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Review

Reconciling patent rights and the human right to access to essential medicines: A critical review

Bhavna Mahadew

University of Technology, Pointe aux sables 11108, Mauritius; bhavna.mahadew@utm.ac.mu

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Abstract: Over 80% of the world's population lives in developing nations, with limited access to medicines like AIDS and malaria. Competition between patented and generic medications can improve access and lower prices, but counterfeit medicines should be avoided. The Doha Declaration, released at the World Trade Organisation Ministerial Conference in 2001, aims to support nations' rights to safeguard public health and encourage access to medicines. It aims to influence the interpretation and application of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner that is health-friendly, considering the responsibility of nations to uphold health rights under international law. The Declaration calls for developed nations to encourage practical solutions for poor people in developing countries, emphasizing that trade agreements should be secondary to defending human rights and achieving the best quality of health for all. International human rights treaties protect the universal human right to health, but rigid trade agreements on patents can hinder affordable medication for low-income populations in developing nations. TRIPS, a treaty that protects intellectual property rights and promotes technological innovation, aims to provide inexpensive medications for HIV/AIDS patients through exclusions from patent admissibility, exceptions, parallel importing, and compulsory licensing.

Keywords: essential medicines; access; right to health; patent rights; human right

1. Introduction

Over eighty percent of people on the planet reside in developing nations, the majority of whom have little to no access to the medicines that have saved and prolonged the lives of people in wealthier, industrialized nations. Twenty million individuals have already passed away from AIDS in the poor countries, which is home to 95 percent of the 40 million human beings living with HIV/AIDS. More than 8000 individuals perish every day, and 15,000 more are HIV-positive. Entire nations and regions are being devastated by the worldwide epidemic. Similar to TB, malaria kills many people and disproportionately affects the world's poorest and most vulnerable people due to their exceedingly low access to efficient kinds of treatment [1].

Conditions will be set up to favor more or less competition between producers of patented and generic medications, depending on the applicable patent laws (definitions of these terms are provided below). Lower prices are a proven outcome of more competition, and hence improvement in access to medications. Although there are several factors that affect access, the elevated cost of medications is a significant hurdle that cannot be fully and sustainably overcome by foreign aid and medicine contributions alone [2].

Only the patent holder is permitted to manufacture, use, import/export, or sell a medicine that has been patented. A patented drug is typically marketed under a brand name that is exclusively reserved for its owner, i.e., the person or business that was given a patent on that innovation, as per the WHO's Action Programme on Essential Drugs. A generic medicine is a pharmaceutical item that is typically manufactured to replace the original copyrighted drug since it accomplishes identical goal ("bioequivalent"). A generic medication is typically produced and commercialised after the patentee's ownership of the patent expires, unless an earlier arrangement with the patent owner exists [3].

Instead of using a proprietary or brand name, a generic medicine is sold under a non-proprietary or authorized name. Drugs that are generic should not be confused with those that are fake. "Generally speaking, counterfeit items are those that involve the slavish imitation of trademarks. A counterfeit medicine is one that has been purposefully and fraudulently mislabeled with regard to identification and/or source, according to the WHO. Both branded and generic products can be the subject of counterfeiting, and these goods may have the right ingredients, the wrong ingredients, no active substances, the wrong amount of active ingredients, or phony packaging.

The primary aim of this article is to discuss the potential of striking a balance between intellectual property rights for manufacturers of medicines and the human right to health of individual in terms of having access to essential and life-saving medicines. Given that from both perspectives there are critical interests to be taken into account, a human rights-based approach to access to essential medicines, especially in terms of prices, is essential. This article therefore, firstly, provides an overview on the legal framework government patent and related intellectual property rights implications. This is done on the basis of the Agreement on Trade-Related Aspects of Intellectual Property Rights. Secondly, the nexus between property rights and the right to health is then discussed by focusing on the legal framework on the right to health at the international level and particularly regarding access to medicines that are considered as essential or life-saving. Thirdly, a balance between economic rights of producers through patent and the right to health of human beings is discussed through the lens of the Doha Declaration. In terms of methodology, the article adopted a doctrinal legal approach which is characterised by the study and analysis of legal rules on the subject matter from a qualitative perspective.

