Patents and the Trans-Pacifica Partnership: how TPP-style intellectual property standards may exacerbate the access to medicines problems in the East African community.

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Patents and the Trans-Pacific Partnership: How TPP-style Intellectual Property Standards may Exacerbate the Access to Medicines Problem in the East African Community

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Abstract

Least developed countries (LDCs) generally enjoy some exemptions under the WTO TRIPS Agreement. Despite these exemptions, patents continue to pose a major challenge to access to affordable medicines in the East African Community (EAC), especially with respect to the HIV/AIDS pandemic. The EAC is a regional economic bloc made up of 6 states, with 5 of the member states currently ranked as LDCs by the United Nations. This article argues that the implementation of the patent protection standards following the model adopted in the Trans-Pacific Partnership is likely to further exacerbate the access to medicines conundrum of the EAC.

1. Introduction

Since the adoption of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement), there has been a continuing debate on its implications for generic drug manufacturing and access to medicines, especially in developing countries. The TRIPS' patent regime makes it obligatory on all nations to grant patents in areas of technology that some nations did not offer patent protection for before its adoption (Rubinson 2017, p. 468). Before the entry into force of TRIPS, many nations did not offer patents for pharmaceuticals in order to promote low cost access to life-saving and life-enhancing drugs (Luo and Kesselheim 2015, p. 1563). With the advent of the TRIPS Agreement, all WTO member states became bound to maintain the standard of patent protection favoured by the most advanced countries that have the infrastructure to manufacture drugs and to sell them across the globe (Davis 2014, p. 187).

This article examines some of the challenges posed by the international intellectual property law regime embodied in the TRIPS Agreement to access to medicines in developing countries and LDCs. It also examines patent protection provisions of the Trans-Pacific Partnership (TPP) agreement and how they may impact the global access to medicines conundrum, especially in the East African Community (EAC). The article notes that while up to 80 percent of the EAC countries are legally exempted from implementing TRIPS until 2021 (WTO 2013) with an additional drug patent exemption until 2033 (WTO 2015), the benefits accruable from these exemptions are already circumscribed by the lack of pharmaceutical manufacturing capacity in the region. The article argues that the implementation of the provisions of the TPP, whether through its entry into force or the adoption of similar standards in subsequent regional trade agreements, is likely to further limit the ability of EAC states to have access to medicines. It thus observes that it is exigent for the region to begin to explore regional options for addressing this challenge.

The first part of the article presents a background to the TRIPS Agreement and its impact on access to medicines in developing countries. The article, thereafter, highlights how the Trans-Pacific Partnership Agreement has taken the standards of intellectual property protection beyond the TRIPS regime and the potential impact on countries outside the TPP, especially the least developed nations. It then proceeds to examine how the TPP may affect access to medicines in the East African Community, a regional trade bloc with an 80% LDC membership. The article concludes by

positing that the higher standards under the TPP may affect the flexibilities available to LDCs in the EAC under the TRIPS Agreement.

1.1. The TRIPS Agreement

The emergence of the TRIPS Agreement has been attributed to the dominant role of private actors consisting of pharmaceutical, entertainment, and software industries that are based in the U.S., Europe, and Japan (Sell 2003, p. 1-2). Susan Sell explained that these private actors '*worked together, exercised their authority and achieved a result that effectively narrows the options open to sovereign state firms, and extends the opportunities of those firms that succeed in gaining multilateral support for a tough global IP instrument*' (Sell 1999, p. 171).

During the TRIPS negotiations, the idea of intellectual property rights protection within an international trade regime was met with stiff opposition from developing countries such as Brazil and India who contended that such a regime would only impede trade through monopolistic practices (Dutfield 2009, p. 238). However, these countries were constrained to accept the 'TRIPS package' because they believed that the new arrangement, which eventuated in the emergence of the World Trade Organization, would offer them a potential market access advantage and compensate for the costs of implementing minimum IPRs protection (Dutfield 2009, p. 238). Besides, the formation of the World Trade Organization would shield them from any unilateral restrictive practice from developed countries (Dutfield 2009, p. 238). Thus, when concluded, the TRIPS Agreement requires member states to guarantee minimum standards of protection for intellectual property rights, including copyright and related rights, trademarks, patents, geographical indications, industrial designs, layout designs of integrated circuits, and confidential information (WTO TRIPS Agreement).

Developing countries argued during the debates for TRIPS conclusion that they were being asked to extensively protect intellectual property products produced by developed nations in a way that may be detrimental to their national interests (Gervais 2005, p. 507-508). To allay the fears of developing countries, the final text of the TRIPS Agreement reflects the flexibilities that may be resorted to, particularly where access to medicines poses a major public health challenge (Gervais 2005, p. 507-508). Apart from flexibilities such as the exhaustion of intellectual property doctrine and compulsory licensing, Article 65 of the TRIPS Agreement allowed a transitional period of 5 years from January 1, 1995 for developing countries already protecting products patents and 10

years for developing countries obliged by the TRIPS Agreement to extend product patent protection to fields of technology that were not patentable in their countries prior to its adoption. The TRIPS Agreement also granted least developed countries (LDCs) a transitional period of 11 years from January 1995 (10 years from the date of application of the TRIPS Agreement as defined under Article 65.1) to implement the substantive provisions of the Agreement in recognition of the significant administrative and financial costs such countries would incur in implementing the provisions of TRIPS (WTO TRIPS Agreement, Art 66.1).

