²²

In addition, higher effective demand for the same medicines due to climatic conditions and other geographical reasons will result in lower consumer prices for medicines due to increased economies of scale in procurement and distribution.¹¹²³ Other important benefits include: the lowering or offsetting of the costs associated with adapting medicines to the region due to increased economies of scale; stronger local technological capacities or domestic innovation resulting from the pooling of adequate resources including financing; and the stimulation of human and physical capital.¹¹²⁴

Where there exist insufficient institutional and human resources, Ghana could always mitigate this by reaching out to international organisations that continue to provide technical assistance

¹¹¹⁸ The GATT 1994 (n 817).

¹¹¹⁹ "Implementation of Paragraph 6 of the Doha Declaration" (n 47).

¹¹²⁰ Harper and Gyansa-Lutterodt (n 127) 42.

¹¹²¹ Sisule Musungu, Susan Villanueva and Roxana Blasetti, 'Utilising TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks' (Geneva: South Centre, 2004) xiv.

¹¹²² *ibid.* 37. Note that there is already the West African Health Organisation (WAHO) formed in 1987 by a protocol of the Economic Community of West African States (ECOWAS) to pool resources and cooperate with one another and with others for a collective and strategic combat against the health problems of the region. See West African Health Organisation was created by Protocol A/P2/7/87, Jul. 9, 1987. See also ECOWAS Regional Pharmaceutical Plan (WAHO Essential Medicines and Vaccines programme, WAHO Technical Document No. WAHO/TD/RPP/WA/2014.03, 2014) 5. The WAHO continues to mobilise partnerships, financial and technical support to countries in the sub-region. See Jude Aidam and Issiaka Sombie, 'The West African Health Organization's Experience in Improving the Health Research Environment in the ECOWAS Region' (2016) 14 *Health Research Policy and Systems* 30, 11.

¹¹²³ Musungu, Villanueva and Blasetti (n 1121) 37.

¹¹²⁴ *id.*

to developing countries,¹¹²⁵ for example, WIPO,¹¹²⁶ UNCTAD and ICTSD.¹¹²⁷ Support for the local production of pharmaceuticals has been the subject of intense discussion in international and regional forums since the 1970s.¹¹²⁸ The past two decades have seen a stronger emphasis on the issues of local production, technology transfer and access to medicines.¹¹²⁹ The WTO has also cooperated with other intergovernmental organisations such as the UNCTAD and the UNDP, which provide technical advice to countries on local pharmaceutical production and related technology transfer.¹¹³⁰

Importantly, in 2016, the UN Human Rights Council adopted a Resolution on enhancing capacity-building in public health.¹¹³¹ The Resolution urges the international community to increase investment, by building on existing mechanisms and through partnership, to improve health systems in developing countries with the aim of providing sufficient infrastructures, management systems and supplies to meet the targets specified in SDGs Goal 3 by 2030.¹¹³² The Council was convinced that capacity-building is critical in enhancing public health systems in developing countries and called upon the international community to continue to promote cooperation in regard to strengthening the capacity of developing countries, including through financial and technical support and the training of personnel, in particular, to obtain essential medicines that are affordable, safe, efficacious and of high quality.¹¹³³

¹¹²⁵ For example, the South Centre, the ICTSD, the Quaker United Nations Office (QUNO), the International Development Research Centre (IDRC), Oxfam and Médecins sans Frontières have active policy research and dialogue programmes related to IP and linkages to sustainable development issues.

¹¹²⁶ Patent-Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels (Geneva, Fifth Session of the Committee on Development and Intellectual Property, CDIP/5/4 Rev. Aug. 18, 2010).

¹¹²⁷ UNCTAD and ICTSD Programme on Capacity Building for Developing Countries. Available at: <http://unctad.org/en/Pages/DIAE/Intellectual%20Property/IPRs-and-Sustainable-Development.aspx> [Accessed Oct. 17, 2017].

¹¹²⁸ The subject of local production appeared in WHO as part of the ‘Report of the International Conference on Primary Health Care and in Resolution WHA 31.32’ (World Health Organisation, 1978) paras. 74 & 93.

¹¹²⁹ Pharmaceutical Production and Related Technology Transfer: Landscape Report (World Health Organisation, 2011) 13, observing that the local production of drugs in developing countries has long been seen as a potential way to increase access to medicines and improve public health.

¹¹³⁰ *ibid.* 35.

¹¹³¹ ‘Promoting the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health through Enhancing Capacity-Building in Public Health (Human Rights Council, thirty-second session, Agenda item 3, A/HRC/32/L.24/Rev.1, Jun. 30, 2016).

¹¹³² *ibid.* para. 1.

¹¹³³ *ibid.* para. 3.

In addition, the lengthy intergovernmental negotiations that led to the adoption of the WHO Resolution WHA 61.21 on a GSPA-PHI¹¹³⁴ underscored the important institutional role of the WHO in securing a place for local production and technology transfer on the international agenda.¹¹³⁵ The GSPA-PHI outlines a new focus on local production as a means of contributing to the overall goals of promoting innovation, building capacity and improving access.¹¹³⁶

Against this backdrop, the EU has supported local production and relevant technology transfer through its initiative Aid for Poverty-Related Diseases (HIV/AIDS, Tuberculosis and Malaria).¹¹³⁷ The EU conceptualised and launched this initiative with the underlying premise of delving deep into the highly complex interface of technology transfer and local production in developing countries like Ghana with a view to supporting such local production and the related transfer of technology to improve access to medicines.¹¹³⁸

Thus, having regard for its report on an EU Regulation on Aid for Poverty Diseases (HIV/AIDS, Malaria and Tuberculosis) in developing countries, it recognised an appropriate structural response, which is both comprehensive and coherent and beyond the financial and human resources of most developing countries,¹¹³⁹ and called for US\$ 7-10 billion per year to fight these diseases.¹¹⁴⁰ With this, the EU intends to provide, where appropriate, technical assistance to developing countries to help them address public health issues in accordance with the provisions of TRIPS, as clarified in the Doha Declaration, so as to enable them to protect public health and promote access to medicines for all.¹¹⁴¹

Importantly, the EU has given an indication that it is looking into ways of improving its support for developing countries implementing the TRIPS Agreement — including its flexibilities in

¹¹³⁴ WHA Resolution WHA62.16. Report of the Commission on Intellectual Property Rights, Innovation and Public Health (Eighth plenary meeting, agenda item 12.8., A62/VR/8, May 22, 2009) Annexes.

