Essential Medicines And The Complexity Of Implementing Nationally Based Compulsory Licensing: On The Need For A Regional System Of Compulsory Licensing In Sub-Sahara African

Abstract

The global enforcement of pharmaceutical patents under the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement makes essential medicines very expensive for Least Developed Countries (LDCs), limiting supply for the majority of patients in sub-Saharan Africa (SSA). Nevertheless, essential medicines are a component of the human right to health according to Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The experience of developing countries outside SSA shows that the successful exploitation of the TRIPS flexibilities, in particular, compulsory licensing constitutes a potential means of obtaining affordable medicines. The aim of this article is to examine the feasibility of a regional system for compulsory licensing in order to manufacture and distribute essential medicines in SSA. The hypothesis of this article is that compulsory licensing by SSA countries will not provide a suitable means of procuring essential medicines in view of their individual economic and political constraints. This hypothesis is premised on the inability of LDCs in SSA to obtain compulsory licences for the procurement of affordable medicines and to distribute them according to need. While the article identifies legal, institutional, and particularly, political pressures as major obstacles to the implementation of the WTO Paragraph 6 programme, it proposes a regional system for compulsory licensing that is arguably compliant with TRIPS, in order to overcome the complexity in compulsory licensing. Consistent with the hypothesis, the article recommends a regional arrangement for a pharmaceutical compounding programme as a pooled manufacturing scheme to distribute essential medicines within SSA.

Keywords
African countries; compulsory licensing; generic medicines; regional strategies; public health; TRIPS Agreement;

Introduction

Access to essential medicines remains critical to the fulfilment of key objectives of the Millennium Development Goals (MDGs).[1] The conclusion of the TRIPS Agreement in 1995 brought fundamental changes in the regulation of Intellectual Property (IP) by mandating Member States to implement global standards of IP protection.[2] The resulting opportunity for international patent enforcement has progressively reduced the potential for LDCs to protect IP in accordance with their level of socio-economic development.[3] Significantly, the enforcement provisions of TRIPS means Member States that violate the patent provisions contained in Article 27(1) are under threat of legal action from the pharmaceutical industry.[4] Article 28 confers on patentees' exclusive rights, such that the patentee could commence a legal action against any company or government subsequent to an infringement of its patent rights. For example, following the enactment of the South African Medicines and Related Substances Control Amendment Act, 1997, more than 39 pharmaceutical companies, mostly multinational corporations, sued the South African government claiming an infringement of the enforcement provision of patents within the TRIPS Agreement.[5]

Responding to the difficulty of accessing affordable essential medicines under TRIPS, specifically Article 31(f), LDCs took their case to the WTO calling for TRIPS to be part of wider national and international action to address the problem of access to affordable medicines.[6] In Paragraph 6 of the Doha Declaration on TRIPS and Public Health, the WTO recognized that LDC Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of

[1] The Millennium Development Goals, 2000 (Target 17: Goal 8 namely child mortality, improving maternal health, and combating HIV/AIDS and other diseases).
[2] The TRIPS Agreement was adopted as part of the Final Act of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299 in Marrakesh, Morocco on 15 April 1994.
[3] Frederick Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health (2005) 99 *American Journal of International Law* 2, 317-358.
[4] Naomi Bass, Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century (2002) 34 *George Washington International Law Review* 1, 191-210.
[5] David Barnard, In the High Court of South Africa, Case No. 4138/98: The Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries (2002) 12 *Kennedy Institute of Ethics Journal* 2, 159-174.
[6] The Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 20 November 2001, 41 I.L.M. 755, (2002).

compulsory licensing under the TRIPS Agreement, and instructed the Council for TRIPS to find an expeditious solution to this problem. As a result, some three years later, in their 30 August 2003 Decision, WTO Members approved the so-called 'Paragraph 6 Programme' which was designed to facilitate compulsory licensing for the manufacture of generic, affordable medicines for LDCs.[7] Meanwhile, the TRIPS Agreement allowed developing countries to stagger the implementation of a higher patent protection so that India, for example, was not required to amend its national laws to provide pharmaceutical product patents until 2005.[8] In terms of the special needs of LDCs, their economic, financial and administrative constraints, they were not required to apply the provisions of TRIPS for the first decade of the Agreement.[9] In 2002, the obligations of LDC Members under TRIPS Article 70(9) were waived, so that they are not required to provide pharmaceuticals patents until 2016.[10]

The absence of manufacturing capacity in SSA has largely rendered the WTO programme for compulsory licensing worthless.[11] Notably, attempts by countries to exploit the flexibilities have foundered on administrative complexity, which is so marked that, to date, only Rwanda has availed itself of the opportunity to obtain essential medicines by this means.[12] Invariably, leading developing countries, such as Brazil and India, have proved capable of taking national action, amending and enforcing their patent legislation in favour of local manufacturing and distribution of affordable medicines.[13] The fact is that SSA countries tend to seek medicines from countries such as India with a

[7] The 30 August Decision of the WTO/TRIPS General Council on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540 and Corr.1: 1 September 2003).
[8] The Indian Patents (Amendment) Act, No 15 of 2005. See Also Sudip Chaudhuri, TRIPS Agreement and Amendment of Patents Act in India (2002) 37 *Economic and Political Weekly* 32, 3354-3360.
[9] TRIPS Article 66(1).
[10] The WTO/TRIPS General Council Decision of 8 July 2002 on Least-Developed Country Members - Obligations Under Article 70(9) of the TRIPS Agreement with Respect to Pharmaceutical Products (WT/L/478 12 July 2002). Pursuant to Article 66(1) of the TRIPS Agreement, LDC Members Group of the WTO requested for an extension of the TRIPS Transitional arrangement on 5 November 2012. See WTO/TRIPS Doc. IP/C/W/583. On 11 June 2013, TRIPS Council confirmed further extension from 1 January 2016 until 1 July 2021. See WTO/TRIPS Official Document IP/C/64.
[11] Anita Hardon, Confronting the HIV/AIDS Epidemic in sub-Saharan Africa: Policy versus Practice, (2005) 57 *International Social Science Journal* 186, 601-608.
[12] Julian Cohen-Kohler, Laura Esmail, Andre Cosio, Canada's Implementation of the Paragraph 6 Decision: Is it sustainable Public Policy? (2007) 3 *Globalization and Health* 1, 12-21.
[13] The Indian Patents Act, No. 39 of 1970 (as amended in 1999, 2002 and 2005). The Industrial Property Law of Brazil: (No. 9.279/96 of May 14, 1996). See Also Janice Mueller, Taking TRIPS to India: Novartis, Patent Law, and Access to Medicines (2007) 356 *New England Journal of Medicine* 6, 541-543.

substantial manufacturing capacity to supply quality affordable medicines.[14] However, efforts to obtain compulsory licensing to increase the supply of the generic equivalent of patented medicines to SSA has been exacerbated by India having to fulfil pharmaceutical patents in compliance with TRIPS.[15] Nevertheless, pressure to increase pharmaceutical patent protection ahead of the TRIPS Agreement schedule has been constant through bilateral trade agreements from the home governments of the pharmaceutical industry.[16] In particular, the European Union (EU) and the United States (US) have been able to utilise the TRIPS-plus Agreements to apply political pressure on LDCs to comply with higher levels of patent protection than that provided in TRIPS.[17] In this regard, SSA countries are facing difficulties in the exploitation of the TRIPS flexibilities in order to address the shortages and high costs of essential medicines for fear of economic sanctions.

Therefore, the aim of this article is to examine the feasibility of a regional system for compulsory licensing in order to manufacture and distribute essential medicines in SSA. The hypothesis of this article is that compulsory licensing by SSA countries will not provide a suitable means of procuring essential medicines in view of their individual economic and political constraints. This hypothesis is premised on the inability of LDCs in SSA to exploit the TRIPS flexibilities to obtain compulsory licences for the procurement of affordable medicines and to distribute them according to need. While the article identifies legal, institutional, and particularly, political pressures as major obstacles to the implementation of the WTO Paragraph 6 programme in SSA, it proposes a regional system for compulsory licensing that is arguably compliant with TRIPS to overcome the complexity of compulsory licensing. Consistent with the hypothesis, the article then recommends a need for a regional arrangement on a pharmaceutical

[14] Brenda Waning, Ellen Diedrichsen, Suerie Moon, A Lifeline to Treatment: The Role of Indian Generic Manufacturers in supplying Antiretroviral Medicines to Developing Countries (2010) 13 *Journal of the International AIDS Society* 1, 35-48.
[15] Fabienne Orsi, Cristina D'Almeida, Lia Hasenclever, Mamadou Camara, Paulo Tigre, Benjamin Coriat, TRIPS post-2005 and Access to New Antiretroviral Treatments in Southern Countries: Issues and Challenges (2007) 21 *Journal of Aids* 15, 1997-2003.
[16] Susan Sell, TRIPS-plus Free Trade Agreements and Access to Medicines (2007) 28 *Liverpool Law Review* 1, 41-75.
[17] TRIPS-plus is a term used to describe the implementation of tougher provisions or more restrictive conditions in patent laws than are required by the TRIPS Agreement. See Carlos Correa, Implications of Bilateral Free Trade Agreements on Access to Medicines (2006) 84 *Bulletin of the World Health Organization* 5, 399-404.

compounding programme as a pooled manufacturing scheme to distribute essential medicines within SSA.