In November 2001, the WTO Ministers adopted the Doha Declaration on TRIPS and Public Health which extended the deadline for least developed countries to introduce pharmaceutical patent protection to January 1, 2016 (WTO 2001). The transitional period for least developed countries to implement the substantive provisions of the TRIPS Agreement was later extended to July 1, 2013 following a request for extension by LDCs pursuant to Article 66.1 of the TRIPS Agreement (WTO 2005). On June 11, 2013, WTO members agreed to extend the transitional period for LDCs to implement the TRIPS Agreement to July 1, 2021 (WTO 2013). The Council for TRIPS, on November 6, 2015, further extended the drug patent exemption for LDCs to January 2033 (WTO 2015). Incidentally, on November 5, 2015, a day before the official extension of the drug patent deadline for LDCs to 2033, the text of the Trans-Pacific Partnership Agreement (TPPA), that was being clandestinely negotiated since the U.S. joined the TPP negotiations, was made public (Dolack 2015). As will be seen later in the article, the TPP contains patent protection standards that exceed those required by the TRIPS Agreement, especially in relation to patentability and test data protection, and these may further aggravate the global access to medicines challenge, even in countries that are not parties to the TPP. The relevant provisions of the TRIPS Agreement on the patentability of pharmaceutical products are discussed below.

1.2. Patents Protection under the TRIPS Agreement

Articles 27 to 34 of the TRIPS Agreement relate particularly to patents. Under Article 27 of the TRIPS Agreement, patents are to be available in all fields of technology without discrimination as to the place of origin or whether the inventions are worked locally, provided the inventions are new, involve an inventive step, and are capable of significant utility. It has been argued that since the TRIPS Agreement does not contain a definition of the criteria for patentability, it is open to member states to define these in line with national priorities and developmental goals (Azam

2014, p. 409; El Said 2010, p. 228). Novelty under the TRIPS Agreement requires that the invention should not be part of an existing invention and must possess an inventive step (WTO TRIPS Agreement, Art. 27). It also means that it must be one that is not ordinarily obvious to people skilled in the inventor's field of technology (Correa 2000, p. 60). The use of a strong standard for novelty and inventive step in determining the criteria for patentability is to ensure that the duration of patent protection does not get unduly prolonged by a subsequent patent from an inconsequential improvement (VanDuzer 2003, p. 33-34). The practice of extending patent protection by adding trivial improvements to existing patents is popularly known as evergreening (Banerjee 2013, p. 204). It has already been suggested that national governments should remove barriers to legitimate competition by developing guidelines for patent examiners on the implementation of patentability criteria, and changes could be made to national patent legislations where necessary (WHO 2006, p. 133).

Intellectual property protection generally involves continually achieving a balance of rights and obligations (WTO TRIPS Agreement, Art. 7). This explains why intellectual property rights, like most other rights, are subject to some exceptions and limitations. For instance, under Article 30 of the TRIPS Agreement, WTO member states may provide some limited exceptions to the exclusive rights conferred by patents provided they do not unduly conflict with the normal exploitation of the patent or prejudice the interest of the patent owner. The experimental use or Bolar exception may therefore be applied under Article 30 of TRIPS.

The Bolar exception derived its nomenclature from *Roche Prods., Inc. v. Bolar Pharm. Co., 733 F. 2d 858 (Fed. Cir. 1984),* where Bolar Pharmaceutical, a generic manufacturer, used the patented chemicals in experiments to determine the bioequivalence of Valium, a product patented by Roche Products. The experiments were carried out so that a generic version of Valium could be made by Bolar Pharmaceutical for FDA approval upon the expiration of the patent. Bolar contended that its action was not an infringement as public policy was in favor of generic manufacturing following the expiration of pharmaceutical patents. The U.S. Court of Appeals for the Federal Circuit in rejecting Bolar's contention held that the experimental use did not apply as Bolar’s use had a commercial purpose and any change to the law would have to be made by Congress. Congress subsequently passed a law allowing the use of patents products for experiments necessary for obtaining FDA approval through the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984.

Early working use has thus become more popular, and Bolar exceptions have become recognized in many jurisdictions. In *Canada--Patent Protection of Pharmaceutical Products* (WT/DS114/R) 28 for instance, the WTO Dispute Settlement Panel upheld the validity of the Bolar exception under the WTO Law. Commenting on the issue, Bryan Mercurio opined that Article 30 of TRIPS allows exceptions to patent rights for things such as 'research, prior user rights, and pre-expiration testing' (Mercurio 2005, p.1065). Article 30 thus covers the use of patented products in research or experiments for both scientific and commercial purposes, and it is therefore crucial to enhancing innovation, scientific progress, and the transfer of technology (Mercurio 2005, p. 1065).