2. Brief literature review

Hoen has discussed the importance of the Doha Declaration in striking the balance between pharmaceutical patents and access to essential medicines. She has argued that the Doha Declaration emphasises public health and healthcare access in TRIPS implementation, allowing countries to regulate intellectual property protection. However, inefficient funding for research and development for neglected diseases remains a concern. To address this, additional international mechanisms such as burden sharing or compulsory medical research are needed [4]. Zainol et al. have argued that the World Trade Organisation's TRIPS agreement has sparked debates about the impact of intellectual property rights on public access to essential medicines in sub-Saharan Africa. It is argued that patents will diminish access, while

others are of the view that the protection of patent has the potential to enhance the development of the pharmaceutical industry. Their research found that, in a combined manner, factors related to both patent and non-patent issues may come together to inhibit access. Sub-Saharan African countries should review their policies related to taxation and tariffs, improve infrastructure, strengthen healthcare systems, and ensure IP systems support public healthcare needs [5].

Delgado has focused on the patent system's legitimacy in the pharmaceutical field is defended, but opined that criticism remains. He argued that historically, mechanisms for balancing patent law with health access rights have been weak. In the COVID-19 pandemic, there is a greater desire to prioritise health over patent property rights, as access to healthcare is crucial for all countries [6]. Focusing on access to essential medicines as a fundamental human right, Hunt and Khosla have argued that the UN Committee on Economic, Social and Cultural Rights developed a framework in 2000 to define the right to health, including freedoms, entitlements, healthcare, non-discrimination, participation, and monitoring. This framework is applied to medicines, a health issue outlined in the Millennium Development Goals. The right to health contributes to improving access to medicines, enhancing analysis of causes and responsibilities, and promoting equitable, sustainable, and effective policies. Traditional human rights techniques, such as "naming and shaming," continue to play a crucial role [7].

3. Understanding the legal framework on patent

An "intellectual property right" in an innovation is a patent. Intellectual property rights (IPRs) are privileges accorded to an individual or a firm over works of the mind, such as a writer's copyright in a book or a musician's recording rights, a business's distinctive brand on its goods, or a patent on a technological discovery. An innovation can only be made, used, imported, or sold by the person who has the patent (the "patentee"). To put it another way, a monopoly is granted by patent to the holder for the invention. Typically, a patent is given for a set period of time, like 20 years [8].

The domestic laws of a nation, which may be impacted by international rules, govern the granting of patents. Depending on the law of the country in question, a patent may have restrictions or exceptions. A new method of producing a product is also a type of patented invention. A novel invention must meet three requirements in order to be eligible for a patent: it has to be original; it should not be apparent or obvious but rather constitute a "inventive step"; and it has to be practical to use. Drugs used for treating illness are patentable inventions.

The Agreement on Trade-Related Aspects of Intellectual Property Rights is also informally called the TRIPS. The World Trade Organization (WTO) is in charge of enforcing a series of agreements in relation to trade, including the TRIPS Agreement. It lays out guidelines for intellectual property rights that all WTO members' countries must incorporate into their own domestic legislation. A number of standards in the TRIPS Agreement must be met by WTO members in their domestic legislation. Prior to the TRIPS Agreement, the majority of industrialized nations issued drug patents, but a significant number of developing countries did not. In

some instances, nations only granted patents for the method of making an invention (such as the method of making a medicine) rather than the finished good (the drug itself) [9].

Because pharmaceutical items could not be protected in some countries, generic versions of these medications might be produced or imported into those nations without first obtaining consent from a patent holder. This meant that because generic pharmaceuticals competed with patented ones for market share, drug prices were frequently lower. This is ended by the TRIPS Agreement.

There is the requirement that governments recognize patents on goods and processes in (nearly) all disciplines of technology under the TRIPS Agreement (Article 28), and to provide the patent holder the exclusive right to create, use, sell, or import the good in their nation for a specific amount of time. (A patent holder may decide to grant the right to do these activities to another person or business. A "voluntary license" is the name given to this authority.) According to Article 33 of the WTO Agreement, all members must now grant patents on inventions in the pharmaceutical sector for a minimum of 20 years after the patent application date. A drug cannot be manufactured, used, sold, or imported by anyone other than the patent holder while it is still protected by a patent. Because of the monopoly of the patent holder, patented drugs are frequently much more expensive than they would be in a competitive market.

