The Effect of Patent Registration and Protection on Access to Vital Medication in Developing Countries - Analysis on the TRIPS Agreement.

By

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Contents

1 Introduction

The World Trade Organization (WTO) is the international organization that regulates the rules of trade existing between nations[1] and 159 countries were members of the WTO as of March 2013.[2] The WTO was established on the 1st of January in 1995 where it replaced the General Agreement on Tariffs and Trade (GATT) which dates back to 1948.[3] This was as a result of the decision taken by governments after seven years of deliberations and negotiations which were referred to as "The Uruguay Round" which ended in 1994.[4] The creation of WTO expanded trade protection to new areas;[5] the GATT only focused on the trade in goods only, WTO covers trade in services and intellectual property as well.[6]

Upon becoming a member of the WTO, member states undertake to adhere to the 18 specific agreements annexed to the Agreement establishing the WTO.[7] With the exception of a few agreements – the so called "plurilateral" agreements that are not obligatory, member states cannot choose to be party to some of the agreements and not the others within the WTO agreement.[8] Of all the agreements, Trade-Related Aspects of Intellectual Property Rights (TRIPS), it is the one that has the greatest impact on the pharmaceutical sector and the access to medicines.[9]

2 Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement

In its Preamble, The TRIPS Agreement gave that its main aspiration is to reduce distortions and impediments to international trade paying due cognizance to the "need to promote effective and adequate protection of intellectual property rights…"[10] and also put mechanisms in place that will make sure that protections will not interfere with the free trade between countries. Item (b) in the Preamble of the Agreement also emphasizes that the TRIPS Agreement recognizes the

[1] http://www.who.int/medicines/areas/policy/wto_trips/en/.
[2] www.wto.org/english/thewto_e/acc_e/members_brief_e.doc.
[3] WTO Agreements and Public Health, WTO/WHO VII – 2002- 6,000, p25.
[4] http://www.wipo.int/policy/en/global_health/trilateral_cooperation.html.
[5] http://www.wto.org/english/thewto_e/coher_e/wto_who_e.htm.
[6] WTO Agreements and Public Health, p25.
[7] http://www.who.int/medicines/areas/policy/wto_trips/en/.
[8] http://www.who.int/medicines/areas/policy/wto_trips/en/.
[9] http://www.who.int/mediacentre/news/releases/who64/en/.
[10] Preamble of TRIPS Agreement.

need for new rules concerning adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights.[11]

In terms of the Agreement, member states are obliged to give effect to provisions of the agreement and at their own will, they can create laws that are more stringent and strict within their legal systems provided their provisions will not contravene with the provisions of the agreement itself.[12] Article 7 of the Agreement provides the objectives of the Agreement and it is worthy to note that the main aim for the agreement is to protect and enforce intellectual property rights which should contribute to the promotion of the technological innovation and to the transfer and dissemination of technology.[13] This has to be achieved in the interest of the mutual benefit of both the producers of technological knowledge and the users of such knowledge in a manner that is conducive to social and economic welfare, balancing the rights and obligations involved.[14]

As a condition set out in the Agreement, member states shall afford equal treatment to both their citizens and the citizens of other nations with regards to the protection of intellectual property,[15] and members are free to adopt measures within their states that protect public health and nutrition in sectors of vital importance as long as it does not contravene the provisions of the Agreement.[16]

Section 5[17] is of particular importance to this discussion as it deals specifically with patents and these are covered by articles 27 through to article 34.[18] A patent, in its simplest meaning, is a government authority or license conferring a right or title for a set period, especially the sole right to exclude others from making, using, or selling an invention.[19] The Agreement does not provide a definition for a patent but rather outlines the rights that are conferred to a patent holder.

The rights conferred to a patent holder are listed in article 28[20] which are as follows;

1. "A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

[11] Preamble of TRIPS Agreement.
[12] Article 1 of TRIPS Agreement.
[13] Article 7 of TRIPS Agreement.
[14] Ibid.
[15] Article 3 of Agreement.
[16] Article 8 of Agreement.
[17] TRIPS Agreement.
[18] TRIPS Agreement.
[19] https://www.google.co.za/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF8#q=what%20is%20a%20 .
[20] TRIPS Agreement.

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts."

3 Implications of TRIPS Agreement

Depending on the laws that are put in place, the conditions such laws create will result in either of the two scenarios. The conditions can favor more competition between manufacturers and producers of drugs, a case that would in most cases result in lower prices of the drugs[21]- which in turn will contribute towards increased access to medicines. Alternatively, the conditions will cause less competition which will have an opposite effect. In order to analyze the impact of patents on the accessibility of drugs, a distinction has to be made between patented drugs and generic drugs.