¹¹³⁵ “Pharmaceutical Production and Related Technology Transfer” (n 1129) 35.

¹¹³⁶ “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property” (n 725). Element 3, on building and improving innovative capacity, highlights key areas for investment including capacities related to science and technology, local production of pharmaceuticals. Element 4, on transfer of technology, emphasises north–south and south–south development cooperation, partnerships and networks to build and improve transfer of technology related to health innovation.

¹¹³⁷ Committee on Development and Cooperation on the Proposal for a European Parliament and Council Regulation on Aid for Poverty Diseases (HIV/AIDS, Malaria and Tuberculosis) in developing countries (Rapporteur: Anders Wijkman, COM(2002) 109 – C5-0100/2002 – 2002/0051(COD)) A5-0394/2002, Nov. 13, 2002).

¹¹³⁸ *id.*

¹¹³⁹ *ibid.* Recital 6.

¹¹⁴⁰ *Ibid.* Recital 5.

¹¹⁴¹ *ibid.* Amendment 26, Article 3(f).

appropriate cases, such as health emergencies.¹¹⁴² Under Amendment 20, Article 3, community financial support shall be given to specific projects designed to further the objective of increasing the affordability of key pharmaceuticals.¹¹⁴³

In this direction, the EU committed itself to providing the necessary technical, scientific and normative input in order to prioritise health interventions within the total development co-operation budget and improve health outcomes related to these three major communicable diseases.¹¹⁴⁴ Importantly, this commitment extends to improving pharmaceutical policies and practice, and helping developing countries, at the regional or national levels, to develop quality local production of key preventive and therapeutic pharmaceuticals consistent with the Doha Declaration.¹¹⁴⁵

In so doing, the EU stated that it will initiate a programme of action towards the transfer of technology and know-how, where possible, for the purpose of local pharmaceutical production.¹¹⁴⁶ Importantly, in 2005, UNCTAD's Commission on Investment, Technology and Related Financial Issues recommended that 'UNCTAD should ... assess ways in which developing countries can develop their domestic productive capability in the supply of essential medicines in cooperation with pharmaceutical companies'.¹¹⁴⁷

UNCTAD continues to develop a "Stakeholders' Reference Guide to IP and Related Policies", which is intended to provide concise and practical information on ways in which to promote local pharmaceutical production and improve access to medicines through a variety of policy tools, focusing on the flexibilities provided under TRIPS, and the interfaces between IP, trade and investment, medicines regulation and procurement strategies.¹¹⁴⁸

¹¹⁴² Trade, Growth and Intellectual Property - Strategy for the Protection and Enforcement of Intellectual Property Rights in Third Countries ({SWD(2014) 204 final} 1.7.2014 COM(2014) 389) 9, para. 2.2.7.

¹¹⁴³ *ibid.* Amendment 19, Article 2(b).

¹¹⁴⁴ *ibid.* Amendment 21, Article 3(a).

¹¹⁴⁵ *ibid.* Amendment 24, Article 3(c).

¹¹⁴⁶ *ibid.* Amendment 32, Article 4(1), point (da).

¹¹⁴⁷ Agreed Recommendations (Ninth Session of the Trade and Development Board Commission on Investment, Technology and Related Financial Issues, Agenda items 3, 4, 5 and 9, United Nations Conference on Trade and Development, TD/B/COM.2/L.22, 2005), para. 9(c).

¹¹⁴⁸ 'Building Local Pharmaceutical Production/Supply Capacity' (United Nations Conference on Trade and Development, 2002). <<http://unctad.org/en/Pages/DIAE/Intellectual%20Property/Building-local-pharmaceutical-production--supply-capacity.aspx>> [Accessed Apr. 5, 2017].

UNDP is also undertaking analytical work on local production with an emphasis on south–south cooperation, including a completed study on Brazil (“Technical, economic and legal assessment of the Brazilian antiretroviral production capacity”, produced jointly with the Ministry of Health/National AIDS Programme and UNAIDS Brazil),¹¹⁴⁹ and a study on the Indian pharmaceutical industry and the impact of recently adopted laws.¹¹⁵⁰ Overall, many different types of organisations have played a facilitating role in the various local production and technology transfer initiatives.

In 2016, a UH Human Rights Council Resolution recognised the fundamental importance of the transfer of sound technologies to developing countries on favourable terms, including concessional and preferential terms, as mutually agreed.¹¹⁵¹ This was driven by several NGOs. They are involved in technology transfer, training and funding to support local production, conducting research, advocacy and analysis, giving policy advice and facilitating networking. Active NGOs include Oxfam, Medecins Sans Frontieres, Medeor, Cordaid, ICTSD, InWent, OTECI, MSF and Technoserve.¹¹⁵² Evidence within the WTO system suggests that Ghana has benefitted from capacity building initiatives using Article 67 of TRIPS.¹¹⁵³

6.9. Conclusion

This chapter has examined whether the implementation of Section 84 in Ghana would threaten the attainment of socio-economic objectives due to the loss of inward FDI opportunities, retaliatory action and their potential frustration owing to the impact of FTAs. Significantly, contrary to the common perception that a country like Ghana may potentially face significant socio-economic drawbacks in relation to inward FDI opportunities if it were to implement a Section 84 model, this chapter has argued that in the context of Ghana this would not be an expected outcome.

¹¹⁴⁹ Francisco Rossi, Technical, Economic and Legal Evaluation of Antiretroviral Production Capacity in Brazil (The Bureau for Development Policy, United Nations Conference on Trade and Development, 2008).

¹¹⁵⁰ Sudip Chaudhuri, Chan Park and Kunnathully Madhavan Gopakumar, The Indian Pharmaceutical Industry After TRIPS. In: FIVE YEARS INTO THE PRODUCT PATENT REGIME: INDIA’S RESPONSE, Kajal Bharadwaj (ed.), (United Nations Development Programme, 2011)

¹¹⁵¹ Promoting the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health through Enhancing Capacity-Building in Public Health (Human Rights Council, Thirty-second session, Agenda item 3, A/HRC/32/L.24/Rev.1, Jun. 30, 2016).

¹¹⁵² “Pharmaceutical Production and Related Technology Transfer” (n 1129) 39.

¹¹⁵³ Technical Cooperation Activities: Information from Members of the European Communities – Addendum (Report on the Implementation of Article 67 of the TRIPS Agreement, Council for TRIPS. IP/C/W/539/Add.7, Feb. 24, 2010) 17.