Consequently, Part I of this article examines the patent provisions of the TRIPS Agreement as they apply to pharmaceuticals in accordance with Article 27(1). It discusses the impact of pharmaceutical patents on access to medicines in SSA before and after the implementation of product patents in 2005 for developing countries. Part II traces the origin and nature of compulsory licensing in WTO jurisprudence under the Paris Convention, the TRIPS Agreement, Doha Declaration on TRIPS and Public Health as a safeguard tool capable of delivering affordable essential medicines to LDCs. Part III analyses the practical shortcomings of the WTO Paragraph 6 programme, not only from the viewpoint of internal capacity constraints but also from the perspective of pharmaceutical industry threats of lawsuits and their home governments political pressures driving TRIPS-plus Agreements. Part IV proposes a regional system for compulsory licensing as a possible mechanism to overcome the operational shortcomings of the Doha Paragraph 6 programme in SSA. Moreover, it assesses the operational failure of the previous pooled procurement schemes in SSA. Consistent with the hypothesis, it recommends a regional arrangement for a pharmaceutical compounding programme, and then explains its opportunities as a pooled manufacturing scheme to distribute essential medicines within SSA.

PART I

READING THE TRIPS AGREEMENT FROM THE STANDPOINT OF ACCESS TO ESSENTIAL MEDICINES IN SSA

Introduction

Articles 27 and 28 of the TRIPS Agreement provide universal standards for patent protection, allowing LDCs relatively little flexibility in the supply and pricing of essential medicines. The accompanying enforcement provisions of Part III of TRIPS mean that the principal pharmaceutical corporations, who are owners of the majority of the pharmaceutical patents, are able to significantly influence the conditions of manufacture,

supply and pricing. This part of the article explains how the position of LDCs with regard to the supply of essential medicines became even less tenable after 2005 when countries, such as India, that possessed a substantial manufacturing capacity were required to provide patent protection for pharmaceutical products. As a result, manufacturers of generic pharmaceuticals that were still under patent protection were required, under threat of legal action for infringement, to halt production. As Part II will explain, to maintain the supply of necessary medicines, the ability to exercise the compulsory licensing provision of TRIPS is still more significant for LDC governments.

The Article 27.1 and 28 of the TRIPS Agreement

A patent confers an exclusive right granted by a State to an inventor for a certain period of time in return for the disclosure of his/her invention so that during the term of the patent, any person or a company imitating the invention or new manufacturing process without the consent of the patent holder, is committing an act of infringement.[18] The TRIPS Agreement requires WTO Members to provide protection for patents.[19] Article 27(1) establishes a very broad international minimum standard for the subject matter of patent protection. It contains an overriding requirement that patents be made available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[20] It includes a general obligation of patentability, addressing in this manner one of the major concerns raised by the pharmaceutical industry with respect to prevailing regimes prior to

[18] Part II Section 5 of TRIPS covers both substantive standards as well as specific issues of enforcement that are generally applicable to patents. See US Title 35 U.S.C. § 271(a). See Also Carlos Correa, Implementing the TRIPS Agreement in the Patents Field (1998) 1 *The Journal of World Intellectual Property* 1, 75-99.

[19] Jerome Reichman, Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement (1995) 29 *The International Lawyer* 2, 345-388.

[20] An invention is any product, process, or innovation thereof. Patents are granted in relation to products and processes, dealt with in Paragraphs 1 and 2, respectively, of Article 28. '*A product is a thing or substance produced by natural process or manufacture, whiles a process is a series of operations in manufacturing.'* See Kevin Nowak, Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause in TRIPS Article 27 (2004) 26 *Michigan Journal of International Law* 3, 899-944.

TRIPS.[21] Article 27(1) stipulates:

> [S]ubject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be 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.

The duration of patent rights is established in Article 33 of TRIPS, which mandates a minimum term of twenty years counted from the date of filing of the application. For the purposes of Articles 3 and 4, protection should include matters affecting the availability, acquisition, scope, maintenance, use and the enforcement of IPRs. According to Article 3(1), each Member should accord to the nationals of other Member States treatment no less favourable than it accords to its own nationals with regard to the protection of IPRs. This provides a basis for limiting the power of national authorities to differentiate the treatment conferred to products locally produced or imported.[22] Article 28 of the TRIPS Agreement confers on patentees exclusive rights to prevent unauthorized third parties from working, selling, or importing the patented product or process.[23] In addition, Article 28(2) provides patentees with the right to assign the patent and, significantly, to conclude licensing contracts.[24] Moreover, the patent monopoly is strengthened by the possibility of applying for process patents in so far as Article 28.1(b) allows patentees to prevent

[21] Robert Weissman, Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the remaining WTO Legal Alternatives Available to Third World Countries (1996) 17 *University of Pennsylvania Journal of International Economic Law* 4, 1069-1125. See Also Peter Drahos, Developing Countries and International Intellectual Property Standard-Setting (2002) 5 *The Journal of World Intellectual Property* 5, 765-789.

[22] Ibid 19

[23] See Section 5: Part II of the TRIPS Agreement on Standards concerning the Availability, Scope and Use of Intellectual Property Rights.

[24] In the Canada-Patent protection of pharmaceutical products case, the panel stressed that the exclusion of "all forms of competition" is the essence of patent rights. It held that "The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity . . . Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined" See Report of the WTO Dispute Panel (WT/DS/114/R, para. 7.55).

unauthorized third parties from the act of using the process, and from the acts of selling or importing the product obtained directly by that process.

Moreover, the enforcement provisions of the TRIPS Agreement mean that patentees can rely on international law to sue for infringement in both domestic courts and before the dispute settlement body of the WTO.[25] To this end, Article 41 imposes an obligation on Member States to ensure that enforcement procedures are available under their national laws in order to permit effective action against any act of infringement of IPRs, including expeditious remedies to prevent infringements as a deterrent.[26] Despite the proviso that such enforcement procedures should be applied so as to avoid the abuse of patent rights, LDCs individually are rarely going to have the necessary resources or institutional capacity to implement the necessary rules of competition law.[27] In sum, Articles 27, 28 and 41 together act to significantly restrict local pharmaceutical manufacturers in LDCs from importing active pharmaceutical raw materials for the manufacture of generic copies of patented medicines.

Patent protection and the position of SSA countries before and after 2005

Generally speaking, before TRIPS, some developed countries had well-established patent regimes that offered a great deal of protection through elaborate legislation and proactive enforcement mechanisms.[28] Historically, the principle of territoriality governing patents was such that national governments had the power to legislate for patents and to determine the scope of patent protection.[29] Prior to TRIPS, developing countries had

[25] TRIPS Article 64 Dispute Settlement; See Julio Lacarte-Muro, Petina Gappah, Developing Countries and the WTO Legal and Dispute Settlement System: A view from the Bench (2000) 3 *Journal of International Economic Law* 3, 395-401. See Also Gregory Shaffer, *How to make the WTO Dispute Settlement System work for Developing Countries: Some Proactive Developing Country Strategies* (International Centre for Trade and Sustainable Development (ICTSD), 2003).

[26] Jerome Reichman, Enforcing the Enforcement Procedures of the TRIPS Agreement (1996) 37 *Virginia Journal of International Law* 2, 335-356.

[27] Bernard Hoekman, Peter Holmes, Competition Policy, Developing Countries and the WTO (1999) 22 *The World Economy* 6, 875-893.

[28] Jerome Reichman, Rochelle Dreyfuss, Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty, (2007) 57 *Duke Law Journal* 1, 85-130.

[29] Graeme Dinwoodie, *Developing a Private International Intellectual Property Law: The Demise of Territoriality* (Oxford Legal Studies Research Paper No. 52/2009, 2009).

greater freedom to formulate their IP laws and policies in keeping with their level of industrialization. As a result, the government of India, for example, in the Patent Act of 1970 provided only process patents for pharmaceuticals.[30] This allowed Indian scientists to develop cost-effective manufacturing processes for molecules already invented and patented in developed countries and this helped to expedite the production of generic versions of patented medicines.[31]

However, this is no longer the case following the minimum, effectively universal, standards of patent protection provided by TRIPS. The principles of non-discrimination, provided by the combined operation of national, and most favoured nation treatments, further serve to strengthen international patent protection.[32] The transitional provision of the TRIPS Agreement provides for Member States undergoing economic development.[33] Article 65(2) does so by allowing developing countries from five to ten years with possible extensions of time, to introduce protection of both process and product patents.[34] Moreover, in compensation for not granting product patents, developing countries had to establish a "mailbox" system for receiving and filing patent applications from the

[30] Product patents confer broader rights than process patents. Product patents provide for absolute protection of the product, whereas process patents provide protection in respect of the technology and the process or method of manufacture. Protection for process patents would not prevent the manufacture of patented products by a process of reverse engineering. Section 3 of the Indian Patent Act, No 39 of 1970 introduced restrictive changes related to the patenting of inventions injurious to public health, especially in the field of pharmaceuticals. This allowed the development of domestic industries that were able to produce and market copies of products patented elsewhere. See Sudip Chaudhuri, *Is Product Patent Protection necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS* (Indian Institute of Management Calcutta, Working Paper Series 614, 2007).

[31] The India pharmaceutical industry gained decisive competitive advantages in copying the chemical substance from patented products by changing the method by which the patented molecule was produced and to market them in India. See also Gail Evans, Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries (2008) 34 *American Journal of Law & Medicine* 2, 175-223.