When a drug is patented, it can only be made, used, imported or exported or sold by the patent holder.[22] A drug that is patented is usually marketed under a brand name reserved exclusively to its owner, i.e. the person or company that is granted a patent on that invention.[23] On the other hand, a generic drug is a pharmaceutical product which is a bioequivalent of the patented drug and can be used interchangeably with the patented drug since it achieves the same results as a patented drug.[24] A generic drug is usually made and marketed after the expiry of patent rights held by a patentee unless if there is a prior agreement that has been issued by the patent holder.[25] Important thing to note is that generic drugs should not be confused with counterfeit drugs. Counterfeit drugs are deliberately and fraudulently mislabeled with respect to their identity and their source. Counterfeiting can happen to both patented drugs and generic drugs.

Before the advent of TRIPS most developed countries were already granting patents that fell within the pharmaceutical domain but most developing countries were not issuing such patents. In other countries, States were only issuing patents on the process of manufacturing the product only and not the final product itself, in our case the important one will be the drugs themselves.[26] Due to this arrangement, a provision could be made in countries that did not issue patents for generic drugs to be made without obtaining the prior consent of the patent holder for a particular drug.[27] As a result, drugs prices were often very low due to the generic competition against the patented drugs.[28] The TRIPS regime brought this to an end.

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[21] Elliot and Bonin "Patents, International Trade Law and access to Essentials Medicines" (2002) 1.
[22] Ibid.
[23] World Health Organization - Action Programme on Essential Drugs, Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement, DAP Series No. 7, 1999.
[24] Elliot and Bonin "Patents, International Trade Law and access to Essentials Medicines" (2002) 2.
[25] Ibid .
[26] Ibid.
[27] Elliot and Bonin "Patents, International Trade Law and access to Essentials Medicines" (2002) 2.
[28] Ibid.

The provision in the TRIPS agreement that state that patent rights are enjoyable without discrimination as to the place of invention, field of technology and whether products are imported or locally produced[29] were in part to a response to the lack of protection for pharmaceutical products in countries such as India. Their Patents Act[30] granted patent rights only to manufacturing processes rather than to the end product itself which essentially gave Indian firms the opportunity to 'reverse engineer' the production process and manufacture generic copies of the drug.[31]

Pharmaceutical companies in the United States and the European Union had campaigned in favor of the agreement as such provisions ensured that any company that invented a drug would have exclusive rights over its production and distribution for the duration of the patent which typically is 20 years.[32] This however prevented the production of cheap generic drugs that were under patent and as a result there were serious ramifications for the public health. Such ability of patents to restrict access to treatments for diseases became glaringly evident with the rapid spread of HIV/AIDS.[33]

HIV/AIDS has been one of the greatest health challenges of the last century and the first cases of AIDS (Acquired Immune Deficiency Syndrome) were documented in the United States and the United Kingdom.[34] By 1997 UNAIDS reported that 30 million people were infected with HIV and of these approximately 3 million were in India alone and Sub-Saharan Africa accounted for more than half the HIV/AIDS cases that were recorded.[35] The development of antiretroviral (ARV) treatments for HIV/AIDS is arguably one of the remarkable success stories within the last two decades and there has been more than 20 highly effective drugs that have been developed over this period.[36] Unfortunately, patented versions of these remarkable discoveries are not accessible to the majority of the people who actually need that medication; the most afflicted who are residing in the developing countries.[37] It is estimated that patented ARV treatment drugs costs an average of US$10,000 to US$15,000 person of which the population of people in developing countries live under a dollar per day.[38] Given that per capita health expenditures in low income developing countries average US$23 per year, only a tiny fraction of those infected with AIDS in developing countries could afford such treatment.[39]

One of the cases that have been relevant to the implications of TRIPS Agreement that has arisen within WTO so far is the case of Brazil.[40] In 1996 the Brazilian government began offering free ARV therapy to HIV/AIDS patients and as the cost of this program grew exponentially, the government expanded its health budget and increased its production and import of generics.[41]

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[29] Article 3 TRIPS Agreement.
[30] Patents Act of India 1970.
[31] Saddiqi "Patents and Pharmaceutical Drugs – The Need for Change" (2005) 1.
[32] Ibid.
[33] Ibid.
[34] Avert, "The history of AIDS up to 1986" http://www.avert.org/his81_86.htm.
[35] WTO Agreements and Public Health, p25 .
[36] Saddiqi "Patents and Pharmaceutical Drugs – The Need for Change" (2005) 2.
[37] Ibid .
[38] Ibid.
[39] Saddiqi "Patents and Pharmaceutical Drugs – The Need for Change" (2005) 2.
[40] WTO Agreements and Public Health, p25.
[41] Ibid.