Patents generally confer on the right holder an exclusive right to exploit the invention, including a right to exclude others from making or selling the products, importing for resale purposes, or use without the authorization of the right holder. This right is, however, subject to Article 6 of the TRIPS Agreement which explicitly provides that nothing in the Agreement shall be used to question member countries' use of the exhaustion doctrine. The exhaustion doctrine in intellectual property rights states that the right of an IP holder cannot be used to restrain the subsequent sale of the product after it has been sold by the right holder or under his authorization, as the act of selling the product by the right holder or with his authority entails the exhaustion of that right (WHO 2005, p. 240). There are three different types of exhaustion regimes. Exhaustion of rights could be a national exhaustion, a regional exhaustion, or an international exhaustion (Owoeye 2015a, p. 360). With respect to national exhaustion, the right is exhausted upon sale in a national market (Owoeye 2015a, p. 360). In a regional exhaustion regime, the right is exhausted upon sale in a regional market, while in respect to international exhaustion, the right is exhausted upon first sale in any market (McKeith 2013, p. 295-297). Under Article 6 of the TRIPS Agreement, countries have the right to determine the exhaustion regime that suits them, and this point has been further accentuated in the Doha Declaration on TRIPS and Public Health (WTO 2001). It has thus been suggested that developing countries should allow parallel imports whenever the rights have been exhausted overseas, and they should include provisions to facilitate parallel imports in their national legislations (Commission on Intellectual Property Rights 2002, p. 52).

A distinction can be drawn between product patents, which involve protection for the making of new things, and method or process patents, which have to do with new ways of doing or making known things (Hamilton 2010, pp. 167-168). Thus, while a product patent is only available to one

who invents something that was not previously in existence, a process patent is granted for new methods of manufacturing old or well-known things (Wojcik 1992, pp. 209-210). Article 27 (3) (a) of the TRIPS Agreement allows countries to completely exclude therapeutic methods for the treatment of humans from their patent systems. It has been argued that an invention for the therapeutic use of a chemical, which is the essence of pharmaceutical products, does not need to be granted patent protection under TRIPS having regards to the provision of TRIPS Article 27 (3) (a) (Davis 2014, p. 195). It is further argued that although therapeutic methods may be excluded from patent protection, the exclusion should not extend to products used in such methods (Davis 2014, p. 195-199). The provision relating to therapeutic methods is generally viewed entirely in the physical as against pharmaceutical terms (Davis 2014, p. 199). Therapeutic methods are therefore generally considered as pertaining to medical procedures like surgery or diagnosis which are addressed separately by TRIPS (WTO TRIPS Agreement 1994, Art. 27.3). The view that the use of a drug is a medical process is arguably recognized implicitly in the New Zealand case of *Wellcome Foundation, Ltd. v. Commissioner of Patents* [1983] NZLR 385 (CA). It is, however, doubtful if the case can be used to support the proposition that therapeutic methods include new methods or processes for making drugs.

Furthermore, it has been contended that the argument that therapeutic methods extend to methods of producing pharmaceutical products finds support in the fact that pharmaceutical companies normally refer to their drug process patents as 'therapeutic methods' in their patents application documents (Davis 2014, p. 200). It is argued that as most of the drugs used for treating HIV, malaria, and tuberculosis are method patents and not product patents. Excluding therapeutic methods from patent protection will effectively allow developing countries to get such drugs from the least expensive generic pharmaceutical manufacturer available without having to resort to the more expensive and cumbersome options of compulsory licensing and parallel importation (Davis 2014, p. 204).

While the argument that countries may exclude process or method pharmaceutical patents from patentability may sound attractive, the validity of the argument is highly suspect. It is indeed very doubtful if it can be rightly argued that the exclusion of new processes or methods of making drugs from patent protection is fully countenanced by the provision of the TRIPS Agreement, and it is beyond doubt that such an exclusion will be fiercely resisted by the pharmaceutical industry and countries with substantial pharmaceutical manufacturing interests.

The standards imposed by the TRIPS Agreement are generally considered to be too high, especially for least developed countries, and exemptions have been granted to such countries till 2033. Some free trade agreements, however, impose intellectual property protection standards that are higher than the TRIPS requirements. These TRIPS-plus provisions may have a significant impact on least developed countries despite the current exemption they enjoy under WTO law. A particularly relevant mega-regional agreement in this context is the Trans-Pacific Partnership Agreement (TPPA). The provisions of the TPP that are relevant to this discourse are examined below with a view to highlighting the potential consequences, in relation to access to medicines, in least developed countries that are not within its membership.