It has been shown that the fear that the implementation of Section 84 could lead to a withdrawal of investments is a general claim that would not be applicable to Ghana because, where almost all of the FDIs go to the oil and gas sector, it cannot be true that the implementation of Section 84 would threaten inward FDI opportunities and the attainment of socio-economic objectives. Notably, treating IP as an investment matter, and subjecting it to treaty arbitration, can have undesirable impact on the hard-bargained flexibilities in IP laws and on public health safeguards as suggested by Yu.¹¹⁵⁴ However, it is unlikely Ghana would sign a trade and investment agreement with the EU or the US that includes a restrictive provision that tends to treat IP as an investment made by investor corporations, allowing private investment disputes to be raised against the Ghana whenever there is a threat to their IP.

Moreover, it has been argued that there are inadequate linkages between robust IP rights protection and inward FDI opportunities; therefore, Ghana would be able to implement a Section 84 model and still attain its socio-economic objectives. This argument is premised on the fact that there is not a single mainstream pharmaceutical company that has a manufacturing or research facility in the country and the implementation of Section 84 could possibly encourage the generic pharmaceutical industry in the local market. Furthermore, it has been shown that the FDI retributive effect is not a possibility. Ghana could mitigate any potential threat of withdrawal of investment if it was prepared to work with its neighbours to build resilience,¹¹⁵⁵ and where this is the case no reasonable investor would want to withdraw its investments from the entire sub-region.

Accordingly, it is worth noting that relying on such a misleading account produces only negative results given the difference in market size argument in different countries. Policymakers need to understand why FDI does flow to Ghana, because this will help them to formulate and execute policies to attract the right investments.¹¹⁵⁶ Importantly, the chapter considered the potential threat of legal challenges by the pharmaceutical industry and the

¹¹⁵⁴ Yu (n 803) 392–400, examining the growing use of bilateral and regional trade agreements to push for higher intellectual property standards. See also Yu (n 217) discussing Articles 7 and 8 of TRIPS, 869-879, examining Article 31*bis* and the Doha Declaration. Yu (n 830) 835.

¹¹⁵⁵ Drahos (n 832) 19.

¹¹⁵⁶ Economic Development in Africa: Rethinking the Role of Foreign Direct Investment (Geneva, New York: UNCTAD, UNCTAD/GDS/AFRICA/2005/1, 2005) 2, suggesting that FDI carries costs consequently, policymakers must fully evaluate the impact of FDI if it is to become a complementary component of a wider package of development measures needed to raise growth and diversify into more dynamic activities.

possibility of high litigation costs being incurred. However, it has been shown that it is highly unlikely that the pharmaceutical industry would challenge the legality of the implementation of Section 84 to promote affordable medicines in the light of the Doha Solution.¹¹⁵⁷

Additionally, this chapter has assessed potential retaliatory action owing to impacts of FTAs if Ghana were to implement Section 84 as India has done. Nevertheless, it has been revealed that no FTA provision would operate directly to prevent Ghana from implementing a Section 84 model and that it is free to do so. Lastly, the analysis has confirmed that following the Doha Solution, it is unlikely that developed countries, particularly the US and the EU, would adopt any aggressive response such as economic sanctions or bilateral pressure in response to the implementation of Section 84.¹¹⁵⁸ Hence, if Ghana could mitigate its domestic capacity issues pertaining to local manufacture for distribution, the country could implement a Section 84 model. The next chapter draws all of the other chapters together in an attempt to affirm the hypothesis regarding the consistency of Section 84 with TRIPS and its adoption by Ghana.

¹¹⁵⁷ Drahos (n 832) 19, stating that the Doha Declaration isolated the pharmaceutical industry. Odell and Sell (n 1086) 98, stating that the pharmaceutical industry will be cautious given the public relations disaster of the litigation by pharmaceutical multinationals against South Africa.

¹¹⁵⁸ *id.*, stating that the Doha Declaration isolated the US.

Chapter 7

Reaffirming the Hypothesis: Consistency of Section 84 with TRIPS and its Adoption by Ghana

7.1. Aim of the Chapter

This chapter draws all of the other chapters together in an attempt to affirm the hypothesis, regarding the consistency of Section 84 with TRIPS and its adoption by Ghana. Moreover, the chapter reasserts the international community's support for Ghana in regard to implementing the section 84 model to promote affordable medicines.

7.2. Introduction to the Chapter

As can be seen from the preceding discussion, Section 84, which allows the granting of a compulsory licence provided that the patented invention had not been worked in the territory of India, is consistent with TRIPS. Notwithstanding this, the substantive part of Article 27(1) of TRIPS, which specifically requires that Members' treatment of patented inventions should be on a non-discriminatory basis irrespective of whether they are produced locally or imported, is often relied upon as the basis of a conflicting interpretation.¹¹⁵⁹

Needless to say, this has resulted in various misinterpretations that have tended to completely eliminate any reference to the local working of a patent as an independent condition for the granting of compulsory licensing, and in its place, the argument has been made that importation alone can satisfy the obligation to manufacture a patented invention locally.¹¹⁶⁰ This interpretation would seek to make Section 84 contrary to the obligation enumerated under Article 27(1) of TRIPS.¹¹⁶¹

Not only that, it would also seek to undermine the substantive provision of Article 5(A)(4) of the Paris Convention, which has the same legal construction as Section 84 and in part stipulates that a compulsory licence may not be applied for on the grounds of failure to work or

¹¹⁵⁹ Bonadio (n 53) 720.

¹¹⁶⁰ Kur and Levin (n 459) 584.

¹¹⁶¹ Bonadio (n 53) 720, stating the ruling might be a violation of Article 27(1) of TRIPS, which precludes India, as a Party to the Agreement, from discriminating between patented products that are imported and those that are locally produced.

insufficient working before the expiration of a period of four years from the date of the filing of the patent application or three years from the date of the granting of the patent, whichever period expires last.

In short, the same approach would seek to weaken Article 5(A)(2) of the Paris Convention, which provides that Ghana and each WTO Member shall have the right to take legislative measures; providing for the granting of compulsory licences to prevent an abuse of exclusive patent rights exemplified by failure to work a patented invention locally. Nevertheless, as far as Section 84(1)(c) is concerned, which purposely allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, Article 2(2) of TRIPS remains vital, as the Agreement seeks to impose Article 5(A) of the Paris Convention provisions on the TRIPS rules relating to patents by specifically requiring that Members shall not derogate from existing obligations that they may have to each other under the Paris Convention.