The government also used the threat of compulsory licensing authorizing companies to produce generic copies of patented drugs thus forcing the patent holders to cut their prices significantly.[42] As a result the drug prices in Brazil are much lower than other countries and the government has succeeded in cutting AIDS mortality rates by 50 percent.[43]

In response to Brazil's actions, the United States filed a complaint with the WTO in early 2001, accusing the government of violating TRIPS Agreement.[44] The United States argued that this provision for the grant of compulsory licenses in the event that a patented invention was not used in domestic production was a protective industrial policy measure and was not in line with the provisions of the TRIPS Agreement.[45] In their defense, the Brazilians took the view that this measure was a necessary part of their programme to combat HIV/AIDS and it was fully consistent with the TRIPS Agreement.[46] Following bilateral consultations between the United States and Brazil, the two countries announced that they reached an understanding in July 2001 and they decided to withdraw their WTO case.[47]

Another case that has drawn much of the International community's attention – though it was not a WTO dispute, was the challenge in South Africa by 39 pharmaceutical companies to the South African Medicines and Related Substances Control Amendment Act.[48] The amendment of this Act came up as a response to the alarming growth of HIV of HIV infections in the country thus the parliament passed a law that gave the government the "blanket powers" to produce or import cheap alternatives to the brand name drugs for HIV and other diseases.[49] Producers of generic drugs do not need to invest money in research hence they can sell generic drugs at a fraction of the cost of a patented drugs for which this fraction can be a little of one-sixth of the patented drug price.[50] The companies contended that this legislation entailed a violation of the TRIPS Agreement because it effectively empowered the Minister of health to authorize and prescribe the conditions for the importation of drugs under patent protection in South Africa.[51] In its defense, the South African government argued, on the same basis as the Brazilian government in the case highlighted above, that its legislation was entirely consistent with the TRIPS Agreement which gave room for flexibilities which, for example allowed parallel importation of patented drugs.[52] The case was never taken to WTO for arbitration on the grounds that South Africa had breached the provisions of the TRIPS Agreement. And with pressure mounting from a multitude of Non-Governmental Organizations like Oxfam and Medecins Sans Frontieres (MSF) which sharply criticized these pharmaceutical companies for attempting to restrict access to health, the pharmaceutical companies withdrew their suit and the South African government continued to implement its regulations, some of which allowed for

[42] Ibid.
[43] Saddiqi "Patents and Pharmaceutical Drugs – The Need for Change" (2005) 2.
[44] Ibid .
[45] WTO Agreements and Public Health, p15.
[46] Ibid.
[47] Saddiqi "Patents and Pharmaceutical Drugs – The Need for Change" (2005) 3.
[48] Act 90 of 1997.
[49] Saddiqi "Patents and Pharmaceutical Drugs – The Need for Change" (2005) 3.
[50] Ibid.
[51] WTO Agreements and Public Health, p17.
[52] WTO Agreements and Public Health, p27.

parallel importation of patented medicines.[53] This has made a significant impact towards these two states in assisting the general population to have access to medication.

4 The human right to health and TRIPS Agreement.

Intellectual property law and human rights law have been so distant from each other until recently and this has been largely so because intellectual property has not been informed by socioeconomic concerns.[54] The introduction of patents in areas that are directly linked to the fulfillment of basic needs such as health has given rise to a renewed way of thinking into the new dimension of this fusion of intellectual property and human rights law.[55] Health as a human right has been included in a number of international instruments even though it has been criticized for being vague in content and intersecting with too many other rights.[56] The human rights law, through the covenant on Economic, Social and Cultural Rights has made a very significant contribution to the codification of the human right to health.[57]

One of the most detailed pronouncements of the right to health is found in the International Covenant on Economic, Social and Cultural Rights (ESCR Covenant) which recognizes everyone's right to the enjoyment of the highest attainable standard of physical and mental health.[58] The right to health implies the obligations to respect protect and fulfill the right to health.[59] States are to refrain from intervening directly or indirectly with the enjoyment of the right and they should take measures to prevent third parties from interfering with the guarantees provided; and they should adopt legislative, administrative and other measures towards the full realization of that right.[60] In essence, all member states are to take all feasible steps to the maximum of their available resources progressively to attain the full realization of the protected rights.[61]