States have to make patents as well as patent rights accessible "without discrimination" on specific grounds, according to Article 27 of the TRIPS Agreement. TRIPS prohibits nations from treating domestic and foreign inventions differently. Others contend that nations are not permitted to discriminate between different product categories (e.g., by setting different regulations for computers versus medications). Finally, TRIPS states that national patent laws cannot make distinctions between imported goods and domestically produced goods. The TRIPS Agreement applies to all WTO members' countries. By 1 January 1996, all "developed" nations had to amend their domestic legislation to comply with TRIPS regulations. "Developing" nations have until 1 January 2000 to comply, but if they hadn't already done so, they have until 2005 for pharmaceutical product patents. The "least developed" nations have until 1 January 2006, and they are allowed to request extensions, to modify their laws.

Other nations may bring a country before a trade tribunal if it disobeys a treaty like TRIPS. The WTO's role includes giving nations a platform to resolve trade disputes. The Dispute Settlement Understanding (DSU), one of the WTO accords, outlines the steps to be taken when a country wants to put in question the laws and practices of another country. A tribunal established under the WTO that finds that a country has violated a trade agreement "shall recommend" that the nation put its laws or policies into compliance and may make suggestions for how to do so. The nation can follow the "recommendations" by altering its legal framework or foreign policy [10].

It can also opt to ignore the verdict and instead provide "satisfactory compensation"—possibly ongoing—to the nation that filed the lawsuit. The complaining nation may ask the WTO for permission to impose trade penalties as reprisal, including in other trade areas, if it does not get adequate compensation.

Defaulting to the WTO How is the WTO structured? The WTO is governed by all of its members, in principle. Government ministers meet at the WTO's Ministerial Conference every two years to debate trade-related topics and establish the agenda for next conferences.

Government diplomatic missions in Geneva carry on their regular operations in between these meetings. The EU, US, Canada and Japan, collectively known as the "Quad," make up the majority of the world's wealthiest and most powerful nations, despite the fact that decisions are theoretically "taken by consensus" among all member nations. To be able to meet their healthcare demands, developing nations have begun to call for more flexibility in the global trading system in recent months.

This was made clear at the most recent Ministerial Conference, which took place in Doha, Qatar, in November 2001. At this meeting, TRIPS and access to medications were major topics. Access to Essential Medicines, International Trade Law, and Patents, May 2002 Until all of the member nations (apart from the ones concerned in the dispute) reject this request to authorize sanctions, 4, it will be accepted. Sanctions are not supposed to be imposed by nations prior to this procedure. The sanctioned nation may request that an arbitrator determine whether the sanctions are just.

4. The nexus between TRIPS and health

According to the TRIPS Agreement, patent monopoly rights must be weighed against other significant interests. It claims that encouraging technological innovation and facilitating the transfer and diffusion of technology should be made possible by safeguarding and upholding intellectual property rights. TRIPS's Article 7 states that this should take place "in a manner conducive to social and economic welfare, and to a balance of rights and obligations" and that it should benefit both the producers and the users of technological information. In addition, Article 8 of the TRIPS Agreement lays out some fundamental guidelines for interpretation.

It states that nations "may take measures necessary to protect public health" while drafting their own laws. It also acknowledges that nations may need to take "appropriate measures" to stop patent holders from "abusing" their rights or to stop actions that "unreasonably" impede trade or harm the transfer of technology internationally. However, these actions must be "consistent" with TRIPS's rules. The idea that nations have a right to flexibility in how they fulfill their commitments to protect patent rights is supported by these TRIPS rules [11].

TRIPS contain provisions that nations might utilize to encourage the availability of inexpensive medications for those suffering from HIV/AIDS and other diseases (see below). Additionally, member nations released a Declaration on the TRIPS Agreement and Public Health at the most recent WTO Ministerial Conference in Doha in November 2001, stating that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all." The interpretation of the TRIPS Agreement still has some gray areas, nevertheless.