1.3. The Trans-Pacific Partnership and Implications for Access to Medicines

Even though the flexibilities available under the TRIPS Agreement may be helpful in promoting access to medicines, especially in developing countries, it is also important to note that a number of the available flexibilities under TRIPS stand the risk of being substantially whittled down by the TRIPS-plus provisions incorporated into free trade agreements that are constantly being negotiated across the globe by the United States and its various trading partners (Roffe and Spennemann 2006, p. 76). The Trans-Pacific Partnership (TPP) is a new free trade agreement that may pose serious challenges to access to patented pharmaceuticals, especially in relation to the provision of Article 18.37 (2) that tends to favor evergreening (Medicines Sans Frontieres 2012) and its stringent test data protection regime. The U.S. led TPP was negotiated by the U.S., Australia, Canada, New Zealand, Japan, Malaysia, Mexico, Peru, Vietnam, Chile, Brunei, and Singapore. The main objective of the TPP, as outlined in its preamble, is to deepen economic relations among contracting states and boost their economies. Under the Obama administration, the U.S. expected more countries to join the TPP, thereby increasing members' financial opportunities and access to a bigger market (Rajamoorthy 2013, p. 4-5). However, the U.S. withdrew from the TPP in January 2017 pursuant to an executive order made by U.S. President Donald Trump (Barlow 2017). While withdrawal of the U.S. is a major setback for the TPP, there are concerted ongoing efforts to make the deal effective for the remaining member states (Barlow 2017; Kyodo News 2017). It is reported that the remaining TPP countries may be considering a proposal to implement the TPP through the adoption of a separate protocol that makes the TPP binding on any country that agrees to it or by implementing it through the Regional Cooperative Economic Partnership currently being negotiated by the Association of Southeast Asian Nations (Kyodo News 2017). There is also a real

likelihood that the U.S. may pursue IP standards that are even higher than the TPP standards in its bilateral trade agreements with other nations (Lopert, Gleeson, and Kilic 2016).

The TPP intellectual property (IP) chapter has been a source of major controversy, particularly in relation to pharmaceutical patents and digitization (Patel 2015, p. 482). The TPP member nations aim to affirm the standards imposed by the TRIPS Agreement while at the same time expanding on the TRIPS standards (Office of the USTR 2011). It may be argued that the TPP seems to be designed to be a model or precedent for future trade negotiations and practices (Schwab 2012, p. 2-3). Under Article 18.6 of the TPP, parties to the TPP affirm their commitment to the Doha Declaration on TRIPS and Public Health and reiterate the position that nothing in the TPP intellectual property chapter should prevent the use of the TRIPS public health solution. Article 18.6 (c) of the TPP provides that where a waiver of any provision of the TRIPS Agreement enters into force with respect to any TPP member and the application of such waiver runs contrary to the TPP, the TPP parties shall immediately hold a consultation to adapt the TPP as appropriate to the new waiver.

Although the foregoing may seem to indicate that the TPP poses no further challenge to the TRIPS public health conundrum, the provisions of the TPP, when closely scrutinized, indicate that the TPP has clearly taken the level of patent protection beyond the scope of the TRIPS Agreement. Not less than five major TRIPS-plus provisions in the TPP are identified and discussed below. They include: evergreening, test data protection, patentability requirements, patent term adjustments, and provisions on biologics. The investor-state dispute provision is also briefly examined to highlight how it does not give much allowance for the use of national measures in pursuance of health objectives.

(a) Encouragement of Evergreening

Article 18.37 (2) of the TPP provides that 'each party confirms that patents are available for inventions claimed as at least one of the following: *new uses* of a known product, *new methods* of using a known product, or *new processes* of using a known product.' This provision relates largely to process patents, and it is clearly wider than the scope of patentable subject matter under Article 27 of the TRIPS Agreement. The provision may have the effect of promoting patents for trivial improvements whilst limiting the ability of countries, especially in the developing world, to adopt measures to limit the evergreening of patents. Even if it could be argued that process patents may, in some cases, be excluded under the TRIPS Agreement, such an exclusion would clearly run

contrary to the spirit of Article 18.37 (2) of the TPP having regard to its detailed coverage of the patentability of process patents.

The practical implication of the above provision is that after enjoying exclusive rights over a patented pharmaceutical product for 20 years, an owner of a pharmaceutical patent can file for and easily obtain, at the very least, another 20 years exclusivity for coming up with new uses of the same product; or new methods of using the same product; or for discovering new processes of using the same product. In all, patent protection for the same product can effortlessly subsist for 40 years in respect of a single pharmaceutical product, instead of the intended 20 years. This will be contrary to the foundational objectives of the TRIPS Agreement as expressly encapsulated in Articles 7 and 8. Article 7 requires that the protection and enforcement of intellectual property rights must contribute to technological innovation and transfer of knowledge, while Article 8 permits member states to adopt measures needed to promote public health and nutrition. Article 18.37 (2) of the TPP will not only limit technological innovation and technology transfer, it will also affect the flexibility otherwise available to member states to adopt measures needed for them to address issues of public health and nutrition. Developing countries, and by implication most African countries, that heavily rely on generics will have to wait for approximately 40 years before manufacturers of generics can enter the market with the generic versions of branded drugs. Some developing countries, such as India, have been very resolute in limiting the registration of ever-green patents. Thus, Section 3(d) of the Indian Patents (Amendment) Act of 2005 contains a provision that was designed to address the evergreening problem. Section 3(d) of the Indian Patents Act provides thus:

> 3. The following are not inventions within the meaning of this Act,—
> the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

The TPP provision on the evergreening of patents is one of the reasons why the IP chapter of the TPP has been heavily criticized. As a matter of fact, Article 18.37(2) of the TPP seems to have been included in the agreement in response to the Indian Supreme Court's decision in *Novartis AG v Union of India* Supreme Court of India, Civil Appeal Nos 2706-2716 of 2013, April 1, 2013, where

the Indian apex court held that Novartis Gleevec drug (patented in the U.S. and Europe) was not patentable under Section 3(d) of the Indian Patents Act of 1970, as it was a mere trivial improvement on a known drug which failed to meet patentability criteria under Indian law (Owoeye 2014, p. 917).