This interpretation gains strength through its confirmation by the Doha Declaration, that TRIPS preserves Ghana and other WTO Members' discretion to grant compulsory licences on any grounds, including for pharmaceutical products in as much as their national legislations permit subject to certain procedural requirements and substantive conditions only under Article 31 of TRIPS. Hence Ghana, and other developing countries, might adopt the Section 84 model provided that they have the technical capacity for local manufacturing, there are no major conflicting provisions in FTAs, and like India, they are prepared to withstand bilateral pressure and bear litigation costs in respect of the pharmaceutical companies.

7.3. Reaffirming the Hypothesis of the Thesis

Throughout this work, attempts have been made to reconcile Section 84 with the TRIPS Agreement, as a suitable model for Ghana to promote affordable medicines. Consequently, after drawing on applicable sources of law, the preparatory work of the TRIPS Agreement and the history behind patent law, and then analysing the issue in strict adherence to the principles of treaty interpretation, which also guide the interpretation of WTO law, it has been shown that any conflicting claim regarding the inconsistency of Section 84, which specifically allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is generally not based on a well-founded interpretation.

This is because such an interpretation ignores the entire TRIPS Agreement and rather takes a narrow view of one clause (Article 27(1) of TRIPS) without regard to the text or document as a whole or its context, object and purpose.¹¹⁶² As emerged above, the principle of treaty interpretation, as set out in the VCLT¹¹⁶³ which has been consistently applied by the WTO/DSU Panel and Appellate Body reports as the most fundamental in seeking to clarify the provisions of the WTO Agreement in yielding an interpretation that is harmonious and coherent and fits comfortably in the treaty as a whole so as to render the treaty provision legally effective.¹¹⁶⁴

This principle gives the broadest possible understanding that where two treaties (Paris Convention and TRIPS) treat a common subject-matter (patents) their provisions may point in different directions, and if they do, it is the task of legal reasoning to establish meaningful relationships between them so as to determine whether they can be applied in a mutually supportive way or whether one rule or principle should have priority over the other.¹¹⁶⁵ As reasoned by the International Law Commission, and also adopted by the WTO Appellate Body as a principle of treaty interpretation: ‘When a treaty is open to two interpretations one of which does and the other does not enable the treaty to have appropriate effects, good faith and the objects and purposes of the treaty demand that the former interpretation should be adopted’.¹¹⁶⁶

It is significant that pursuant to WTO law, Section 84 provision ordinarily arises with regard to the construction of an earlier-enacted specific provision (Article 5(A) of the Paris Convention) when a more general provision was later passed (Article 27(1) of TRIPS). This assumption is founded on the premise that the TRIPS Agreement incorporates the substantive provision of Article 5(A) of the Paris Convention, which allows Ghana and other WTO Members’ discretion with regard to the granting of compulsory licences to remedy failure to work before the expiration of a period of four years from the date of the filing of the patent application or three years from the date of the granting of the patent, whichever period expires last, via Article 2 of TRIPS, and this cannot be read down.

¹¹⁶² *id.*

¹¹⁶³ “The VCLT” (n 119).

¹¹⁶⁴ “United States - Continued Existence and Application of Zeroing Methodology” (n 239) para. 268. “United States - Standards for Reformulated and Conventional Gasoline” (n 244) p. 17.

¹¹⁶⁵ *id.*

¹¹⁶⁶ “International Law Commission” (n 529) 219. “Japan—Taxes on Alcoholic Beverages” (n 246) 11, footnote 21.

Therefore, Section 84, which allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is consistent with Article 5(A) of the Paris Convention, and thus, with TRIPS. This contention lends support to the view that local working and importation were never mutually exclusive. Moreover, this reinforces the belief that TRIPS would not prevent Ghana and other WTO Members from granting compulsory licences if a patented invention is not manufactured or the process is not used within the territory of protection.

Consequently, the argument provided in this work contradicts the conflicting interpretation concerning the inconsistency of compulsory licensing with TRIPS pursuant to the general obligation under Article 27(1), which requires that WTO Members do not discriminate irrespective of whether patents are produced locally or imported. As a matter of fact, and in the context of Ghana, discrimination may exist where all patentees who import their technologies are sanctioned without justification. However, there is no discrimination within the terms of Article 27(1) where Ghana justifies differential treatment given that a relevant part of Article 5(A) of the Paris Convention allows patentees to justify their inaction with regard to failure to work a patented invention locally by giving legitimate reasons.¹¹⁶⁷

Simply stated, while the local working of a patented product would satisfy the substantive requirements under Section 84, taking a patent and resorting completely to overseas manufacture would violate the general principles applicable to the working of patented inventions in the territory of India. Thus, failure to comply with this statutory obligation may attract the imposition of a compulsory licence, and this is only subject to the overriding condition - before the expiration of a period of four years from the date of the filing of the patent application or three years from the date of the granting of the patent, whichever period expires last and without any legitimate reasons as referenced by Section 86(1), which is consistent with Article 5(A)(4) of the Paris Convention provision.

Additionally, the analysis in this work has helped to provide an understanding that the legal obligation to make patents available and patent rights enjoyable without discrimination as to whether products are imported or locally produced set out in Articles 27(1) of TRIPS is a

¹¹⁶⁷ Article 5(A)(4).

general provision subject to compulsory licensing permissible under Article 31 of TRIPS because the notion of failure to work as defined by Article 5(A) of the Paris Convention pertains to failure on the part of patentees to engage in the local manufacture of a patented invention, and this is the specific rule. Therefore, discrimination between imported or locally manufactured products in Article 27(1) of TRIPS is unaffected when the patented invention is not worked locally in accordance with domestic statutory requirements such as Section 84.

In other words, there is no discrimination where the wording of a legislated local working requirement captures the general principles applicable to the working of patented inventions locally in the territory of protection. Taking the view of the Panel in *Canada - Patent Products* case, it is concluded that such a local working requirement can be considered justified differential treatment and there is no discrimination where differentiations are justified, i.e. where there are bona fide reasons for differentiating. Hence, Article 27(1) of TRIPS would not prohibit Ghana from adopting and implementing any local working requirements that followed the Indian model in Section 84, in as much as all of the conditions and the procedural requirements under Article 31 of TRIPS are satisfied.