[32] TRIPS Article 3&4. See Bernard Hoekman, Operationalizing the Concept of Policy Space in the WTO: Beyond Special and Differential Treatment (2005) 8 *Journal of International Economic Law* 2, 405-424.

[33] The TRIPS Agreement grants all WTO Members transitional periods so that they can meet their obligations under it. The transitional periods, which depend on the level of development of the country concerned, are contained in Articles 65 and 66.

[34] By virtue of Articles 65.2 & 65.3, developing countries delayed patent protection for pharmaceutical products until 1 January 2005 with an extension to 2005. This was allowed under Article 65.4 provision that say a developing country that did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (on 1 January 1995), are entitled to additional 5-year exemption.

beginning of the transitional period in 1995 onwards. Such applications had to be kept pending, in a patent "mailbox" until it opened in 2005 for examination and grant.[35]

In addition, Articles 70(8) and 70(9) of TRIPS required developing countries to grant five years protection in the form of exclusive marketing rights for any pharmaceutical products granted patent protection by other WTO Members.[36] By 2005, having obtained one five year extension, developing countries, notably India, were required to put in place product patent legislation that was in conformity with the TRIPS Agreement provisions.[37] Prior to 2005, therefore, the importation of quantities of low-cost generic versions of patented medicines from India to SSA countries was a viable proposition.[38] Following the expiration of the transition period in 2005, it was hoped that leading developing countries would assume full compliance with the general obligations set out in TRIPS, particularly Articles 27 and 28.

The apprehension was that developing countries, which have varying degrees of capacity to manufacture low-cost generic copies of patented medicines for export to SSA countries, could no longer be able to do so after the expiration of the relevant transitional period.[39] Consequently, the importation of raw materials to manufacture generic essential medicines locally have become more difficult for LDCs in SSA that have previously relied heavily on supplies from countries such as India.[40] The fact is that the multinational pharmaceutical industry has a strong financial interest in the generic manufacturers of India whose activities represent a sizeable market worth defending through the enforcement regimes laid down by TRIPS.[41] As a result, SSA countries are

[35] Gail Evans, A Preliminary Excursion into TRIPS and Non-Violation Complaints (2000) 3 *The Journal of World Intellectual Property* 6, 867-888.
[36] Carlos Correa, The TRIPS Agreement: How much room for manoeuvre? (2001) 2 *Journal of Human Development* 1, 79-107.
[37] The relevant transitional provision is found in Article 65.4, which permits developing countries to delay until January 1, 2005 the granting of product patent protection for any area of technology not previously protected in that country. See Also Patents (Amendment) Act, 2005 (Act No. 15 of 2005).
[38] Over 90% of the essential medicines consumed in SSA are imported. See *Preventing Chronic Diseases: A Vital Investment* (World Health Organization Global Report, 2005).
[39] Frederick Abbott, 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, 921-987.
[40] Sonja Babovic, Kishor Wasan, Impact of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement on India as a Supplier of Generic Antiretrovirals (2011) 100 *Journal of Pharmaceutical Sciences* 3, 816-821.
[41] Sidip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (Oxford University Press, 2005).

facing huge challenges attempting to sustain the price reduction and the reliable supplies enjoyed from the low-cost generic manufacturers of India.[42] Patented medicines almost always cost more than the generic versions, and this is the underlying rationale why access for the majority of the population in SSA has been curtailed, since they are unable to afford expensive patented medicines.[43]

PART II

THE COMPULSORY LICENSING PROVISIONS OF THE TRIPS AGREEMENT AND THE MANUFACTURE OF ESSENTIAL MEDICINES

Introduction

TRIPS Article 31 reflects the long and widespread use of compulsory licensing as a potential instrument of government policy directed at the supply of essential medicines. Article 5 of the Paris Convention of 1883 allowed each of the Union Members the right to take legislative measures providing for compulsory licensing in certain specific cases, including failure to work the patent locally. Thus, compulsory licensing schemes are justified on the ground that they increase public access to inventions. By comparison, Article 31 of the TRIPS Agreement is broadly drafted; its numerous qualifications on the exercise of compulsory licensing tend to also restrict its use as a general instrument of government health policy. Given its newfound importance to the supply of medicines in the Doha Declaration on TRIPS and Public Health, WTO Members affirmed the right of LDCs to grant compulsory licences as well as allowing them the freedom to determine the grounds upon which such licences are granted. This part of the article traces the origin and nature of compulsory licensing in WTO jurisprudence under the Paris Convention, the TRIPS Agreement, and the Doha Declaration Doha on TRIPS and Public Health as a mechanism to deliver affordable medicines to LDCs provided it is part of a practical and well-administered system.

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[42] *Five Years into the Product Patent Regime: India's Response* (United Nations Development Programme, 2010).

[43] Jonathan Quick, Nana-Adjoa Boahene, James Rankin, Romuald Mbwasi, Medicines Supply in Africa (2005) 331 *British Medical Journal* 7519, 709-710. See Also Stine Haakonsson, Lisa Richey, TRIPS and Public Health: The Doha Declaration and Africa (2007) 25 *Development Policy Review* 1, 71-90.

Compulsory Licensing

A patent is a form of IP granted by a government that gives the owner an exclusive right over an invention. As an exceptional measure, compulsory or involuntary licensing refers to the practice by a government of authorising itself or third parties to use the subject matter of a patent without the authorisation of the right holder for reasons of public policy.[44] It is one mechanism through which governments limit or restrain the exercise of exclusive rights residing in the grant of patents in the public interest.[45] It functions as a significant instrument that mitigates the restrictive effect of exclusive rights over patents, in striking a balance between the title-holders' interest and the public in the diffusion of knowledge, to facilitate access and the affordability of the patented invention.[46]

In other words, the patentee is forced to tolerate the exploitation of his/her invention by a third person or by the government itself.[47] In these cases, the public interest in broader access to the patented invention is considered more important than the private interest of the right holder to fully exploit such exclusive rights.[48] While countries retain the right to determine what constitutes conditions for the grant of compulsory licences, remuneration to compensate patent holders must be fulfilled in the context of TRIPS.[49] The concept and practice of compulsory licensing are not new. They have a long history that has remained a prominent feature of the general philosophy of IP regimes spanning over a century.[50]

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[44] Jerome Reichman, Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA* (co-publication by the International Centre for Trade and Sustainable Development (ICTSD) and the United Nations Conference on Trade and Development (UNCTAD): Issue Paper No. 5, 2003).

[45] Cecilia Oh, Compulsory Licenses: Recent Experiences in Developing Countries (2006) 1 *International Journal of Intellectual Property Management* 1, 22-36.

[46] Robert Bird, Developing Nations and the Compulsory Licence: Maximizing Access to Essential Medicines while Minimizing Investment side Effects (2009) 37 *The Journal of Law, Medicine & Ethics* 2, 209-221.

[47] Ibid 44

[48] Jerome Reichman, Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options (2009) 37 *The Journal of Law, Medicine & Ethics* 2, 247-263.

[49] TRIPS Article 31(h)

[50] Richard Rozek, Renee Rainey, Broad-Based Compulsory Licensing of Pharmaceutical Technologies (2001) 4 *The Journal of World Intellectual Property* 4, 463-480.

However, the recent expansion of patents to cover pharmaceutical products as part of the fundamental changes brought about by TRIPS has highlighted the controversy over the grant of compulsory licensing. The popular misconception is that it violates the rules of WTO.[51] Nonetheless, evidence exists to underpin that, prior to TRIPS, countries throughout the world maintained legislations authorizing the grant of compulsory licensing for their governments to use patented inventions for various reasons, including for public interest purposes.[52] Experience shows that the US has used compulsory licensing several times and, recently, it threatened Bayer Corporation on granting of a compulsory licence for its patented medicine Ciprofloxacin.[53] Some countries have pursued the compulsory licensing measure as a tool for local pharmaceutical industry development; Canada, for instance, has done this to a substantial degree.[54]

Noting this, the EU also affirmed within its current jurisprudence the legal status of compulsory licensing as paramount to public health protection in the LDCs.[55] Moreover, the relevance of compulsory licensing as seen in the discussion of the WTO Paragraph 6 programme could offer a solution to the multiplicity of concerns over access to medicines in SSA. Particularly, it could balance the availability of affordable medicines that meet SSA countries' priority public health needs either through the vehicle of importation or local manufacturing.[56]

Local working requirements under the Paris Convention

[51] James Love, *Recent Examples of the Use of Compulsory Licences on Patents* (Knowledge Ecology International Research Note 2007:2, 2007).

[52] *For Example* Compulsory Licensing in the U.S. Statute Code Title: 28 USC 1498(a). See Also Chapter XVI of the Indian Patents Act, 1970: Section 84 provides the legislative authority for issuing compulsory licensing for patents in India as amended by the Patents (Amendment) Act of 2002, and Patents (Amendment) Act of 2005. Elizabeth Henderson, TRIPS and the Third World: The Example of Pharmaceutical Patents in India, (1997) 19 *European Journal of Intellectual Property Review* 11, 651-663.

[53] 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. Available at: < http://www.cptech.org/ip/health/cl/cipro/americanlawyer012002.html> Retrieved 14/10/2013.

[54] Between 1969 and 1992, Canada is believed to have issued over 613 licences. See Human Development Report, *Making New Technologies Work for Human Development* (The United Nations Development Programme, published by Oxford University Press, 2001, Chapter 5, pp. 107).