(b) Patentability Requirements

In terms of patentability requirements, Article 18.38 of the TPP provides that parties shall disregard public disclosures made by the patent applicant or with his consent in determining whether a patent should be granted, provided the disclosure was made within 12 months of filing the application in the Party's territory. This provision reflects the current position of the U.S. law on prior disclosure of patent information (Horton et al. 2016, p. 16). This is a TRIPS-plus provision as there is no such provision in the TRIPS Agreement. Thus, under the TRIPS Agreement, countries have the right to determine whether prior disclosure would be fatal to a patent application or not. With the incorporation of the liberal approach of the U.S. to prior disclosure into the TPP, this flexibility has been taken away, at least, from TPP states, and prior disclosure within 12 months of filing a patent application can no longer be grounds for vitiating a patent application.

(c) Patent Term Adjustments

The TPP further contains a few provisions aimed at extending the duration of a patent term and offering more protection to patent holders. Under Article 18.46 of the TPP, a Party is obliged to provide a means at the request of the patent holder to adjust the patent term to compensate for unreasonable delays in the issuance of a patent right in its territory. In a similar vein, Article 18.48 requires each Party to provide an adjustment of the patent term, with respect to pharmaceutical patents, to compensate for any unreasonable curtailment of the patent term due to a delay in the marketing approval process. These provisions can be used to extend a patent term to reflect the duration of any delay in the issuance of a patent by the patent office or a delay in the granting of marketing approval. These provisions do not exist in the TRIPS Agreement. In relation to pharmaceutical patents, these provisions can be used to prolong a patent term, and they may also effectively forestall the entry of generics into the market.

(d) Investor-State Dispute Settlement

The TPP's investor-state dispute settlement (ISDS) provisions are believed to be the most controversial part of the TPP agreement (Miles, Beale, and Barnett 2016, p. 25). The ISDS

provisions empower foreign investors to commence arbitral proceedings against host states at international arbitration tribunals with respect to disputes relating to expropriation of their investments and other violations of the agreed minimum standards of investment protection (Yu 2017, p. 832). The ISDS provisions are likely to make signatories vulnerable to expensive disputes and impede their right to regulate (Labonte, Schram, and Ruckert, 2016), p. 493). A major criticism against the TPP's ISDS framework is the argument that it tends to lopsidedly favor the protection of foreign investors over the sovereign rights of states to legitimately pursue public policy goals (Yu 2017, p. 835). This is particularly so because international arbitral tribunals are likely to adopt an expansive interpretation of investment protection provisions (Baker 2016, p. 4). Of relevance to this discourse is Article 9.16 which provides thus:

> Nothing in this Chapter shall be construed to prevent a Party from adopting, maintaining, or enforcing any measure otherwise consistent with this Chapter that it considers appropriate to ensure that investment activity in its territory is undertaken in a manner sensitive to environmental, health or other regulatory objectives.

While this provision may appear to recognize and preserve the power of states to adopt measures in pursuance of environmental or health objectives, the fact that such measures are required to be in consonance with the investment protection standards of the TPP means there is little leeway, in practical terms, for states to adopt measures that derogate from the agreed foreign investment protection standards, even if such measures are in pursuance of social policy goals. In fact, Baker (2016, p. 4) expresses the fear that the TPP's investment chapter may 'greatly expand the enforcement rights of foreign pharmaceutical companies, creating substantial risks to countries' ability to set IP-related policy and to render IP decisions.' In a review of the recent ISDS Panel decision involving Eli Lilly and Canada, Cynthia Ho (2017) observes that even though this decision went in favor of Canada, there are indications from the Panel's decision that 'unique IP laws may be unduly questioned in an investment dispute even if well within the boundaries of TRIPS flexibilities.' Allowing pharmaceutical multinational corporations to challenge the legitimate use of TRIPS flexibilities through investment disputes can only exacerbate the global access to medicines challenge.

(e) Protection of Undisclosed Test Data

The TPP contains detailed provisions on the protection of test data submitted for obtaining marketing approval for pharmaceutical products. These provisions are clearly wider than the scope

of protection available under the TRIPS Agreement and may impose more onerous obligations on generic manufacturers seeking marketing approval for their products. Under the TRIPS Agreement, the protection available for undisclosed test data is protection against disclosure and unfair commercial use. (Owoeye 2015b, p. 106). Thus, it may still be possible for a generic manufacturer to rely on test data submitted for similar products for marketing approval on the basis of bioequivalence under the TRIPS Agreement (Owoeye 2015b, p. 106). However, under Article 18.50 of the TPP, member states are expressly barred from allowing reliance on previously submitted test data for marketing approval for a minimum period of five years from the date of the marketing approval of the product being relied upon. Article 18.50. 1(b) of the TPP provides thus:

> If a Party permits, as a condition of granting marketing approval for a new pharmaceutical product, the submission of evidence of prior marketing approval of the product in another territory, that Party shall not permit third persons, without the consent of a person that previously submitted such information concerning the safety and efficacy of the product, to market a same or a similar product based on evidence relating to prior marketing approval in the other territory for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of that Party.