The evidence deduced so far in this analysis shows that compulsory licensing due to failure to work has been applied in the past by several Members of the WTO to keep the use of a patent within the limits set by the original granting country.¹¹⁶⁸ The Uruguay Round accounts also reveal that during the negotiations of the TRIPS Agreement several developing countries defended the right to impose working requirements.¹¹⁶⁹ The negotiating history of the TRIPS Agreement does not support the assumption that those Members withdrew their position on

¹¹⁶⁸ Ulf Anderfelt, *International Patent Legislation and Developing Countries* (The Hague: Martinus Nijhoff, 1971) 65-66. See Halewood (n 18) 251-252.

¹¹⁶⁹ Negotiation Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Meeting of Negotiation Group of 2, Apr. 4 and 5, 1990 (Note by the Secretariat, MTN.GNG/NG11/20 (Apr. 24, 1990) para. 34. Negotiation Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property (Note Prepared by the International Bureau of WIPO, MTN.GNG/11/W/24 (May 5, 1988) para. 2. Negotiation Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Meeting of Negotiating Group of May, 11-12, 1989 (Note by the Secretariat, MTN.GNG/NG11/12 (Jun. 13, 1989) para. 5. Negotiation Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Meeting of Negotiating Group of Jul. 12-14, 1989 (Note by the Secretariat, MTN.GNG/NG11/14 (Sept. 12, 1989) paras. 75 & 83. Negotiation Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Meeting of Negotiating Group of Oct. 30 – Nov. 2, 1998 (Note by the Secretariat, MTN.GNG/NG11/17 (Dec. 4, 1989) para. 24. Negotiation Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Meeting of Negotiating Group of 11, Dec. 12 and 14, 1989 (Note by the Secretariat, MTN.GNG/NG11/17 (Jan. 23, 1990) para. 41.

local working, as nothing indicated that the parties were entertaining the complete prohibition of local working requirements when they accepted the ambiguous text adopted by Article 27(1) of TRIPS.¹¹⁷⁰

In hindsight, if it really were the WTO Members intention after a lengthy debate to reject local working requirements, one would at least expect to find that remarkable consensus echoed in clear, unambiguous treaty language, such as the US submitted.¹¹⁷¹ But such is not the case. Subsequently, national laws of several WTO Members have adopted and continue to maintain local working obligations,¹¹⁷² and this reinforces the legal position that Section 84 is entirely consistent with TRIPS and remains a suitable model for the country to promote affordable medicines. Thus, pursuant to Section 84 and Article 5(A) of the Paris Convention, the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India would not constitute unjustified detriment or discrimination in the context of Article 27(1) of TRIPS.

This confirms the common proposition that, at least insofar as local working or manufacturing goes, Article 5(A) together with Article 31 of TRIPS take precedence over, and derogate from, Article 27(1) of TRIPS because both are independent provisions dealing with different subject matters. This viewpoint suggests that the compulsory licensing regime under Article 5(A) of the Paris Convention is compatible with Article 31 of TRIPS in relation to Article 27(1) of TRIPS. The starting point with regard to envisioning the compatibility of Article 5(A) of the Paris Convention with Article 27(1) pursuant to Article 31 of TRIPS is to understand that Article 27(1) only imposes a general obligation on Ghana and other WTO Members to make patents available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

Importantly, this provision does not attempt to define the context in which Ghana and other WTO Members must give effect to such an obligation this is left for Members' legislations to

¹¹⁷⁰ Correa (n 518) 241-242.

¹¹⁷¹ Champ and Attaran (n 58) 370. Note that the US sought to bar any possible obligation or remedy there might be for a patentee's failure to work locally.

¹¹⁷² Correa (n 518) 241, footnote 69, citing Oxfam, 'Local Working Requirements and the TRIPS Agreement: Using Patent Law as a Means of Ensuring Affordable Access to Essential Medicines, a Case Study from the US-Brazil Dispute' (2001), finding working obligations in the patent laws and regulations of Indonesia and Cuba; Ghana, Ireland, South Africa, Sudan and Zimbabwe, Turkey, Spain, Portugal, Sweden, Norway, Finland, Iceland, India, Brazil, Israel, Thailand, Pakistan Liberia etc.

determine. In fact, there are limitations to compulsory licensing, which are not strictly legal but only procedural requirements in nature subject to some substantive conditions that must be met as expressed under Article 5(A)(4) of the Paris Convention and Article 31 of TRIPS, as opposed to Article 27(1) of TRIPS control. This means that Article 27(1) of TRIPS cannot be read subject to Article 31 of TRIPS because as per the latter, in as much as Ghana and other WTO Members national laws allow for “Other Use Without Authorization of the Right Holder”, which is implicit in the caption of the title of Article 31, TRIPS would not completely prohibit Ghana and other WTO Members from granting compulsory licences on any grounds or specifically due to failure to work a patented invention in satisfying the laws of the country or territory of protection.

However, the terms of Article 31 of TRIPS appear to be in general permissive and flexible, the substantive conditions and the difficult procedures are too complex and vague.¹¹⁷³ Although, the WTO Members in Doha, attempted to overcome the rigidity in Article 31 of TRIPS that rendered the use of compulsory licensing instrument essentially useless, the solution appears to have compounded the restrictions imposed by TRIPS.¹¹⁷⁴ The formal procedural requirements developed under the Doha Solution prior to issuing a compulsory licence are too complicated.¹¹⁷⁵ There is substantial inflexibility regarding the legal infrastructure, the financial and technical capacities, and the administrative processes as preconditions that Ghana and other WTO Members must satisfy.¹¹⁷⁶

The argument therefore is that, in view of the multiple conditions and the complex procedural requirements for the granting of compulsory licensing, such a complex and burdensome system is largely symbolic and is unlikely to lead to any significant outcome in terms of promoting access to affordable medicines in Ghana.¹¹⁷⁷ The conclusion is that Section 84, which is consistent with TRIPS, and allows the granting of a compulsory licence provided that the patented invention has not been worked, would provide a feasible option for Ghana to mitigate the unnecessarily complex and burdensome procedures that have been created.

¹¹⁷³ Anderson (n 40) 96. Zolotaryova (n 615) 1102. Halajian (n 625) 1191.

¹¹⁷⁴ Anderson (n 50) 173-174.

¹¹⁷⁵ Harris (n 85) 390.

¹¹⁷⁶ Abbott (614) 16.

¹¹⁷⁷ Sampson (n 785) 159.