[55] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006. See Also Case C-7/97, Opinion of Advocate General Jacobs, Oscar Bronner GmbH&Co. KG v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbhH&Co. KG, [1998] E.C.R. I-7813, 65.

[56] Peter Maybarduk, Sarah Rimmington, Compulsory Licences: A Tool to improve Global Access to the HPV Vaccine? (2009) 35 *American Journal of Law and Medicine* 2, 323-350.

The grant of patent represents a social contract between society and the inventor, where society offers exclusive rights to patentees in exchange for the release of an invention of social value.[57] This supports the view that patentees share the benefit of their invention with society. The local working requirement necessitates that the patent holder manufactures the invention, or similarly, applies the patented process within the country granting the patent in order to maintain its exclusive rights.[58] Prior to TRIPS, local working requirements of patents were a feature of national IP laws.[59]

However, this has become contentious after TRIPS, particularly, at a time LDCs are facing a high burden of diseases and a lack of essential medicines. Failure to work the patent locally is regarded as an abuse by the patentee of its exclusive rights.[60] The Paris Convention (1883) envisaged the provision for Member States to take legislative measures for the grant of compulsory licensing to prevent abuses that might result from the exercise of exclusive rights conferred by patents. Article 5(A)(2) states that:

> Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses, which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.[61]

Therefore, compulsory licensing remains a significant mechanism for governments to intervene in the event that a patent holder refuses to work the patented invention locally.[62] The Paris Convention did not limit the grant of compulsory licences but prescribed in Article 5(A)(4), a minimum period of 3 or 4 years before compulsory

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[57] Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (Cambridge University Press, 2010) See Chapter 11: Reclaiming the Patent Social Contract, pp. 285-317.
[58] Bryan Mercurio, Mitali Tyagi, Treaty Interpretation in WTO Dispute Settlement: the Outstanding Question of the Legality of Local Working Requirements (2010) 19 Minnesota Journal Of International Law 3, 275-326.
[59] Ibid 13, see Section 84(1) of the Indian Patent Act, 1970
[60] Michael Halewood, Regulating Patent holders: Local Working Requirements and Compulsory Licences at International Law (1997) 35 *Osgoode Hall Law Journal* 2, 243-284.
[61] The Paris Convention for the Protection of Industrial Property was signed on March 20, 1883 and was revised on various occasions, the last of which was on September 28, 1979.
[62] Joseph Yosick, Compulsory Patent Licensing for Efficient use of Inventions (2001) 2001 *University of Illinois Law Review* 5, 1275-1304.

licensing may be applied.[63] Also, what constitutes an abuse, and the failure to work was a matter for member countries to determine. Notably, Article 5(A)(2) of the Paris Convention remains relevant to the TRIPS Agreement, in reference within Article 2(2) of TRIPS, which consolidates the obligation that binds Member States under the Convention that explicitly grants a right to make use of local working requirements. Hence, legislation requiring local working of patents would not violate any provision of TRIPS in light of Articles 7, 8 and 30 of the TRIPS Agreement.

Exploitation of local working requirements of patents by India and Brazil

Section 84 of the Indian Patent Act of 1970 (as amended) allows for the grant of compulsory licensing. The Controller of Patents have the power to grant a compulsory licence to any interested person after the expiry of 3 years from the grant of a patent to a patentee.[64] In the Natco v Bayer case, the patentee, Bayer Corporation, held the rights to a patent for a cancer medicine, sorafenib tosylate, otherwise marketed as Nexavar. Natco Pharma, an Indian generic medicines manufacturer, approached Bayer for a voluntary licence, which was denied. Subsequently, Natco applied for a compulsory licence before the Controller of Patents, which resulted in the grant of it in 2011.[65]

Bayer however, filed a petition with the Intellectual Property Appellate Board (IPAB) to order a stay on the compulsory licence, but was dismissed accordingly.[66] IPAB upheld the decision of the Indian Controller of Patents on grounds of reasonable public interest, the local working requirement, and the reasonable affordability of the patented product in India. IPAB reasoned that Bayer had failed to manufacture Nexavar locally in accordance with Section 83(f) requiring patentees to work a patented invention in India

[63] Susan Vaughan, Compulsory Licensing of Pharmaceuticals under TRIPS: What Standard of Compensation (2001) 25 *Hastings International & Comparative Law Review* 1, 87-110.
[64] Chapter XVI Working of Patents, Compulsory Licensing and Revocation. See Sections 85 & 88 Revocation of Patents and the Powers of the Controller for the granting of patents for non-working. Available at <http://www.ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf> retrieved 9/10/2013.
[65] *Natco Pharma Ltd v Bayer Corporation*: The Compulsory Licensing Application No. 1 in respect of patent No. 215758, 2011.
[66] Intellectual Property Appellate Board (IPAB) of India Order No. 223: M.P.Nos.74 to 76 of 2012 & 108 of 2012 in OA/35/2012/PT/MUM, 14 September 2012. Available at: < http://keionline.org/sites/default/files/ipab-chennai-order-BayervsNatcoCL.pdf> Retrieved 20/6/203.

or licence another to do so. In addition, it upheld the Controller of Patent's decision that the patentee (Bayer) was importing the patented product (Nexavar) to India contrary to 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".[67] To this end, Bayer has failed to meet the local working requirements of a patent granted in India. Likewise, the prices were so high that it was not affordable to the public, which in essence, defeats the purpose of reasonable requirements of the public in Section 84(5) of the Patent Act.

Similarly, in 1996, Brazil pioneered the promulgation of a post-TRIPS era compulsory licensing regime as part of its health intervention policy to contain the HIV/AIDS epidemic with affordable medicines.[68] Brazil invoked Article 68(1)(i) of the Industrial Property Law, which allows the government to grant compulsory licensing upon a failure of a patentee to meet the local working requirement of the patented invention. This includes the failure to work the subject matter on the territory of Brazil, failure to manufacture or incomplete manufacture of the product, and the failure to completely use a patented process locally.[69] To this end, the actions of both Brazil and India to utilise compulsory licensing facilitated the local manufacture of essential medicines and secured large discounts on the prices of essential medicines.[70]

Local working requirements of pharmaceutical patents in SSA

[67] Ibid 66: See paragraph 29 of the IPAB Decision. See Also Peter Roderick, Allyson Pollock, India's Patent Laws Under Pressure (2012) 380 *The Lancet* 9846, 2-4.

[68] National STD and AIDS Program (NAP) of Brazil 1986; Brazil Law No. 9313 of 13 November 1996 on free antiretroviral medicines for HIV/AIDS patients. Brazil Law No. 7606 of 8 September 1988 extending specified benefits to HIV/AIDS patients. See Julian Cohen, Kristina Lybecker, AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health (2005) 28 *Journal of the World Economy* 2, 211-230. See Also Alan Berkman, Jonathan Garcia, Miguel Munoz-Laboy, Vera Paiva, 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, 1162-1172.

[69] Ibid 13, Section III of the Brazilian Industrial Property Law 1996. See Presidential Decree of Brazil on Compulsory Licensing (Decree No 3,201/99, October 6, 1999: amended by Executive order (Decree) 4,830/03). See Also Paul Champ, Amir Attaran, Patent Rights 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, 365-390.

[70] Thomas Eimer, Susanne Lutz, Developmental States, Civil Society, and Public Health: Patent Regulation for HIV/AIDS Pharmaceuticals in India and Brazil (2010) 4 *Regulation & Governance* 2,135-153.

The pharmaceutical industry maintains that the innovation of medicines is complex, which requires substantial investment; hence, a reasonable patent protection is necessary to compensate for high development costs of essential medicines.[71] Thus, countries wishing to attract pharmaceutical investments need to have strong patent protection.[72] Consequently, conditions in SSA do not compare well with other potential investment destinations deemed attractive to the pharmaceutical industry on a belief that the costs of investments could not be easily recouped.[73]

It is on this basis that the pharmaceutical industry has failed to work patents or manufacture medicines for diseases that affect the continent locally, as a result, SSA countries regularly import their essential medicines need. This is in contrast to the general principle of local working requirements. This situation has however; resulted in the persistent shortages of essential medicines, and where medicines are available they are high-priced.[74] Significantly, working patented inventions locally could stimulate access to affordable medicines.[75] Nevertheless, the institutional, economic, and the political strengths of individual SSA countries are not the same as Brazil and India, and given the hypothesis of this article, individual SSA countries are unable to implement local working requirement.

Compulsory Licensing under Article 31 of the TRIPS Agreement

A comprehensive framework developed under Article 31 of TRIPS governs compulsory licensing. The TRIPS Agreement does not use the exact term 'compulsory licensing'. However, Article 31 is entitled 'Other Use Without Authorization of the Right Holder',

[71] David Henry, Joel Lexchin, The Pharmaceutical Industry as a Medicines Provider (2002) 360 *The Lancet* 9345,1590-1595. See Also Michael Kremer, Pharmaceuticals and the Developing World (2002) 16 The Journal of Economic Perspectives 4, 67-90.
[72] Henry Grabowski, Patents, Innovation and Access to New Pharmaceuticals (2002) 5 *Journal of International Economic Law* 4, 849-860.
[73] *Strengthening Pharmaceutical Innovation in Africa* (Council on Health Research for Development (COHRED); Council on Health Research for Development (COHRED); New Partnership for Africa's Development (NEPAD) 2011). See Also Duff Gillespie, Elizabeth Maguire, Margaret Neuse, Steven Sinding, Joseph Speidel, The African Network for Drugs and Diagnostics Innovation (2004) 373 *The Lancet* 9674, 1495-1576.
[74] Michael Reich, The Global Drug Gap (2000) 287 *Science* 5460, 1979-1981. See Also World Medicines Situation Report, 2011(3rd Edn. World Health Organisation, WHO/EMP/MIE/2011.2.10).
[75] Ibid 58

and refers in its introductory clause to 'other use of the subject matter of a patent without the authorization of the right holder'.[76] Article 31 does not purport to limit the grounds on which compulsory licensing may be granted and leaves WTO Members with a broad scope and freedom to determine the grounds for issuing. It elaborates a detailed set of substantive and procedural conditions constituting minimum standards required of all WTO Members whose respective domestic legislation allows for the compulsory licensing of patented inventions.