There are still issues with the TRIPS Agreement that have not been resolved, therefore it is unclear whether the Doha Declaration will have any good, tangible

effects (see below). To guarantee the most significant flexibility towards the interpretation and implementation of the agreement, advocacy is still required. To ensure that nations can defend their citizens' health and human rights, the Agreement may need to be amended if the required wiggle room cannot be established. While there is a pressing need for access to medications right away, formally revising the agreement's terms might take years and produce unpredictable results.

TRIPS have four primary components that can help nations promote access to inexpensive medications.

Exclusions from patent admissibility:

A nation may refuse to recognize an invention's patent ability if it is "necessary" to do so in order to preserve human life and health (Article 27). It's unclear how to decide whether this is essential and who makes the decision.

Exceptions to patent rights:

According to Article 30, a nation may, while considering the legitimate interests of others, provide in its patent rules "limited exceptions" to a patent owner's rights to prevent others from producing, utilising, selling or importing an invention. These exclusions may not "unreasonably prejudice" the patent owner's legitimate interests and may not "unreasonably conflict with the normal exploitation" of the invention. This article has only been interpreted by the WTO once, in the Generic Medicines issue regarding Canadian patent rules. The TRIPS law was interpreted loosely in that case, favoring more access to reasonably priced generic medications.

Parallel importing:

Drug manufacturers frequently charge less for their products in one nation than in another. This means that importing a patented drug from overseas might sometimes be more affordable for a country with limited resources than buying it at higher costs from the producer at home. Most nations' patent rules provide that the moment a patent holder forsake the rights on its goods, it has no further legal authority over the resale of those same items. In this sense, the patent holder has "exhausted" all of its legal options with respect to the sold good. (The owner of the patent retains the sole authority to create the product, maintaining its monopoly on the "know-how" underlying the innovation).

As a result, a middleman may purchase a patented drug in one state at the manufacturer's lower price and resale it in a different state for less than the manufacturer is asking for its product there. The term "parallel importing" applies here. Nothing in the TRIPS Agreement, according to Article 6, prohibits a nation from allowing parallel imports [12].

Compulsory licensing:

In accordance with TRIPS, a nation's legal framework may allow the state or the courts to provide a "compulsory license," which enables the government, a person, or a business to utilize a drug (i.e., create or import a generic version) without the consent of the patent holder. For reasons of general interest, such as public health, economic development, national defense, and the absence of use (i.e., when the patent holder is not "exploiting" its invention), compulsory licenses are typically issued. The basis on which governments or tribunals may impose compulsory licenses are not restricted by the TRIPS Agreement [13].

Typically, a voluntary license must be attempted to be negotiated with the

owner of the patent "on reasonable commercial terms" within a "reasonable period of time." Nevertheless, it's crucial to note that the effort at negotiations and discussion with the patent holder will not be necessary if the drug is being employed for "public non-commercial use," when there is a "national emergency" or other situation of "extreme urgency," or if the patent owner has been found to have engaged in "anti-competitive" practices.

The patent holder has a claim to "adequate remuneration" (i.e., either a nominal fee honoring the inventor or an adequate and appropriate royalty in lieu of financial compensation for loss of sales) if a forced license is granted. Alternatively, the responsible authorities can decide that a license must be given away without fee. The definition of "adequate remuneration" is not specified in the TRIPS Agreement.

Additionally, unless the license is granted to address "anti-competitive" behavior by the patent owner, the license must be "predominantly" utilized to supply the domestic market in the nation providing the license. Given that many developing nations lack the capacity to create their own generic medications, they would have to import them from nations that do. This presents a potential obstacle to receiving affordable medications. However, TRIPS prohibits those nations that do have a generic drug sector from granting a compulsory license allowing someone to produce a patent-protected drug principally for export to other nations. The WTO is now considering solutions to this barrier to the export of high-quality generic medications to nations who want less expensive medications but must import them because they lack the capacity to produce their own.