More persuasively, the related Doha Declaration under Paragraph 5(b) confirms that Ghana and each WTO Member has the wider discretion to grant compulsory licences and the freedom to determine the grounds on which such licences are founded. Without limiting any grounds *per se*, it can be argued that lack of local working can be invoked as the basis for granting a compulsory licence where the law of Ghana permits, and this will be consistent with TRIPS. The Doha Declaration also provides a specific rule of interpretation, which gives context to the general interpretive provisions in the WTO law, which is supportive of Ghana's right to protect public health using the flexibilities built into TRIPS. Importantly, the realisation of medicines remains a fundamental element of the framework of TRIPS and a well-settled notion under the Doha Programme, which resulted in the subsequent amendment to Article 31(f) of TRIPS.

Moreover, the argument of this work is enhanced by the fact that the US failed to prove an allegation within the WTO under the DSU system against Brazil that its local working requirements remain inconsistent with Articles 27 and 28 of TRIPS. Without limiting the generality of the argument, although the settlement of the dispute between the US and Brazil may not be the utmost basis for claiming the legality of compulsory licensing under TRIPS, the argument is enhanced by the Bayer v Natco's case, in which the Controller invoked Section 84 in granting a compulsory licence to Natco, and to date the legitimacy of this decision remains unchallenged within the WTO under the DSU system.

This paucity adds weight to the interpretation that Section 84, which specifically allows the granting of a compulsory licence provided that the patented invention has not been worked in the territory of India, is consistent with TRIPS, and therefore it would provide a suitable model for Ghana. This is relevant as the provision of Section 84 follows Section 83, which enumerates the "General Principles Applicable to Working of Patented Inventions" in India. This directive principle of patent policy incorporates the philosophy of the patent framework under Indian law and remains the bedrock on which the compulsory licensing instrument is built. It explicitly requires that patents are granted to encourage invention and to ensure that inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay.¹¹⁷⁸

¹¹⁷⁸ Section 83(a) of the Indian Patents Act.

This substantive provision draws in part, from Article 7 of TRIPS, which aims to encourage invention and significantly mirrors Article 5(A) of the Paris Convention, requiring that patentees work their patented inventions locally. Moreover, Section 83(b) of the Indian Patent Act, which draws, in part, on Article 7 of TRIPS, provides that they (patents) are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. It further provides that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare, and to a balance of rights and obligations.¹¹⁷⁹

The above provision makes Section 84 usage consistent with TRIPS, and complementary where, pursuant to the interpretative weight of Article 7 of TRIPS, socio-economic welfare situations may be taken into account to reinforce the notion of local working of patents as a means to determine the extent to which patentees' transfer technology or disseminate the same. The obligation to transfer technology is consistent with the Preamble to the TRIPS Agreement and also remains a well-founded objective of the Agreement. In fact, the Preamble to the TRIPS Agreement recognises the inherent legal flexibility of Ghana and other WTO Members when it states that the Agreement recognises the underlying public policy objectives of national systems for the protection of IP, including developmental and technological objectives.

TRIPS put in place global minimum standards for IP legal regimes but left room for flexibility in how for example, the Ghanaian government decides to enact their laws so long as they meet the TRIPS minimum standards. Thus, a wide range of policy options exist, as built into TRIPS, at the domestic level with regard to how best to pursue public health objectives or implement such flexibilities so that the national IP regime responds to Ghana's individual needs and policy objectives. Moreover, as per Article 5(A)(2) of the Paris Convention, failure to work remains an abuse of the exercise of the exclusive rights conferred by the patent on which Ghana and other WTO Members have the right to take legislative measures – specifically, referencing a compulsory licensing instrument to prevent such abuse.

Thus, the fact that Article 8 of TRIPS also recognises the need to take appropriate measures consistent with the Agreement to prevent the abuse of patent rights by right holders, in order

¹¹⁷⁹ Section 83(c).

to maintain a proper balance between patent protection and public interest, *inter alia*, public health further enhances the value of the hypothesis. Importantly, in regard to matters of public health, Section 83(d) states that patents granted must not impede the protection of public health and nutrition and should act as instruments to promote the public interest, especially in sectors of vital importance for the socio-economic and technological development of India, and that patents granted should not in any way prohibit the Central Government in taking measures to protect public health.¹¹⁸⁰ This Section draws from Article 8(1) of TRIPS – its Principles.

Furthermore, Section 83(f), which also draws on Article 8(2) of TRIPS, the second part of the Principles, maintains that the patent right must not be abused by the patentee or person deriving title or interest on patent from the patentee, and that the patentee or a person deriving title or interest on patent from the patentee must not resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology. This latter part also draws on Article 40(1) of TRIPS. Significantly, the TRIPS Agreement does not specify what constitutes an abuse of patent rights exemplified as failure to work, nor does it provide a definition of the kind of appropriate measure deemed reasonable to which members can resort in order to remedy such an abuse.

Thus, the appropriate measure referred to in Article 8 of TRIPS constructively denotes compulsory licensing, which is consistent with TRIPS by virtue of Article 31. In this connection, Article 5(A)(3) of the Paris Convention mentions that forfeiture of a patent shall not be provided for except in cases where the granting of compulsory licences would not have been sufficient to prevent the said abuse. This means that the right of Ghana and other WTO Members to take legislative measures providing for the granting of compulsory licences to prevent the abuse of patent rights by the right holders is not restricted by TRIPS, as Article 8 envisages this allowance.

As shown in the analysis, essentially the compulsory licensing instrument is common in the patent regimes of WTO Members and has been used to remedy failure to work in the past. Consequently, this settles the established legislative understanding of the principle that underlies patent law, which implies that exclusive rights are granted to patentees to work their patented inventions locally, and therefore, this account validates Section 84 as consistent with

¹¹⁸⁰ Section 83(e).

TRIPS. Moreover, under Section 92, the Indian government can notify the need for the issue of a compulsory licence on the grounds of “circumstances of national emergency”, “circumstances of extreme urgency” and “in case of public non-commercial use”. These grounds are identical to those mentioned in Article 31(b) of TRIPS, which allows Ghana and other WTO Members to issue compulsory licences.

Section 92(3) clarifies that such circumstances can include public health crises, relating to HIV/AIDS, Tuberculosis, Malaria or other epidemics. This is consistent with Paragraph 5(c) of the Doha Declaration, which states that public health crises, including those related to HIV/AIDS, Tuberculosis, Malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. Under Section 92A, a compulsory licence shall be issued for the export of patented pharmaceutical products to a country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product in order to address public health problems. This provision is consistent with the Doha Paragraph 6 Programme, as implemented via the August 30 Decision of the TRIPS Council.