The implication of this is that generic manufacturers must wait for the test data protection period to elapse before they can gain market entry. Given the fact that the EAC is made up of mostly least developed nations, the region lacks the capacity to manufacture generic pharmaceuticals. EAC countries will have to depend on generic manufacturers, especially in Asia, for the local supply of medicines. A delay in the entry of generics due to test data protection in countries adopting the TPP standards will only have the effect of compounding the access to medicines challenge in the region.

Article 18.50.3 of the TPP contains an exception to the test data protection requirement by providing that notwithstanding the provision on test data protection:

> a Party may take measures to protect public health in accordance with:
> (a) the Declaration on TRIPS and Public Health;
> (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration on TRIPS and Public Health and that is in force between the Parties; or

(c) any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health that enters into force with respect to the Parties.

The exceptions recognized under the TPP can hardly be of any benefit to the EAC and other developing or least developed nations that may depend on TPP members or states imposing TPP standards for the supply of medicines for a number of reasons. First, the Doha Declaration on TRIPS and Public Health mainly recognizes the right of each WTO member to adopt measures to address any public health crisis within that member's territory. If there is a public health crisis in an EAC state, it does not provide grounds for the adoption of public health measures in a TPP state. Consequently, countries that may otherwise come to the aid of the EAC may be constrained from doing so as a result of national regulations arising from obligations under the TPP. It is also pertinent to note that the existing waivers for least developed countries in relation to the implementation of the TRIPS Agreement do not apply to the TPP states. Given the EAC's lack of manufacturing capacity in the pharmaceutical sector, the TPP standards will only make it more difficult to procure generic medicines from countries with the capacity to manufacture them.

(f) Provisions on Biologics

The TPP equally contains a number of provisions on biologics. Biologics are a new and evolving class of medicines that are used for diseases that are difficult to cure, such as cancer (Australian Government DFAT 2016). Biologics are created by using highly technical biotechnological processes, and they differ from traditional medicines made from chemical synthesis in terms of both the manufacturing process and cost of production (Australian Government DFAT 2016). Article 18.51 (1) of the TPP requires each Party to provide an effective period of eight-year test data protection to 'a new pharmaceutical product that is or contains a biologic' from the date of the first marketing approval in that Party's territory. Alternatively, each Party may choose to offer such protection effectively for five years and then deliver a protection comparable to the eight-year protection through other measures such as market protection measures. Article 18.51 (2) further provides that the provisions on biologics apply, at a minimum, 'to a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.' The implication of the provision on biologics is that any pharmaceutical product that contains a biologic is entitled to a period test data or similar protection for eight years, and generic manufacturers are practically barred from entering the market until the period elapses (Voon and Sheargold 2016, pp. 361-362).

What are the likely effects of the TPP's provisions discussed above on developing and least developed countries that are not signatories to the Agreement? According to figures obtained from the World Health Organization, Europe and the United States account for over one-third of the global pharmaceuticals market (ANH International 2016). North and South America, Europe, and Japan together account for not less than 85% of the world pharmaceuticals market (ANH International 2016). Given the high significance of the TPP member states to the global pharmaceutical market and the clear ambition of the U.S. to make the TPP a precedent and model for subsequent trade agreements (Barfield 2011), the implications of the TPP IP Chapter's provisions for access to medicines in developing countries can be very grave. With the adoption of such standards by the TPP states, it may become more difficult for other states to resist TRIPS-plus provisions in bilateral and plurilateral trade agreements. Developing countries without significant manufacturing capacity in the pharmaceutical sectors may find it very difficult to import affordable pharmaceuticals from the TPP states.

Even where compulsory licences are issued, the data protection hurdle around clinical trials may present an additional hurdle for developing countries issuing such licences (Owoeye 2015b, pp. 121-124). This is due to the fact that a compulsory patent license only allows the licensee to circumvent the patent monopoly by manufacturing the product without the consent of the patent holder. Test data protection right is a distinct right that is not subject to the term of patent protection. A compulsory license issued by an EAC state will most likely have to be used outside of the African continent by a generic manufacturer with the capacity to manufacture the drug. Thus, where regulatory marketing approval is required in the country manufacturing, a test data protection provision following the TPP model may present an additional hurdle for the use of compulsory licensing.

Although the TPP has only 12 member states, the impact of the TPP's provisions on access to medicines in other regions of the world can be far reaching given the fact that states party to the TPP account for a substantial part of the global pharmaceutical industry. If the intellectual property standards negotiated under the TPP are used as a template for the Transatlantic Trade and Investment Partnership (TTIP) currently being negotiated between the United States and Europe, the effect would be that the nations responsible for at least 85% of the global pharmaceutical market are effectively bound by these standards. Such a development may compound the access to medicines problem in other parts of the world, especially in the least developed regions. For

illustrative purposes, the public health challenge in the East African Community, a regional trade bloc in East Africa, will be examined to highlight how the TPP may aggravate the access to medicines challenge in the region.