These mandated conditions specify that applications for licences should be evaluated on a case by case basis; that applicants should first seek to obtain voluntary licensing from the right holder on reasonable commercial terms and conditions, and that such efforts have not been successful within a reasonable period of time. However, the prior negotiations requirement may be waived in cases of national emergency or other circumstances of extreme urgency, and in cases of public non-commercial use. Also, the authorization to use the patented invention should be non-exclusive,[77] non-assignable, and predominantly for the domestic market.[78] In addition, right holders should receive adequate remuneration, taking into account the economic value of the authorization.[79]

Reform of TRIPS Article 31 on compulsory licensing

Doha Declaration on the TRIPS Agreement and Public Health

In view of TRIPS Article 31(f), which states that products made under compulsory licensing must be predominantly for the supply of the domestic market, some LDC governments have been unsure how this flexibility would be interpreted and, in particular, how far their right to use the TRIPS flexibilities would be respected following the lawsuit in South Africa.[80] Prior to the amendment, Article 31(f) requirement

[76] "Other use" refers to use other than that allowed under Article 30. See Part II of the TRIPS-Standards concerning the availability, scope and use of IPRs.
[77] TRIPS Article 31(d)
[78] TRIPS Article 31(f)
[79] Ibid 49, See Also Anthony Taubman, Rethinking TRIPS: "Adequate Remuneration" for Non-Voluntary Patent Licensing (2008) 11 *Journal of International Economic Law* 4, 927-970.
[80] Patrick Marc, Compulsory Licensing and the South African Medicine Act of 1997: Violation or Compliance of the Trade Related Aspects of Intellectual Property Rights Agreement (2001) 21 *New York Law School Journal of International & Comparative Law* 1, 109-125. See Also Duane Nash, South

hampered the LDCs' ability to avail themselves of compulsory licences to import sufficient quantities of quality essential medicines in the absence of sufficient manufacturing capacity.[81] The African Group was among the Members of the WTO who demanded a clarification to ensure that the TRIPS Agreement did not weaken Members' rights to formulate their own policies in respect of public health.[82] It was this call that brought about the reform of Article 31(f) of TRIPS.

The Doha Declaration on TRIPS and Public Health was adopted on 14 November 2001 during the 4th Ministerial Meeting of the WTO in Qatar.[83] The Declaration has provided an understanding of the purpose of TRIPS that informs the interpretation of its provisions in line with public health objectives.[84] It reflects the aim of promoting a balanced interpretation and the implementation of the relevant provisions of TRIPS in a manner that is supportive of WTO Members' right to protect public health in line with Article 8(2) of TRIPS.[85] The Declaration affirmed that WTO Members have the right to adopt necessary measures, in particular, the grant of compulsory licensing for the promotion of essential medicines.[86]

The WTO Paragraph 6 programme

Paragraph 6 of the Doha Declaration on TRIPS and Public Health recognized the problem that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under TRIPS. Therefore, the TRIPS Council were instructed to find an expeditious solution to

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Africa's Medicines and Related Substances Control Amendment Act of 1997 (2000) 15 *Berkeley Technology Law Journal* 1, 485-504.

[81] Sandra Bartelt, Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health (2003) 6 *The Journal of World Intellectual Property* 2, 283-310.

[82] Statement by the Africa Group on TRIPS and Public Health (Informal Session of the WTO TRIPS Council, 25 July 2001, IP/C/W/296). Available at: < http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm> Retrieved 10/7/2013.

[83] Ibid 6

[84] Jacques Bourgeois, Thaddeus Burns, Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health (2002) 5 *The Journal of World Intellectual Property* 6, 835-864.

[85] Ibid 3

[86]Frederick Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health* (Quaker United Nations Office (QUNO), Occasional Paper 9, February 2002).

this problem and report to the General Council before the end of 2002. This informed the WTO Decision of 30 August 2003 for the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.[87] This decision waived the obligations of exporting WTO Members under Article 31(f) of the TRIPS Agreement with respect to the grant of a compulsory licence to the extent necessary for the purposes of manufacturing, and the exportation of pharmaceutical products to eligible WTO importing Members with insufficient or no manufacturing capacity.[88] This was followed by the amendment of Article 31(f) of TRIPS implementing the 30 August 2003 Decision permanently in 2005.[89]

Importantly, Paragraph 3 of the Declaration acknowledges the concerns over the influence of patents on the prices of essential medicines. Paragraph 4 provides for a precise interpretation such that any measure that is necessary to protect public health cannot be held to infringe the provisions of TRIPS in order to allow Members to fully use the TRIPS flexibilities to promote access to medicines. It stipulates that:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

Paragraph 5(a) confirms that the TRIPS Agreement should be interpreted in the light of its objectives as enumerated in Article 7 of TRIPS. Paragraph 5(b), lays out the key measures and flexibilities provided by TRIPS: "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted". Paragraph 5(c) refers to Article 31(b) of TRIPS, making clear that the definition of the terms 'national emergency' and 'other circumstances of extreme

[87] Ibid 7

[88] Duncan Matthews, WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem? (2004) *7 Journal of International Economic Law* 1, 73-107. See Also Jessica Greenbaum, TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of Paragraph 6 Waiver (2008) 25 *Journal of Contemporary Health Law & Policy* 1, 142-165.

[89] *TRIPS General Council, Amendment of the TRIPS Agreement* (Decision of 6 December 2005, WT/L/641).

urgency' is up to Members' discretion. This statement does not provide for any substantive modifications of TRIPS but only reiterates what is already stipulated therein.

PART III

THE OPERATIONAL SHORTCOMINGS OF THE WTO PARAGRAPH 6 PROGRAMME IN SSA

Introduction

The Article 31bis amendment to the Article 31(f) of the TRIPS Agreement was in response to the call to facilitate the manufacture and the exportation of essential medicines to LDCs.[90] The Doha Declaration on TRIPS and Public Health was accepted in good faith by the international community believing that the WTO had finally acknowledged the difficulties LDCs face in balancing their public health needs with access to medicines.[91] Moreover, despite the WTO clearing the way for the use of the Doha Paragraph 6 programme to facilitate the implementation of compulsory licensing for essential medicines, Rwanda is the only country in SSA able to actually avail itself of the mechanism.[92]

The US and the EU, through bilateral free trade agreements (FTAs) have used their economic and political strengths to deter SSA countries from resorting to compulsory licensing for essential medicines. [93] Also, mindful of foreign direct investment (FDI) and access to the lucrative markets of the EU and the US, SSA countries have been reluctant to invoke the flexibilities in the negotiation of FTAs.[94] In the end, the implementation of the Doha Paragraph 6 programme for the compulsory

[90] See Generally Kevin Outterson, *Disease-Based Limitations on Compulsory Licences under Articles 31 and 31bis* (Research Handbook on Intellectual Property Law and the WTO, Carlos Correa, ed., Edward Elgar, 2009).
[91] Carlos Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (World Health Organization, Essential Drugs and Medicine Policy, 2002).
[92] George Tsai, Canada's Access to Medicines Regime: Compulsory Licensing Schemes Under the WTO Doha Declaration (2009) 50 *Virginia Journal of International Law* 1, 1064-1090.
[93] Ibid 16
[94] Robert Bird, Daniel Cahoy, The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach (2008) 45 *American Business Law Journal* 2, 283-330. See Also Susan Rose-Ackerman, Jennifer Tobin, *Foreign Direct Investment and the Business Environment in Developing Countries: The impact of Bilateral Investment Treaties* (Yale Law & Economics Research Paper 293, 2005).

licensing of affordable medicines has been rendered almost useless. This part of the article analyses the practical and technical shortcomings surrounding the operations of the WTO Doha Paragraph 6 programme not only from the viewpoint of internal capacity constraints but also from the perspective of political forces driving TRIPS-plus.

Institutional immaturity and the absence of technical expertise in SSA

After the Doha Declaration on TRIPS and Public Health, individual SSA countries declared their intention to incorporate the TRIPS flexibilities into their domestic legislation in order to facilitate the grant of compulsory licensing in accordance with TRIPS.[95] Nonetheless, no matter how individual SSA countries amend their IP laws with the view to exploit the flexibilities, such national measures would have little impact on their ability to grant compulsory licensing for access to medicines. This is because the flexibilities are difficult to implement in the region, and various reasons inform this difficulty.