The usage of Section 84 in India demonstrates that as an instrument of government policy, if used, compulsory licensing can be an effective tool to provide access to essential medicines. Therefore, this reference is more supportive of the interpretation that nothing in the light of TRIPS would, in fact, preclude the possibility of Ghana that relies heavily on the importation of essential medicines from implementing a model similar to Section 84 as a practical means to mitigate the high costs and shortages resulting from the failure of patentees to work patented medicines locally. Specifically, the overriding implication of Section 84, and the *Bayer v Natco* decision, if followed, would enable Ghana to grant compulsory licences for any patent protecting a product solely because that product is not being manufactured locally.

More importantly, access to essential medicines has been affirmed as an indicator for the fulfilment of the right to health.¹¹⁸¹ Put differently, if a compulsory licensing measure could be used to provide access to essential medicines to satisfy human rights obligations, such national action would be legitimate under WTO law, a notion subsequently confirmed by WTO Members through the Doha Declaration. It is significant that a comprehensive declaration that

¹¹⁸¹ “Promotion and Protection of All Human Rights” (n 722) para. 1, recognising that access to medicine is one of the fundamental elements in achieving progressively the full realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

carries an authoritative interpretation of the ICESCR¹¹⁸² also states clearly that: ‘IP is a social product ... with a social function and that the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration’.¹¹⁸³

Given that essential medicines remain a key component of the human right to health, it is therefore of significance that the UN sub-Commission on the Protection and Promotion of Human Rights reminded Ghana and other governments of the primacy of human rights obligations over economic policies and agreements.¹¹⁸⁴ Against this background, the human right to essential medicines was also advanced in terms of its normative content and its legal recognition under the WTO system with a view to making access to medicines a permanent goal of states’ policies and programmes.¹¹⁸⁵ This emphasis should encourage Ghana and other WTO Members not to completely abandon their obligations within the international human rights treaties and to provide affordable medicines for their people.

In fact, this direction reflects a measure of recognition that TRIPS should not be read in clinical isolation from public international law since Ghana and all other WTO Members have international obligations outside the IP regime, including human rights – a subject that TRIPS does not promote adequately.¹¹⁸⁶ More significantly, it has been recognised that a treaty must be interpreted by taking into account the consequent socio-economic and other changing circumstances. Accordingly, the European Court of Human Rights held that human rights treaties are: ‘a living instrument which ... must be interpreted in the light of present-day conditions’.¹¹⁸⁷ In a similar vein, the Inter-American Court held that: ‘human rights treaties are living instruments whose interpretation must go hand in hand with evolving times and current living conditions’. It went on to say that such a conclusion is consistent with the ‘general rules of treaty interpretation set forth in the Vienna Convention on the Law of Treaties’.¹¹⁸⁸

¹¹⁸² “The ICESCRs” (n 717).

¹¹⁸³ Economic and Social Council Committee on Economic Social and Cultural Rights, General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of which he is the Author (Article 15, para. 1(c), of the ICESCR), para. 35, U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006).

¹¹⁸⁴ Intellectual Property Rights and Human Rights, Sub-Commission on Human Rights Resolution 2000/7 (U.N. Doc. E/CN.4/Sub.2/Res/2000/7 (Aug. 17, 2000) para. 3.

¹¹⁸⁵ *ibid.*

¹¹⁸⁶ “Resource Book on TRIPS” (n 16) 130.

¹¹⁸⁷ *Tyrer v United Kingdom* - 5856/72 [1978] ECHR 2, Apr. 25, 1978, para. 31.

¹¹⁸⁸ *Case of the Mapiripan Massacre v. Colombia* [Merits, Reparations and Costs] Judgment of Sept. 15, 2005. Inter-Am. Ct. H.R., Series C No. 134] para. 104:

This provides an additional example of the potential use of human rights law by Ghana to secure public health outcomes through affordable medicines for public health protection.¹¹⁸⁹ Moreover, this confirmation is very convincing as the Members referencing the Doha Declaration articulated that the TRIPS Agreement does not, and should not, prevent Ghana and other WTO Members from taking measures to protect public health by using, to the full, the provisions in the Agreement, which provide flexibility for that purpose. Remarkably, while Paragraph 5(b) of the Doha Declaration confirmed that the granting of a compulsory licence is well within the right of Ghana and each WTO Member, the implementation of Section 84 may not provide the means for Ghana to obtain affordable medicines. This is because while local manufacture could promote a reliable supply of medicines at affordable prices, this is only possible where economies of scale can be generated to manufacture on a large scale in order to reduce unit costs.¹¹⁹⁰

That is, a large domestic market that allows substantial economies of scale in production is relevant, as in the case of India.¹¹⁹¹ However, Ghana could mitigate the issue of its small market size if it decided to work with its neighbours in the sub-region to enhance economies of scale to generate more incentive to manufacture essential medicines for distribution. Moreover, other key limitation factors to be considered include whether the implementation of Section 84 would threaten the attainment of socio-economic objectives due to the loss of inward FDI opportunities, retaliatory action and their potential frustration owing to the impact of FTAs. Although, an expanded IP right protection can be derived from the unqualified treatment protection provisions found in some international investment agreements or FTAs on which investor-state arbitration in the enforcement of IP right remains possible,¹¹⁹² nevertheless, as

Human rights treaties, is inspired by higher shared values (focusing on protection of the human being), they have specific oversight mechanisms, they are applied according to the concept of collective guarantees, they embody obligations that are essentially objective, and their nature is special vis-à-vis other treaties that regulate reciprocal interests among the States Parties.

¹¹⁸⁹ Article 73 of TRIPS states that ‘Nothing in this Agreement shall be construed: (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests; (iii) taken in time of.... emergency. See Carvalho (n 55) 464, interpreting that it is up to each member to make its own finding of necessity.

¹¹⁹⁰ Jean-Marc Guimier, Evan Lee and Michel Grupper, *Processes and Issues for Improving Access to Medicines: The Evidence Base for Domestic Production and Greater Access to Medicines* (The DFID, September 2004) 24.

¹¹⁹¹ Warren Kaplan and Richard Laing, *Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines: An Overview of Key Concepts, Issues and Opportunities for Future Research* (Health, Nutrition and Population Discussion Paper, January 2005) 15.

¹¹⁹² The NAFTA (n 994), for example, Chapter 11 of the NAFTA provides for investor-state dispute settlement, in addition to the possibility of state-state dispute settlement under NAFTA Chapter 20.

indicated already, Ghana has not yet signed any of such instruments that might potentially limit the country's right to grant compulsory licences, such as the implementation of Section 84 model to promote affordable medicines.