5. The legal framework on the protection of the human right to health

Countries are required by global human rights instruments to take action, individually as well as collectively, to fully implement the universally acknowledged human right to health in addition to their ethics-driven duties to act in the interest of the public. This includes passing legislation to support and advance this right. In order to uphold the right to health, States ought to additionally make sure that this right is taken into account in international agreements (like TRIPS) and that these agreements do not adversely influence the right to health, according to the UN Committee on Economic, Social, and Cultural Rights. Regarding pandemics like HIV/AIDS and COVID-19, the UN Commission on Human Rights has also acknowledged that access to medicine "is one fundamental element" for achieving everyone's right to health [14].

This justification is frequently used to support a 20-year patent protection period for novel items and techniques. However, it is a misleading generalization that ignores complaints that excessively rigid international trade agreements on patents make it difficult for people in developing nations to get affordable medications. The pharmaceutical sector continues to be the most profitable in the world, considerably outpacing businesses in all other industries. The amount required for a "reasonable" return on their R&D is much in excess of current profits. This is especially true when we take into account the fact that pharmaceuticals sold by multinational corporations were frequently created with substantial public

funding, including direct government involvement in pharmaceutical research as well as tax advantages for R&D.

Additionally, the income they receive from developing nations is really meager. For instance, despite the fact that millions of people require medications for a variety of diseases, all of Africa only contributes to roughly 1% of worldwide pharmaceutical sales. The drug industry's motivation for R&D will not be significantly impacted by restrictions on or overrides of patents in such nations. In any case, a profit-driven system based on private patent rights encourages only the development of the most lucrative drugs. Diseases that primarily afflict low-income populations, who cannot afford expensive medications, will not be lucrative study areas unless there is a sizable enough rich market to make the research investment viable.

When nations have varying degrees of development or opt for different development routes, a world-wide system of patent with a single set of laws does not function. After achieving a particular level of economic, social, and technological development, the majority of industrialized nations adopted their current patent rules. Because drug patent regulations were flexible (and later changed in late 1987 and 1993 to nearly totally abolish any kind of forced licensing), Canada's own generic drug sector was able to flourish. For poorer nations, which cannot afford the expensive access to technologies including medicines when multinational firms have monopolies on that knowledge, imposing the laws of the industrialized world on all nations will offer an extra hurdle to socioeconomic growth. Patent owners are concentrated primarily in developed nations. Monopolies on such information at a global scale will "lock in" the current inequality [15].

The foundation for the industry's development to where it has reached today, being a leading manufacturer of high-quality generic medications and raw materials, capable of inventing new methods for manufacturing medications through reverse engineering, and able to conduct original research and development—was provided by the patent law of India dating back to 1970, which granted patents to 'process' instead of 'product' for pharmaceuticals. The Indian drug sector has boosted research and development since TRIPS was agreed, but for ailments that are endemic to the West rather than those that are indigenous to India, according to evidence from the Indian pharmaceutical industry. Indian research and development priorities were determined, like those of other market-driven businesses, by the significance of potential markets rather than by medical requirements. India is one of the few developing nations with domestic research and development capacity, thus the example is instructive.

There are numerous ambiguities in TRIPS itself. How flexible the TRIPS Agreement can be interpreted and applied is still a topic of significant debate. There haven't been many instances presented to the WTO that provide unambiguous interpretations, but the ruling in the Generic Medicines dispute (see side box above) is worrying. But whether and how countries can safeguard and encourage access to affordable pharmaceuticals will be greatly impacted by how the TRIPS Agreement is legally read and how it is used in a political sense. Despite some recent positive advances, strong lobbying is still required to promote TRIPS' full flexibility for countries to meet their health needs.

6. The importance and relevance of the Doha declaration

At the WTO Ministerial Conference in Doha, Qatar, in November 2001, participating nations released a "Declaration on the TRIPS Agreement and Public Health." It notes that the TRIPS Agreement "can and should" be construed in a way that supports nations' rights to safeguard public health and, in particular, to encourage access to medicines for everyone. It further states that the TRIPS Agreement "does not and should not" restrict countries from taking actions to protect public health. An important step forward is represented by the Doha Declaration. The highest body with the power to adopt interpretations of WTO treaties is the Ministerial Conference [16].