Access to drugs is one of the fundamental components of realizing the human right to health.[62] The arrangement of the current patent regime at an international level is very important because as alluded to earlier, patents have the potential both to improve access by providing incentives for the development of new drugs, and to restrict access because of the comparatively higher prices of patented drugs.[63] In general, accessibility refers to the concept that health policies

[53] Ibid.
[54] Cullet, "Patents and medicines; the relationship between TRIPS and the human right to health", p148.
[55] Ibid.
[56] Ibid.
[57] International Covenant on Economic, Social and Cultural Rights, New York, 16 Dec 1966, report.
[58] Article 12 of the IECSCR right to health.
[59] Cullet, "Patents and medicines; the relationship between TRIPS and the human right to health", p148.
[60] Ibid.
[61] Cullet, "Patents and medicines; the relationship between TRIPS and the human right to health", p142.
[62] Commission on Human Rights Resolution 2001/33. Access to medication in the context of pandemics such as HIV/AIDS.
[63] Cullet, "Patents and medicines; the relationship between TRIPS and the human right to health", p143.

should foster the availability of drugs to all the people that need them at affordable prices.[64] It is not difficult to see why there is a link between the shortfalls in access to medicines and poverty.

Approximately one-third of the world's population does not have access to basic drugs and this proportion rises above one-half in the most affected regions of Africa and Asia.[65] Another important reality that must always be kept in mind is that a large percentage of the people residing in developing countries do not have access to medical insurance and more often than not they have to pay for the drugs themselves.[66]

5 Establishing balance between the rights and obligations of patent holders and patients' interests: The Doha Declaration.

The spread of the pandemic diseases such as AIDS together with the well-publicized cases of Brazil and South Africa cited above played a very huge role in increasing awareness on an international level that patents were threatening to severely restrict access to health to patients residing in developing countries.[67] This instigated in the Ministerial Conference in Doha, Qatar where member countries issued a "Declaration on the TRIPS Agreement and Public Health" on the 14th of November in 2001.[68] The declaration did not offer any substantial revisions to the TRIPS Agreement but it rather recognized and further pronounced the flexibilities that already existed within the Agreement.[69] Paragraph 4 of the Declaration contains the essential component of the Declaration which stipulates that the TRIPS Agreement does not and should not prevent the WTO member states from taking measures to protect the public health, as well as it can and should be interpreted and implemented in a manner that is supportive of the member state's right to protect public health and in particular to promote access to medicines for all.[70]

The declaration also, in paragraph 5, recognizes that the flexibilities stated in paragraph 4 include inter alia that:

b) "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health cries, including those

[64] Ibid.
[65] WTO Agreements and Public Health, 5.
[66] Cullet, "Patents and medicines; the relationship between TRIPS and the human right to health", 144.
[67] Saddiqi "Patents and Pharmaceutical Drugs – The Need for Change" (2005) 2.
[68] Elliot and Bonin "Patents, International Trade Law and access to Essentials Medicines" (2002) 8.
[69] Muswaka "The impact of patent protection and lack of generic competition on the right of access to medicines in South Africa: Explicating Corporate Responsibilities for Human Rights" 2014 5 Mediterranean Journal of Social Sciences 231.
[70] Elliot and Bonin "Patents, International Trade Law and access to Essentials Medicines" (2002) 8.

> relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[71]

Paragraph (b) is of importance since it now allows developing countries to issue or grant compulsory licenses without facing undue pressure from developed countries such as receiving threats to redraw investments primarily by the United States.[72]

Compulsory license is issued by a country's law which allows the either the government or an individual or a company to produce or import a generic drug and distribute it without getting prior authorization from the patent owner.[73] Compulsory licenses are normally granted on grounds of general interest such as public health, economic development, and national defense and there are a few restrictions to such licenses.[74] The restrictions, in short, are that an effort must be made to negotiate a voluntary issue with the owner on reasonable commercial terms; when issued, the patent owner is entitled to be paid adequate remuneration; and must be used predominantly to supply the local market i.e. the country issuing the compulsory license.[75]

Article 31 of the TRIPS Agreement establishes the procedures by which compulsory licensing may be granted.[76] Article 31(f)[77] authorizes the issuing of compulsory license so that a company could produce generic medicines principally or sorely for domestic use and they restrict exportation of such drugs even to developing countries without the capacity to make their own.[78] This represents a serious problem for developing countries that do not have their own domestic manufacturing capacity hence they can't make use of safeguards such as compulsory licensing to access affordable medicines.[79] The Doha Declaration however failed to reverse the burden of proof onto the side of the patent holder to force them to prove that granting a compulsory license is not necessary, instead of forcing the applicant to demonstrate that the patent holder has abused monopoly.[80]