Importantly, despite the common perception that a country like Ghana may potentially face significant socio-economic shortcomings in relation to inward FDI opportunities if it were to implement a Section 84 model, the analysis has shown that in the context of Ghana this would not be an expected outcome. Therefore, the fear that the implementation of Section 84 could lead to a withdrawal of investments is a general claim that would not be applicable to Ghana because, where almost all of the FDIs go to the oil and gas sector, it cannot be true that the implementation of Section 84 would threaten inward FDI opportunities and the attainment of socio-economic objectives.

This is because there are inadequate linkages between robust IP rights protection and inward FDI opportunities in the literature objectively assessing the relationship between the strict enforcement of patent rights and socio-economic development; therefore, Ghana would be able to implement a Section 84 model and still attain its socio-economic objectives. As seen from above, there is not a single mainstream pharmaceutical company that has a manufacturing or research facility in the country, let alone cause that investment to be withdrawn. It is also not convincing to argue that if Ghana fails to implement Section 84, large pharmaceutical companies will invest in the country.

This raises the question, as to why Ghana has not experienced any obvious substantial investment from the large pharmaceutical companies into its pharmaceutical manufacturing or research-related sector since the country adopted its current regime in 2003. Still, where this threat exists, Ghana could work with its neighbours to build stronger resilience against any withdrawal of investments by adopting series of compulsory licences in the sub-region, and where this is the case no reasonable investor would want to withdraw its investments from the entire sub-region.

Furthermore, the analysis considered the potential threat of legal challenges by the pharmaceutical industry and the possibility of high litigation costs being incurred, as Ghana's experience with GSK shows. However, it has been shown that it is highly unlikely that the pharmaceutical industry would challenge the legality of the implementation of Section 84 to

promote affordable medicines in the light of the Doha Solution.¹¹⁹³ Additionally, the analysis assessed potential retaliatory action owing to impacts of FTAs if Ghana were to implement Section 84 as India has done.

Nevertheless, it has been shown that no FTA provision would operate directly to prevent Ghana from implementing a Section 84 model and that it is free to do so. In addition to the possibility of a state-to-state dispute, FTAs investment it has been examined that chapters may sometimes vest the IP owner as an investor with the right to bring the host state to binding international arbitration.¹¹⁹⁴ In this context, the possibility for an IP right-holder to bring a claim against Ghana under the investor-state dispute settlement mechanism for breach of FTA provisions is a further element, which should be taken into account while appreciating the extent to which the country could implement the Section 84 model.

Nevertheless, the possibility of challenging the implementation of Section 84 on the basis of investors' rights even though has been anticipated in some cases,¹¹⁹⁵ Ghana has not signed any international investment agreements or FTAs that purport to exclude the issuance of compulsory licensing consistent with the TRIPS Agreement from the scope of application of expropriation provisions. It follows therefore that, a claim based on the violation of the treatment of IP rights investments in case Ghana implements the Section 84 model to promote affordable medicine will be difficult to pursue against the country.

Furthermore, as revealed, following the Doha Solution, it is unlikely that developed countries, particularly the US and the EU, would adopt any aggressive response such as economic sanctions or bilateral pressure in response to the implementation of Section 84.¹¹⁹⁶ More importantly, although inter-regional policy collaboration remains so far underexploited, one major policy option for Ghana would be to pursue sub-regional economic and political coordination and this would create a better policy condition for addressing the challenges of implementing the Section 84 model, without the fear of potential bilateral pressure.

¹¹⁹³ *id.* 19, stating that the Doha Declaration isolated the pharmaceutical industry. Odell and Sell (n 1086) 98, stating that the pharmaceutical industry will be cautious given the public relations disaster of the litigation by pharmaceutical multinationals against South Africa.

¹¹⁹⁴ The NAFTA (n 1073), for example, Chapter 11 of the NAFTA provides for investor-state dispute settlement, in addition to the possibility of state-state dispute settlement under NAFTA Chapter 20.

¹¹⁹⁵ See (n 1073 and 1074).

¹¹⁹⁶ Odell and Sell (n 1086) 98, stating that the Doha Declaration isolated the US.

It therefore appears that the only problem the country must mitigate is domestic capacity pertaining to local manufacture for distribution of affordable medicines. Nevertheless, several multilateral organisations provide both direct and indirect support to local production efforts, such as policy advice, capacity building, institutional strengthening and analysis. These include UNIDO, UNCTAD, the World Bank, UNDP, the WHO, UNICEF and the WIPO.¹¹⁹⁷ For example, the UNCTAD helps countries to evaluate and formulate capacity building and technical assistance activities.¹¹⁹⁸

A trilateral programme under the auspices of the WTO, WHO and WIPO is aimed at strengthening their cooperation on the interface between IP and public health as part of increasing international efforts to improve the ability of the world's poor to have access to medicines and to ensure the availability of new and more effective medicines.¹¹⁹⁹ The WIPO, in particular, has provided extensive technical cooperation aimed at addressing various issues related to policy, capacity-building, skills development and infrastructure based on specific needs.¹²⁰⁰ These initiatives provide Ghana with the opportunity to seek technical assistance in overcoming any institutional and human resource capacity aspects toward the implementation of the Section 84 model in the country to promote affordable essential medicines. Nevertheless, it is important to stress that while Ghana is now fully aware of the range of TRIPS flexibilities including the right to utilise the compulsory licensing regime under the TRIPS Agreement as an instrument of government policy to promote affordable medicines, it is also the case that political factors and bilateral diplomatic pressure are more likely to operate to prevent the country from implementing a model similar to 84.

¹¹⁹⁷ 'Pharmaceutical Production and Related Technology Transfer' (n 1129) 35, naming UNIDO, UNCTAD, World Bank, UNDP, WHO, UNICEF and the WIPO.

¹¹⁹⁸ 'UNCTAD Trade Capacity Building Resource Guide for Developing Countries'. <http://www.tcbresourceguide.org/multilateral_summaries/unctad.html> [Accessed Apr. 12, 2017].

¹¹⁹⁹ 'Trilateral Cooperation on Intellectual Property and Public Health'. <https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm> [Accessed Apr. 11, 2017].

¹²⁰⁰ 'WIPO Director General's Report' (Eleventh Session of the CDIP on the Implementation of the Development Agenda, May 2013) 14.

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