The Doha Declaration ought to, therefore, as a question of law, influence the reading of the TRIPS Agreement in an increasingly "health-friendly" direction in any future patent conflicts. These interpretations ought to additionally take into consideration the responsibility that nations have to uphold and advance the human right to health as per international law. The TRIPS Agreement is invoked and trade sanctions are threatened when developing countries restrict exclusive patent rights in order to lower the cost of medicines. This pressure technique may be avoided with the aid of the Doha Declaration which made a promise, but whether it will be fulfilled is still up in the air. The deadline for "least developed countries" to adopt the TRIPS provisions requiring them to award exclusive, patent rights for 20 years to pharmaceutical items was further extended by the Doha Declaration until 2016.

The Doha Declaration recognised an additional limitation that the TRIPS Agreement imposed while arguing for a more health-friendly interpretation of the agreement. As previously mentioned, Article 31(f) mandates that mandatory licenses for the manufacturing of generic medicines be restricted to "predominantly" serving the local market of that nation. This clause limits the ability to give a compulsory license throughout a drug's 20-year patent period to a corporation that produces generic medications primarily or exclusively for export to poor nations without the infrastructure to do so.

This poses a severe issue because many poor nations are in fact unable to employ protections like compulsory licensing to gain access to affordable generic medications because they lack manufacturing and supply capacity. If there is no solution identified, the full effects can be felt very quickly. Few developing nations with a generic pharmaceutical industry are still partially exempt (until 2005) from the TRIPS obligation to provide exclusive patent rights on medicines, allowing them to continue exporting more affordable, high-quality generic medications.

However, even if the political and business elites in these nations were willing, they still wouldn't be able to meet the total demand for medicines to treat HIV/AIDS and other ailments in the poor world. Beginning in 2005, they will be governed by Article 31(f) of TRIPS, necessitating the issuance of a compulsory license in order to manufacture generic copies of proprietary medications. Even then, the ability to export generic medications to poor nations in need would be restricted to "predominantly" servicing their domestic market. The Council for TRIPS of the WTO, which is in charge of the agreement, has been given instructions to come up with a "expeditious solution" and submit a report by the end of 2002. A group of

non-governmental organizations has proposed ideas that will provide poor nations the most freedom in getting access to good, affordable generic medications. However, some wealthy nations (particularly the US) are making a concerted effort to push "solutions" that are severely constrained, only temporary, and restricted to dealing with "pandemics" or public health "crises". Canada has so far backed any proposal with these tight criteria. Since the TRIPS Agreement does not impose these kinds of limitations on compulsory licensing, it would be unfair to apply them to poor nations who must import pharmaceuticals in order to employ compulsory licensing effectively while other nations do not have to overcome this obstacle.

This goes against the Doha Declaration's ethos, which called for a solution that would enable developing nations to effectively implement compulsory licensing. Developed nations should encourage practical solutions that would best help poor people grappling with HIV/AIDS as well as other life-threatening diseases in developing countries, instead of limiting the use of the restrictions that are already present in the TRIPS Agreement by developing countries [17].

7. Conclusion

According to the Doha Declaration, public health commitments and the responsibility to support universal access to medicines take precedence over intellectual property rights. Advocates and activists in the health sector should utilize this to advance the idea that trade agreements are secondary to nations' responsibility to defend and advance human rights, which also includes the attainment of the best attainable quality of health for all. People who are worried about developing countries' access to medicine must make sure that the Doha Declaration's promises are kept in good faith. Advocates need to work towards a resolution that swiftly and fairly addresses the problem of approving the production of generic drugs of high quality meant to be exported to developing nations and that avoids establishing onerous requirements that will hinder access to a wider range of reasonably priced medicines, increasing the number of avoidable deaths. If advocates follow the actions permitted under the TRIPS Agreement to enhance access to essential and life-saving medicines, they must also make sure that the advances reflected in the Doha Declaration are not reversed by political pressure on developing nations. These protections must be included in any regional or bilateral trade agreements that deal with patents, and they should not go beyond TRIPS in bolstering private intellectual rights at the expense of low-income people who require access to medicines.

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