Significantly, two levels of constraints are currently at the heart of the failure of SSA countries to exploit the TRIPS flexibilities to obtain compulsory licensing for the manufacture of affordable medicines. Firstly, the principal reason is due to the absence of technical expertise.[96] Secondly, in the absence of legal expertise, policymakers lack the capacity to build an adequate legal and institutional infrastructure to implement the flexibilities in their domestic legislation because they lack practical understanding of the ways in which they might exploit the flexibilities.[97] Thirdly, threats of economic sanctions from leading developed countries often intimidate SSA countries from implementing TRIPS flexibilities.[98] Most importantly, their attempt to exploit the

[95] The AU Conference of Ministers of Health undertook to make use of the Doha Declaration on the TRIPS and Public Health to pursue the Local Production of Generic Medicines (Gaborone Declaration CAMH/Decl.1(II) 3 (10-14 October 2005).
[96] Tenu Avafia, Jonathan Berger, Trudi Hartzenberg, *The Ability of select sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries* (UNCTAD/ICTSD Project on IPRs and Sustainable Development, 2006).
[97] Human Development Report, *Making New Technologies Work for Human Development* (The United Nations Development Programme, published by Oxford University Press, 2001, Chapter 5, pp. 107).
[98] Ibid 39

flexibilities has come into conflict with provisions of TRIPS-plus bilateral trade agreements and the major pharmaceutical industry.[99]

Substantively, the patent laws of the developed countries continue to shape the national patent systems of SSA countries.[100] These are often based either upon laws made with the help of technical assistance from the World Intellectual Property Organization (WIPO) or the patent offices of developed countries.[101] Significantly, most of the technical assistance that has gone to these countries is more concerned with the strict compliance of patent provisions in the interests of the rights holders rather than the application of the flexibilities within the TRIPS Agreement to facilitate affordable medicines for public health protection.[102]

Bilateral and regional trade agreements

In a broader historical context, the increasing use of TRIPS-plus standards suggests that bilateral and regional FTAs rather than the multilateral forum of the WTO remains the preferred platform whereby the US seek to advance the protection of IP belonging to its corporations. These agreements are a direct reflection of key US domestic legislations meant to protect its economic interest.[103] While on its face, these agreements offer the

[99] Carlos Correa, Investment Protection in Bilateral and Free Trade Agreements: Implications for the granting of Compulsory Licences (2004) *26 Michigan Journal of International Law* 1, 331-353.

[100] For Example a three-day conference on IP enforcement planned for 3-5 April 2012 in Cape Town, South Africa, entitled: Africa Intellectual Property Forum: Intellectual Property, Regional Integration and Economic Growth in Africa was postponed indefinitely by WIPO due to protest it lack developmental agenda. See A letter written on the 7th February 2012, addressed to WIPO Director General Francis Gurry, 'Africa IP Summit: Lacking a Development Dimension' signed by 86 Global NGOs and 14 Academics. Available at: >http://www.ghwatch.org/sites/www.ghwatch.org/files/AfricaIPSummit2012_0207.pdf> Retrieved 21/10/2013. Also published by William New of the Intellectual Property Watch on 12 February 2012, under the headline: US, WIPO Training Program On IP Rights In Africa Comes Under Fire.

[101] Following the proposal by Argentina and Brazil on the need for capacity building WIPO General Assembly adopted 45 recommendations in 2007, WO/GA/31/11. (Out of the 111 original proposals made by the Provisional Committee on Proposals related to the WIPO Development Agenda (PCDA). Available at: < http://www.wipo.int/ip-development/en/agenda/recommendations.html> Retrieved 18/10/2013.

[102] Ibid 57, See Also 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, Washington D.C. 2001). See Also Gregory Shaffer, Can WTO Technical Assistance and Capacity Building serve Developing Countries? (2005) 23 *Wisconsin International Law Journal* 4, 643-686.

[103] The specific objectives for IP in the Trade Act of 2002 (Pub. L. 113-31) were spelled out in 19 USC § 3802 (b)(4) as important negotiating objective for the US. The power to conclude trade agreements 'Trade Promotion Authority' or so called 'fast track' emphasizes the need for the promotion of an IP regime that 'reflect(s) a standard of protection similar to that found in United States law'. See Section (A)(i)(II), in

prospect of market access to SSA countries; they take away key flexibilities from countries.[104] The inability of SSA countries to implement the TRIPS flexibilities to obtain affordable medicines is due to incompatible provisions in regional FTA, which prevent countries from doing so; and a classic example is Ghana.[105] This is contrary to the conventional view that a regional FTA offers an overriding opportunity to mitigate most of the socio-economic problems faced by SSA countries.[106]

The resulting opportunity for market access means African policymakers' are not able to pay detailed attention to the TRIPS-plus provisions, and how such agreements would restrict access to essential medicines. Notwithstanding, the criticism of the US on the use of TRIPS-plus standards to rebalance its trade interest to the detriment of SSA signatories,[107] it must be noted, however that SSA countries do not hesitate to trade off the stringent enforcement of IPRs in exchange for market access for their exports. This is clearly evident from the willingness on the part of SSA countries to negotiate in spite of concerns raised by observers on the impact of TRIPS-plus provisions on the implementation of the TRIPS flexibilities.[108]

African Growth and Opportunity Act, 2000

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particular, instructing United States Trade Representatives (USTR) to seek IPR provisions that reflect a "standard of protection similar to that found in United States law."

[104] Peggy Chaudhry, Changing levels of Intellectual Property Rights Protection for Global Firms: A Synopsis of recent US and EU Trade Enforcement Strategies (2006) 49 *Business Horizons* 6, 463-472.

[105] Between 2000 and 2005 Ghana tried unsuccessfully to import affordable medicines from India after signing the AGOA initiative. This is because as part of the spirit of AGOA Ghana must procure its essential medicines from US Pharmaceutical Corporations. Given the high costs involved in the importation of patented medicines from the US instead of India, the Ghanaian Ministry of Health issued a compulsory licensing for (HIV/AIDS) Antiretroviral medicines in line with Section 13 of the Patent Act (Act 657) 2004. Available at: <http://www.cptech.org/ip/health/cl/Ghana.png> Retrieved on 10/9/2013. The purpose of this licence was non-commercial, because it served as a basis for the procurement of medicines for the national HIV/AIDS programme. Since the Government of Ghana had declared an emergency situation with respect to the HIV/AIDS situation in the country, there was no need to negotiate for a voluntary licence from the patent holder prior to the grant of the compulsory licence. However, given the political pressure on Ghana as part of its obligation under AGOA the country abrogated its plan to implement the compulsory licensing.

[106] Federal officials have asserted that the AGOA initiative would increase FDIs; create jobs; increase government revenue, and the industrialization of the continent. For Example, Carrie LaCrosse, *AGOA IPRs Session Highlights Importance of IP Protection for African Business* (U.S. Department of State, Office of Intellectual Property Enforcement, Volume 3: No. 1 January 2010).

[107] Jean-Frederic Morin, Multilateralizing TRIPS-Plus Agreements: Is the US Strategy a Failure? (2009) 12 *The Journal of World Intellectual Property* 3, 175-197.

[108] Ibid 17

The African Growth and Opportunity Act (AGOA) is part of the Trade and Development Act of 2000,[109] passed by the US Congress and signed into law on 18 May 2000.[110] The concept of AGOA is very simple; SSA countries would protect IPRs belonging to U.S. companies in exchange for market access to the U.S. AGOA extends liberal access to duty-free and quota-free exports into the US market by SSA countries.[111] Specifically, it moderately strengthens some of the Generalized System of Preferences (GSP) programmes,[112] which empowers the US President through the executive provisions to determine the eligibility of a country in SSA for additional preferential tariffs treatment.[113] The Act offers tangible incentives for SSA countries to continue their reform efforts to open their economies in line with US trade policy and the commercial direction of US corporations.

Since its implementation, AGOA has encouraged substantial investments in trade and, again, helped to promote the successful integration of the continent into the multilateral trading system, which has made SSA countries more attractive to commercial partners from the US.[114] The specific AGOA criterion for IP is found in Section 104, which authorizes the US President to designate a SSA country as a beneficiary of trade concessions if the President determines that such country has established or is making continual progress towards establishing, in particular, the elimination of barriers to US trade and investment, including the provision of national treatment and measures to create an environment conducive to domestic and foreign investment and the protection of IP - inter alia, the resolution of bilateral trade and investment disputes.[115]

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[109] Trade and Development Act of 2000, Pub. L. 106-200 (May 18, 2000).

[110] Section 506A(a) (1) of the Trade Act of 1974, as amended (the "1974 Act") (19 U.S.C. 2466a(a)(1)), as added by section 111(a) of the African Growth and Opportunity Act (title I of Public Law 106-200).

[111] Section 112(c) of the AGOA, as added in section 6002 of the Africa Investment Incentive Act of 2006 (Division D, title VI of Public Law 109-432) (19 U.S.C. 3721(c)), provides special rules for certain apparel articles imported from lesser developed beneficiary sub-Saharan African countries.

[112] Generalized System of Preferences program, Title V of the Trade Act of 1974, as amended, 19 USC 2461.)

[113] Country eligibility criteria under the AGOA: Section 104 of the Trade and Development Act of 2000 under Subtitle A and Section 111 of that Act under Subtitle B in effect amending the GSP Act consolidating AGOA to GSP via Section 506A.

[114] Vivian Jones, Brock Williams, *US Trade and Investment Relations with sub-Saharan Africa and the African Growth and Opportunity Act* (Congressional Research Service Report RL31772, November 14, 2012).