Regionalism and Access to Medicines – The East African Community

The East African Community (EAC) is one of the eight existing regional economic communities in Africa. The East African Community is a regional intergovernmental organization comprising of Burundi, Rwanda, Kenya, Uganda, Tanzania, and South Sudan (EAC 2016a). The HIV/AIDs pandemic is a very grave public health issue in Eastern Africa, and it has been ranked second in the world after Southern Africa (UN Office on Drugs and Crime 2016). The region has also been exposed to health risks, especially in relation to trans-boundary human, crop, and animal diseases (EAC 2007). In 2002, this concern led to the establishment of an EAC Sectoral Council on Regional Cooperation on Health with the responsibility of providing guidance on issues related to the initiation and strengthening of regional collaboration in health (EAC 2016b). Other health burdens identified by the EAC are preventable diseases such as trypanosomiasis, anthrax, malaria, pneumonia, measles, tuberculosis, and infestation by pests. For example, from December 2006 to May 2007, the outbreak of Rift-Valley viral haemorrhagic fever claimed over two hundred human lives (EAC 2016b). In 2014, the EAC Sectoral Council of Ministers of Health highlighted the high out-of-pocket expenditures on health and inadequate access to appropriate technologies which continued to affect the region (EAC 2014).

The EAC is an African regional economic bloc with probably one of the most ambitious integration plans in the continent (EAC 2016c). Not less than 80% of the EAC's states are currently ranked as least developed countries by the United Nations (UN 2015). Given the economic constraints of LDCs and the existing exemptions granted to them under the TRIPS Agreement, the access to medicines challenge of the EAC member states would be more effectively addressed through the EAC's framework. Just like other developing regions of the world, access to medicines remains a serious challenge in the continent due to the unavailability of drugs at affordable prices (Cameron et al. 2009, p. 240). This position was clearly captured by Hiroko Yamane when he declared that 'high prices together with the underdeveloped state of health care systems in many developing countries and general lack of financial resources have made it difficult for most patients to get access even to old, unpatented drugs' (Yamane 2011, p. 275). It has been suggested that investing in local pharmaceutical manufacturing might be the best option for national governments in Africa,

and the diversification of local drug production could help enhance the development of the local drug industry (Russo and Banda 2015, p. 279). The EAC countries established a customs union in 2005 and a common market in 2010. The EAC states are presently working towards establishing a monetary union as a prelude to the formation of a Political Federation of East African States (Russo and Banda 2015, p. 279).

It is pertinent to note that 5 out of the 6 member states of EAC are currently ranked as least developed by the United Nations (UN 2015). Thus, Kenya is the only member state not covered by the LDCs exemption from the implementation of the TRIPS Agreement under WTO Law. With the recent WTO extension of the LDCs exemption from the protection of pharmaceutical patents until 2033, Burundi, Rwanda, Tanzania, and Uganda do not have to extend patent protection to pharmaceutical products until 2033 under WTO law. The current WTO waivers applicable to LDCs in relation to the TRIPS Agreement therefore suggest that patents should ordinarily not impede access to medicines in these countries. Different factors may, however, make access to medicines difficult in low income countries. The necessary infrastructure to deliver pharmaceutical products may be unavailable in low income countries, and affordability may also be a major challenge in such countries (Europe Economics 2001, pp. 4-5).

Even though the development of local manufacturing capacity in developing countries would be desirable, it is uncertain if regional economic communities the size of the EAC, and with 80% of its members being least developed countries, would have the financial strength to build any significant manufacturing capacity in the pharmaceutical sector. Nonetheless, the EAC is in a stronger position to address the access to medicines challenge of member states as a regional bloc. Under the WTO's General Council's Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, compulsory licences may be granted by members of a regional bloc sharing the same public health problem without the need for each state in the regional trade grouping to issue a separate licence if half of the regional bloc's membership is made up of states ranked as least developed by the United Nations (WTO 2003). The EAC clearly meets this requirement and can, therefore, issue compulsory licences as a regional bloc under WTO law.

Although the TRIPS Agreement provides a transitional period for LDCs to comply with its provisions, it is important to note that TRIPS only provides minimum standards for intellectual

property protection and the rights of states to impose higher and more extensive IP protection are at large. This explains why Rwanda, an EAC member state and a least developed country, has an intellectual property law with a robust patent protection framework. For instance, Article 40 of the Rwandan Law of Intellectual Property provides for a national patent exhaustion regime although the TRIPS Agreement allows nations to adopt any exhaustion regime that suits them, including an international exhaustion regime. Article 290 of the Rwandan law further provides that the provisions of any international IP treaty to which the country is a party shall apply, and where there is a conflict with local law, the international treaty will prevail. Even though Rwanda has a comprehensive IP legislation covering many of the areas that LDCs are not yet obliged to protect under WTO law, it would appear the country will be bound by the standards imposed under its local law. Nonetheless, the current exemption from drug patent for LDCs will still apply, as Article 18 of the Rwandan IP law exempts 'pharmaceutical products, for the purposes of international conventions to which Rwanda is party' from the ambit of patents protection under the law.