6 Conclusions

The matters of access to health and medical research leading to intellectual property conflicts have sparked interesting debates over the last two decades and importantly so because the international community has noticed the importance of the link that exists between the two

[71] Doha Declaration, 2001.
[72] Sterokx, "Patents and access to drugs in developing countries: An ethical analysis" *Developing World Bioethics* 2004 71.
[73] Elliot and Bonin "Patents, International Trade Law and access to Essentials Medicines" (2002) 5.
[74] Ibid.
[75] Cullet, "Patents and medicines; the relationship between TRIPS and the human right to health", 144.
[76] TRIPS Agreement.
[77] Of TRIPS Agreement.
[78] Elliot and Bonin "Patents, International Trade Law and access to Essentials Medicines" (2002) 6.
[79] Sterokx, *Developing World Bioethics* 2004 73.
[80] Sterokx, *Developing World Bioethics* 2004 71.

areas. Strong drug patents are hard to justify on natural rights or fairness grounds and these drugs are often very important for large groups of people.[81]

Patent protection poses a huge challenge to the enjoyment of the fundamental right to health, which is directly linked to the right to have access to medication as recognized by various regional and international human rights instruments and declarations.[82] It has been noted earlier that patents are an influential factor in determining the prices of drugs and more often than not they sustain the high price of drugs thereby hindering accessibility of drugs by the large groups of people who do not have financial means.[83] The conclusion of the Declaration in Doha made the world move in a way in which a consensus was reached to have differential pricing of drugs – making the costs of medicine cheaper for people in developing countries than in developed countries, improving access of such drugs to the vulnerable.[84] John Barton then observed that, "It seems reasonable that the burden of these costs, which benefit humanity, should fall more heavily on the wealthy than on the poor."[85]

It can therefore be concluded that, in light the discussion held above, the balance of the fundamental human right to health can be balanced with the right to intellectual property can be achieved and improvements still need to be done to achieve this status for the benefit of all the parties concerned especially governments within developing countries- particularly the ones without the industrial capacity to ta advantage of the Doha Declaration resolutions.

[81] Ibid.

[82] Muswaka 2014 *Mediterranean Journal of Social Sciences* 231.

[83] Ibid .

[84] Saddiqi "Patents and Pharmaceutical Drugs – The Need for Change" (2005) 3.

[85] John H Burton, "TRIPS and the global pharmaceutical market", Health Affairs, Vol. 23, Issue 3, 146-154.

7 Bibliography

International Legislation

1. Trade-Related Aspects of Intellectual Property Rights Agreement, Marrakesh, 15 April 1994. 33:1197, 1994.
2. WTO Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, WTO Doc. WT/MIN(01)/DEC/2 (2001).

National Legislation

1. South African Medicines and Related Substances Control Amendment Act 90 of 1997 of South Africa.
2. Patents Act of 1970, India.

Articles

1. Phillipe Cullet, "Patents and medicines; the relationship between TRIPS and the human right to health" *International Affairs (*2003) *79*, 1.
2. Richard Elliot and Marie-Helene Bonin "Patents, International Trade Law and access to Essentials Medicines" (2002).
3. Linda Muswaka "The impact of patent protection and lack of generic competition on the right of access to medicines in South Africa: Explicating Corporate Responsibilities for Human Rights" 2014 5 *Mediterranean Journal of Social Sciences* 231.
4. Ahmad Saddiqi "Patents and Pharmaceutical Drugs – The Need for Change" *Intellectual Property Law* (2005).
5. Sigrid Sterokx, "Patents and access to drugs in developing countries: An ethical analysis" Developing World Bioethics (2004).

United Nations Reports

1. Commission on Human Rights Resolution 2001/33. Access to medication in the context of pandemics such as HIV/AIDS.
2. International Covenant on Economic, Social and Cultural Rights, New York, 16 Dec 1966, report.
3. WTO Agreements and Public Health, A joint report by the secretariats of WHO and WTO WTO/WHO VII – 2002- 6,000.

Internet Sources: Accessed 16/09/14.

1. http://www.who.int/medicines/areas/policy/wto_trips/en/.
2. www.wto.org/english/thewto_e/acc_e/members_brief_e.doc.
3. http://www.wipo.int/policy/en/global_health/trilateral_cooperation.html.
4. http://www.wto.org/english/thewto_e/coher_e/wto_who_e.htm.

5. http://www.who.int/medicines/areas/policy/wto_trips/en/.
6. http://www.who.int/medicines/areas/policy/wto_trips/en/.
7. http://www.who.int/mediacentre/news/releases/who64/en/.