[115] See Section 104 (a)(1)(C)(ii) of AGOA.

Section 111 of the AGOA, which is a direct reflection of Section 506(A) of the GSP Act, stipulates the strengthening of IPRs protection for US firms in accordance with sub-paragraph (5) of Section 502(C) of the Trade Act 1974 as a fundamental requirement for designating countries as beneficiaries.[116] The vast majority of SSA countries have embraced AGOA except that the initiative has prevented them from exploiting the TRIPS flexibilities since; at the heart of AGOA is the enforcement of higher IP standards beyond what was agreed in TRIPS.[117] The AGOA enterprise is scheduled to expire in September 2015, exactly three months before LDCs enforce TRIPS pharmaceutical patents.[118]

The threat of pharmaceutical industry lawsuits

Ghana and the GlaxoSmithKline case

Due to the spread of HIV/AIDS in the late 1990s, the health authorities in Ghana tried urgently to contain the HIV/AIDS epidemic with the importation of affordable anti-retroviral medicines from India.[119] About five per cent of the Ghanaian adult population was tested positive for this disease,[120] and virtually the majority of these patients were unable to afford life extending HIV/AIDS medication because the medicines were priced out of their reach.[121] As a result, a Ghanaian medicines distributor, Healthcare Pharmacy, secured a low-cost generic supply agreement with Cipla, an Indian generic medicines manufacturer for Duovir, combination copies of zidovudine+lamivudine, which was a

[116] AGOA authorizes the President to designate a country listed in section 107 of the AGOA (19 U.S.C. 3706) as a beneficiary SSA country if the President determines that the country meets the eligibility requirements set forth in section 104 of the AGOA (19 U.S.C. 3703), as well as, the eligibility criteria set forth in section 502 of the Trade Act, 1974 (19 U.S.C. 2462).

[117] Julian Cohen-Kohler, Lisa Forman, Nathaniel Lipkus, Addressing Legal and Political Barriers to Global Pharmaceutical Access: Options for Remedying the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Imposition of TRIPS-plus Standards (2008) 3 *Health Economics, Policy and Law* 3, 229-256. See also Katrina Manson, *US Seeks Better Access to Africa as Part of AGOA Review* (Financial Times, Monday, 12 August 2013).

[118] See Ibid 10. Also on 18 November 2009, and during the 1st Session of the 111th Congress Senator Bill McDermott one of the architects of the AGOA legislation and a leading sponsor of US Trade Bills introduced Bill H. R. 4101 (New Partnership for Trade Development Act of 2009), which seek to extend AGOA to the end of 2019 provided that there is a successful conclusion of the WTO Doha Development Agenda Round of Negotiations before the end of 2015.

[119] *HIV/AIDS in Ghana: Background, Projections, Impacts, Interventions, and Policy* (3rd Edn. National AIDS/STI Control Programme-Disease Control Unit: Ministry of Health, 2001). See Also Ghana Population and AIDS Programme (Ministry of Health, 1993).

[120] *The AIDS Situation in Ghana: Document Prepared For Parliament* (Ministry of Health, 1993).

[121] *The Medium Term Plan for the Prevention and Control of AIDS in Ghana* (MOH/WHO/GPA, 1989-93).

generic version of Combivir. In 2000, a consignment of Duovir totalling US$ 16,000 was shipped to Ghana at a cost of 90 cents per pill, as opposed to about $10 per pill for the same in the US. GlaxoSmithKline (GSK) claimed that it had exclusive patent rights in Ghana covering active pharmaceutical formulations of AP11, AP136, AP162, AP300 used in the manufacturing of Duovir, as well as patent rights to the brand name Combivir in the US.

As a result, GSK tried to block Cipla (India) from manufacturing for export and Healthcare Pharmacy (Ghana) from importation and distribution of the same. To this end, the then head of the Global Intellectual Property Office at GSK, in a letter dated 10 August 2000, ordered Cipla to stop manufacturing Duovir for export to Ghana.[122] The letter warned that the manufacture of Duovir for export to Ghana by Cipla or any of its affiliates represented an infringement of GSK's exclusive patent rights. Also, in November 2000 GSK intimidated Healthcare Pharmacy (Ghana) with a legal action if it continued to import Duovir.[123] Cipla was left with no practical option but to stop the manufacture and exportation of Duovir accordingly, which left Ghana without lifesaving medicines for its HIV patients.[124] Prior to this on 18 October 1998, GSK, which controlled more than one-third of the HIV antiviral medicines market, was nonetheless a principal claimant in a lawsuit against the government of South Africa over Section 15(c) of the Medicines and Related Substances Control Amendment Act, No. 90 of 1997.[125]

[122] See copy of letter. Available at: <http://www.cptech.org/ip/health/africa/glaxocipla08102000.html> and a similar letter on Uganda at: <http://www.cptech.org/ip/health/africa/glaxocipla11202000.html> Retrieved 23/10/2013.

[123] Mark Schoofs, *Glaxo attempts to block Access to Generic AIDS Drugs in Ghana* (Wall Street Journal, Friday 1st December 2000).

[124] Dr Yusuf Hamied, CEO of Cipla letter to GSK. Available at: <http://www.thebody.com/content/art1606.html> Retrieved 12/7/2013.

[125] There have been concerns that some pharmaceutical corporations have adopted consistent intimidations to keep affordable generic medicines out of the hands of patients in SSA. For example, objecting to many of the provisions included in the South Africa's Act, 90 of 1997, which seeks to amend the Section 15(c) of the Medicines and Related Substances Control Act, No. 101 of 1965, about 40 pharmaceutical companies filed suit at the Pretoria High Court to block the legislation arguing that it violated the TRIPS Agreement. 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> Retrieved on 3/7/2013. See Also Craig Smith, Anne Duncan, GlaxoSmithKline and Access to Essential Medicines (2009) 2 *Journal of Business Ethics Education* 1, 123-132.

PART IV

OVERCOMING THE OPERATIONAL SHORTCOMINGS OF THE WTO PARAGRAPH 6 PROGRAMME IN SSA

Introduction

As seen from earlier discussion, the TRIPS Agreement leaves WTO Members some flexibility to integrate public health concerns into their IP regimes in order to adopt appropriate measures to protect public health. In particular, Article 31 expressly allows the granting of compulsory licences, also confirmed by the Doha Declaration on the TRIPS Agreement and the Public Health. It clarified that TRIPS did not and should not prevent Members from taking measures to protect public health. Accordingly, the Doha Declaration on TRIPS and Public Health reiterated the need to interpret and implement TRIPS in a manner supportive of WTO Members' right to promote access to medicines for public health protection.

Furthermore, as examined earlier, the political considerations tending to dominate the increasing use of the political pressures has drastically reduced the use of the TRIPS flexibilities for public health matters. As a result, the ability of the LDCs in SSA to implement national initiatives to promote access to affordable medicines has been eroded by the complex provisions of FTAs. This is because the protection of patents remains an overriding objective in FTAs, where mostly, the leading developed countries seek this forum to have their interests broadened while limiting the grants of compulsory licences. Nonetheless, a number of developing countries, including Brazil, and India have successfully implemented national measures on compulsory licences to facilitate a considerable reduction in the prices of essential medicines.

Given the inability of individual SSA countries to implement compulsory licensing, this part of the article explores a regional system for the compulsory licensing as a vital tool to overcome the operational shortcomings of the WTO Paragraph 6 programme. This exploration has become important given that the compulsory licensing by SSA countries will not provide a suitable means of procuring essential medicines for distribution in view of their individual economic and political constraints. Therefore, this

part of the article contends that the legal complexity surrounding the inability of the LDCs in SSA to exploit the TRIPS flexibilities could be overcome if countries were to adopt a common regional legal infrastructure.

Therefore, a regional system for compulsory licensing is required in order to procure and distribute essential medicines within the SSA countries. Moreover, while this part briefly assesses the operational failures of the previous pooled procurement schemes in SSA, it recommends a regional arrangement on a pharmaceutical compounding programme that is consistent with the hypothesis of this article. It then explains its opportunities as a pooled manufacturing scheme for the distribution of essential medicines within SSA.

The operational failures of the pooled procurement approaches in SSA

Almost 26 years ago the United Nations International Children's Emergency Fund (UNICEF) and the World Health Organisation (WHO) invited some African Health Ministers to Bamako, Mali in order to try to improve access to essential medicines and health services.[126] The Bamako Initiative (BI) was based on the realisation that, despite accepting in principle the core tenets of comprehensive 'Health for All' concept formalized 9 years earlier at the 1978 Alma-Ata Conference,[127] many SSA suffered from a lack of resources and practical implementation strategies.

At the core of the initiative was the willingness to increase access to primary health care by raising the effectiveness, efficiency, financial viability, and the equity of health services in order to implement an integrated minimum health-care focusing on delivery of essential medicines. This strategic direction resulted in several approaches to pooled procurement among SSA countries with the aim of facilitating a reliable supply of quality affordable medicines for public health protection.[128] However, almost all the

[126] WHO Regional Committee for Africa, Thirty-seventh session Resolution AFR/RC37/R36 (Bamako Mali, 9-16 September 1987).

[127] 'Health for All' was proposed and was formally put forth in the 1978 WHO-UNICEF Alma-Ata Declaration. Declaration of Alma-Ata, International Conference on Primary Health Care, Alma- Ata, USSR, 6-12 September. 1978.