The EAC as a regional bloc may benefit significantly from the TRIPS compulsory licensing regime and the flexibility available under the TRIPS exhaustion of intellectual property framework by adopting a regional or international exhaustion doctrine that allows free movement of products within the region (Owoeye 2015c, p. 238). With respect to compulsory licensing, the EAC can legally issue compulsory licences for the entire region under the current WTO law pursuant to the Doha Paragraph 6 Implementation Decision (Owoeye 2015c, p. 238). It is also possible for the region to collectively negotiate voluntary licensing with pharmaceutical manufacturers, and the EAC may equally benefit from voluntary licencing schemes available through initiatives such as the Medicines Patent Pool.

However, the TPP is bound to make access to generic medicines from TPP signatories more difficult. Countries with strong generic manufacturing capacity may find it increasingly difficult to produce generic medicines with the increasing standards of global intellectual property law. India, for instance, may soon find it more difficult to rely on its Section 3(d) requirement to prevent evergreening with the increasing pressure from the U.S. and the United States' continuing criticism of the laxity of Indian patents law (USTR 2015, pp. 48-50). In 2008, Rwanda imported HIV drugs from Canada under the Doha Paragraph-6 Implementation Decision System, and it remains the only country that has used the system to date (UNAIDS 2011, p. 5). The implementation of the TPP's intellectual property provisions would make it even more difficult for countries like Rwanda

and others in the EAC to have access to new drugs as generic manufacturers would find it difficult to come to their aid until the patents and data exclusivity regimes, which can be extended beyond the TRIPS standard through evergreening strategies and adjustments for 'unreasonable delays', have expired.

Although Article 18.6 of the TPP affirms members' commitment to preserving the public health measures under TRIPS, it goes without saying that the patent evergreening and elongation provisions available under the TPP would create a situation where EAC countries would continue to require compulsory licences under the Doha Paragraph-6 System, even when the patent could have ordinarily expired under the TRIPS Agreement. Given the fact that the Doha Paragraph-6 System has not been shown to be a particularly effective option, the implementation of the TPP or standards adopting the TPP model are likely to negatively impact access to medicines and public health in the EAC. It may, therefore, be necessary for the EAC to begin to consider regional measures for facilitating access to patented medicines in the region.

Conclusion

The adoption of the TRIPS Agreement in 1994 brought about an unprecedented harmonization of patent protection standards across the world as Article 27 of the Agreement makes it obligatory on all countries to extend patent protection, without discrimination, to all fields of technology. Thus, a country like India that had been known as the pharmacy of the developing world because of its ability to supply generic versions of branded drugs was required, following the adoption of TRIPS, to offer protection for product patents no later than 10 years after the entry into force of the TRIPS Agreement. African countries, given their insignificant manufacturing capacity in the pharmaceutical sector, are the most adversely affected by this development. While the TRIPS Agreement does clearly contain some flexibilities designed to ensure intellectual property rights do not make the pursuit of national interests and the strengthening of public health systems unduly arduous, intellectual property rights still constitute a barrier to access to medicines in developing countries (Nicol and Owoeye 2013, p. 533).

For African countries, addressing the access to medicines challenge in the continent seems to require a collaborative strategy, and this may be pursued through regional integration. Although there is presently no continent-wide regional trade agreement in Africa, the existing regional economic communities in the continent can harness their resources to lead regional efforts to

facilitate access to medicines. While there are exemptions for LDCs under the TRIPS Agreement as noted above, these exemptions may be of little value without a significant local pharmaceutical manufacturing capacity. The East African Community is a regional economic bloc in Africa that is largely made up of least developed states. However, the extent to which the EAC may fully utilize the TRIPS flexibilities to its advantage is an issue that deserves some investigation, as its success in doing this may provide a blueprint for other LDCs in maximizing benefits offered by the TRIPS flexibilities.

With the conclusion of the TPP negotiations and the increasing agitation for the imposition of TRIPS-plus provisions in free trade agreements by developed countries, the constraints of intellectual property protection on generic manufacturing is likely to become more onerous. The EAC is a unique regional economic bloc with 80 percent of its membership currently ranked as least developed by the United Nations. As already mentioned, LDCs are exempted from implementing the TRIPS Agreement until 2021, and they do not have to grant pharmaceutical patents until 2033. Thus, ordinarily intellectual property should not be a barrier to access to medicines in such countries. However, given the fact that LDCs, for obvious reasons, lack the capacity to manufacture drugs and will have to import medicines from countries fully bound by international intellectual property standards, intellectual property continues to be a real challenge to access to medicines in these countries. In the EAC's case, a regional framework under its auspices may be a more pragmatic option for exploring immediate solutions to the access to medicines challenge of member states. The TRIPS flexibilities may not be enough. The EAC may have to start finding regional answers to regional problems.

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