[128] This includes the African Association of Central Medical Stores for Generic Essential Drugs; the Dakar Declaration on African Association of Essential Drugs National Purchasing Centres; the East African Community (EAC) Pooled Procurement Programme; Pooled Procurement in East, Central and Southern

pooled procurement initiatives between the SSA countries were characterised by failure.[129]

There has never been a single, successful pooled procurement approach in SSA and, significantly, internal rather than external factors have led to such failures. These have included: institutional problems; poor management; the absence of technical capacity; excessive profit intention of pooled procurement schemes; the inability of governments to fulfil their financial commitments; failure to consider local manufacturing; and, the overreliance on philanthropy alone for the procurement of essential medicines. Despite these failures, many scholars still argue that pooled procurement among LDCs in SSA offers the real solution to the problem of access to medicine.[130]

Obtaining essential medicines with the regional system for compulsory licensing

A need for a regional arrangement on a pharmaceutical compounding programme

The manufacture of essential medicines locally is an important vehicle for LDCs to improve people's access to essential medicines.[131] It is on this basis that the Pharmaceutical Manufacturing Plan for Africa (PMPA) was endorsed to promote local manufacturing of essential medicines on the continent.[132] However, PMPA is not feasible for individual countries due to their weak market situations, and little political strength to

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Africa Communities (ECSA); and recently, the Southern African Development Community (SADC) Pooled Procurement for Essential Medicines and Health Commodities. See also The 2nd Ordinary Session of the Conference of African Ministers of Health (CAMH2), Theme: *"Sustainable Access to Treatment and Care for the Achievement of the Millennium Development Goals"* (Report of the Expert Consultation on Bamako Initiative on Essential Medicines, Gaborone Botswana, 10-14 October 2005: CAMH/EXP/7 (II)).

[129] The Southern African Development Community (SADC) Pooled Procurement for Essential Medicines and Health Commodities is in it early stages. See SADC, Pharmaceutical Business Plan 2007-2013. 27th June 2007. See Also The SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities, 2013-2017 (SADC Secretariat, September, 2012). Available at: < http://www.sarpam.net/wp-content/uploads/2012/12/SADC-PP-Strategy-16-11-12-final-English.pdf> Retrieved 19/10/13.

[130] Jerome Reichman, *Procuring Essential Medicines under the Amended Trips Provisions: The Prospects for Regional Pharmaceutical Supply Centres*-A Paper prepared for the Seminar on Intellectual Property Arrangements: Implications for Developing Country Productive Capabilities in the Supply of Essential Medicines (United Nations Conference on Trade and Development (UNCTAD) Geneva, Switzerland 18-20 October 2006).

[131] Warren Kaplan, Richard Laing, *Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines* (World Bank HNP Discussion Paper, 2005). See Also *Local Production for Access to Medical Products: Developing a Framework to Improve Public Health* (World Health Organization, 2011).

[132] The Pharmaceutical Manufacturing Plan for Africa (CAMH/Decl.1 (II) 13(ii)).

withstand the possible political pressures by the home governments of pharmaceutical industry. Importantly, given the failure of SSA countries to utilize pooled procurement schemes, as well as, the economic constraints hindering the efforts of individual countries to facilitate the distribution of essential medicines, a new regional collaborative action is essential, where policymakers must focus on straightforward cost-containment policy measures to realise essential medicines. Consistent with the hypothesis of this article, it is argued that a regional arrangement on a pharmaceutical compounding programme remains the only practical option capable of increasing the availability of affordable essential medicines in SSA. The regional pharmaceutical compounding programme is a pooled manufacturing system based on a voluntary but shared arrangement for the setting up of pharmaceutical plants across the various sub-regions of SSA in order to manufacture and supply essential medicines.

Reasons for stimulating pooled manufacturing of essential medicines

The global market failure regarding medicines for tropical diseases [133] makes SSA governments' active role in the pursuit of affordable medicines vital. Governments cannot afford to withdraw from innovative approaches that will deliver affordable medicines amidst the high burden of diseases coupled with the frequent shortages and high costs of essential medicines.[134] In order to facilitate affordable essential medicines in the wider interests of public health, essential medicines must be manufactured locally.[135] This is based on the assumption that their prices would be in line with the purchasing parity of the local population, far below the costs of medicines imported from the open

[133] Fifty-ninth session of the World Health Organization Regional Committee for Africa *"Tackling Negleted Tropical Diseases in the Africa Region"* (Provisional agenda item 8.8, AFR/RC59/10: 15 June 2009). See Patrice Trouiller, Els Torreele, Piero Olliaro, Nick White, Susan Foster, Dyann Wirth, and Bernard Pecoul, Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure? (2001) 6 *Tropical Medicine & International Health* 11, 945-951.

[134] World Health Report (World Health Organisation, 2011). See Levels and Trends in Child Mortality (United Nations Inter-agency Group for Child Mortality, 2012). See Also Colin Mathers, Ties Boerma, Doris Ma Fat, Global and Regional Causes of Death (2009) 92 *British Medical Bulletin* 1, 7-32.

[135] WHO-Regional Committee for Africa fifty-fifth session Resolution AFR/RC55/10, *Local Production of Essential Medicines, Including Antiretrovirals: Issues, Challenges and Perspectives in The African Region* (Provisional agenda item 8.4, Maputo, Mozambique, 22-26 August 2005). See Also *United Nations Global Project: Strengthening the Local Production of Essential Medicines in Developing Countries* (Volume 3, United Nations Industrial Development Organisation, November 2011).

market. Additionally, since the financial requirement for the setting up of manufacturing plants within SSA countries could entail huge overheads, a pooled manufacturing approach could assist countries to alleviate the lack of investment incentive while gaining economies of scale.

Moreover, at the practical level, it could help technology transfer and influence its application; particularly, the use of good manufacturing practice (GMP) for assured quality medicines. It is also a means of combatting the circulation of substandard and counterfeit medicines that endanger human lives, since a considerable amount of these harmful medicines are obtained from the importation of medicines. Significantly, stock-out and other supply interruptions are prevalent within the SSA health setting due to the reliance on the importation of essential medicines. Local, pooled manufacturing could rapidly facilitate the supply of medicines in times of public health crises. Furthermore, it would cater for orphan medicines that are not attractive to private pharmaceutical corporations or otherwise hard to obtain due to the small quantities required for addressing specific needs of diseases that disproportionately affect the region.

Conclusion

At a given point in a nation's economic development patents might be considered vital for pharmaceutical products innovation.[136] Notwithstanding they remain a major obstacle to making essential medicines available to the LDCs.[137] The burden of diseases within the LDCs has prompted several scholars to question the relevance of enforcing a global minimum standard for patents, which has proven to make it more difficult for LDCs to access medicines.[138] This debate has resulted in a renewed interest in the compulsory licensing of pharmaceutical patents, which now figures more prominently among

[136] Robert Merges, *Justifying Intellectual Property* (Harvard University Press, 2011). See Also Joan Busfield, Globalization and the Pharmaceutical Industry Revisited (2003) 33 *International Journal of Health Services* 3, 581-605.
[137] *Determining the Patent Status of Essential Medicines in Developing Countries* (Health Economics and Drugs EDM Series No. 17: World Health Organisation, WHO/EDM/PAR/2004.6).
[138] Peter Drahos, The Regulation of Public Goods (2004) 7 *Journal of International Economic Law* 2, 321-339. See Also Frederick Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health (2005) 99 *American Journal of International Law* 2, 317-358.

solutions being implemented in countries such as India.[139] Although the WTO affirmed in the Doha Declaration on TRIPS and Public Health that TRIPS permits compulsory licensing and Members have the discretion to grant such licences, to date, no successful compulsory licences have actually been granted in SSA.[140] The foregoing analysis has shown that this paucity is not as a result of the internal capacity constraints but is due significantly to threats of lawsuits by the pharmaceutical industry and economic sanctions by their home governments.

Given the legal and administrative complexity impeding individual SSA countries from the implementation of the TRIPS flexibilities, this article has revealed the need for a regional system for compulsory licensing in order to manufacture and distribute essential medicines according to need. Firstly, this system could simplify the complexity surrounding the exploitation of the TRIPS flexibilities, which would ensure considerably more legal certainty for countries. Secondly, compulsory licensing founded on a single country's legislative intervention is bound to face political pressures; this system could shield individual countries against the threat of lawsuits by the pharmaceutical industry and economic sanctions by their home governments. Additionally, given the economic constraints facing individual countries, this article has shown that a regional arrangement for a pharmaceutical compounding programme could facilitate the manufacturing and distribution of essential medicines within SSA.

[139] Enrico Bonadio, Compulsory Licensing of Patents: The Bayer/Natco Case (2012) 34 *European Intellectual Property Review* 10, 719-728. See Also Janice Mueller, Taking TRIPS to India: Novartis, Patent Law, and Access to Medicines (2007) 356 *New England Journal of Medicine* 6, 541-543.

[140] For a general discussion of the complexity of the TRIPS flexibilities See Cynthia Ho, *Complicated Compulsory Licences: The Waiver/Article 31bis 'Solution'* (Loyola University Chicago School of Law Research Paper No. 2011-032, 2011). See Also Christina Cotter, The Implications of Rwanda's Paragraph 6 Agreement with Canada for other Developing Countries (2008) 5 *Loyola University Chicago International Law Review* 2, 177-189.