Patent Protection and the Global Access to Essential Pharmaceuticals during Patent Infringements under TRIPS

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ABSTRACT

This paper examines the arguments for sustaining international patents and explanations for patent infringements, especially when there are serious medical needs of pandemic and global proportions within the context of TRIPS and ethical principles.

Keywords: patents, innovation, bioethics, intellectual property

INTRODUCTION

Patents are negative legal rights that act as stop signs to prevent non-innovators from making, using, or selling inventions without expressed permission from inventors. Infringements on patents are serious violations from the legal and ethical perspectives. It is therefore not surprising, that there were mixed feelings when the Supreme Court of India rejected Novartis's patent protection claim against the Indian pharmaceutical production of the generic version of *Gleevec*. In the wake of the HIV/AIDS pandemic, Brazil, South Africa, and Thailand defiantly broke international protocols on patent protection and manufactured patented medicines for their citizens at relatively affordable prices.[i] It is important to note here that these countries are all signatories to the World Trade Organizations' (WTOs) *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS).[ii] This leads one to question why these countries infringed on such laws that they have made a commitment to keep. Should there be legal consequences for stark violations of these laws? Are these actions ethical? To what extent should there be a sense of accountability in these matters?

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Scope

The first part of the paper will examine some treatises or applicable laws on international patents. The second part will analyze reasons why certain patents *may* be infringed especially in the context of South Africa, and I will then conclude with some ethical arguments for making essential medicines accessible within the framework of patent laws.

Background

In the wake of the global HIV/AIDS pandemic, the governments of Thailand, South Africa, and Brazil issued compulsory licenses for the importation and manufacture of the generic versions of some essential antiretroviral medicines in line with the World Trade Organization's TRIPS Article 31, which *inter alia* grants exemptions for infringements when there are health emergencies. While these decisions were accepted internationally as bold and novel, patent holders challenged the legality of infringing upon such patents. Furthermore, patent holders argued tacitly that the reasons given for patent infringements were not health emergencies *per se*, challenging Thailand's issuance of compulsory license for the generic versions of Plavix – used for treating patients with heart diseases – as a violation of WTO international laws.

On the other hand, many have suggested that infringements of patents should be construed or judged on a case by case basis. But is it true that international laws such as WTO's TRIPS prohibit such infringements? Or do these laws/agreement actually support such actions? Are these international norms inadequate? If so, why, and further, how could these be resolved? Why is the South African (SA) case significant in 1996? What impact could it have on the world?

In perspective, the South Africa case is significant for many reasons and I intend to contextualize it. It is instructive to note that demographically, SA had a total population of 40.5 million people; 50 percent were black, 13.6 percent were white, 8 percent mixed race and 2.06 percent Indians. Unemployment was at 31 percent with a per capita income of $2,700, compared to $37,500 in the United States. At the peak of the HIV/AIDS pandemic in 1996, about 20 percent of all adults were living with the disease in SA alone. It was obvious that the cost of treatment for HIV/AIDS – pegged at $12, 000 per year at the time – far exceeded any financial capacity of the victims. The proportions were higher in places like Johannesburg and some mining cities. Furthermore, only 20 percent of the population was covered by adequate private health insurance while the rest relied on a public health system fraught by "irrational use of resources, poor working conditions, and inadequate infrastructure."[iii]

Faced with this existential public health pandemic and national emergency, the South African government made reforms to their health sector and passed the *Medicines Act Amendments of 1997* and in particular granted certain legal powers to the Minister of Health such as:

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported; and (c) prescribe the registration procedure for, as well as the use of, the medicine referred…

The rationale among other things was ostensibly to provide affordable antiretroviral medicines for the victims of the HIV/AIDS pandemic. The promulgation of these laws and the subsequent issuances of licenses were received with mixed feelings evidenced in many protests and legal actions. Many legal scholars believe the bone of contention was the insertion of *Section 15C*into the *South African Medicines and Related Substances Control Act* (MRSCA). The *Pharmaceutical Manufacturers Association* of South Africa (PMA) filed a complaint with the Public Protector of South Africa (a neutral investigative body with limited power) alleging that some officials of the Ministry of Health of SA created distorted and offensive statements, thus creating *"a perception in the minds of the general public that medicines in South Africa are unreasonably expensive and moreover that the blame for such expensive medicines lies with the manufacturing and primary importing companies"*.[iv] In February 1998, the pharmaceutical companies filed a lawsuit before the High Court of South Africa contesting the legality of MRSCA and patent infringements.[v] But was this lawsuit justified? Which laws and legal precedents serve as the *prima facie* case for this lawsuit? How does SA counter this lawsuit? In attempt to answer these questions, the next sections will examine a medley of these applicable and relevant laws.

Relevant Laws and Precedents

In February 1998, pharmaceutical companies filed a lawsuit before the *High Court of South Africa* alleging that SA was violating international laws such as Article 27 of TRIPS, as well Articles 25, 44, and 231 of the SA constitution which prohibits the use of patents without permission and compensation. The lawsuits in part states:

2.4 it is discriminatory in respect of the enjoyment of patent rights in the pharmaceutical field which discrimination is in conflict with the provisions of Article 27 of the Trade Relates Aspects of Intellectual Property Rights Agreement [hereinafter referred to as the "TRIPS Agreement"], an international agreement binding the Republic and to which Parliament has given effect by the promulgation of the Intellectual Property Laws Amendment Act, No. 38 of 1997, and consequently such provision is in conflict with Section 44(4) of the Constitution read with Sections 231(2) and 231(3) of the Constitution;[vi]

Each party to the lawsuit made references to international laws/agreements on patents as well as the SA Patents Act 57 of 1978**.** The first law in contention was the WTO TRIPS agreement which was promulgated in the Uruguay Round of the *General Agreement on Tariffs and Trade*(GATT) in 1994. GATT formed the basis for the formation of the World Trade Organization in 1995 which conferred intellectual protection to members of the organization, including patents rights. The WTO therefore enforces all intellectual property laws under the TRIPS. According to Section 28 of TRIPS*, "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"*.[vii] While TRIPS *de facto* stipulates protection of all intellectual property, laws including patents on pharmaceuticals, Articles 8, 30 and 31 respectively grants certain exemptions.[viii]

SA countered these allegations by first responding that MRSCA was promulgated to grant powers to the Minister of Health in order to circumvent patents in consonant with *Article 31* of TRIPS. This was because, before the promulgation of MRSCA, SA had limited legal powers to issue compulsory licenses under the *Patents Act* of 1978. But faced with such national pandemics, the SA government promulgated its new laws to ensure that victims of the HIV/AIDS would have access to affordable medicine which they asserted was consistent with international laws.

It is important to note that the general public interest exemptions were stipulated in Article 8 (1) of TRIPS which categorically requires members to *"adopt measures necessary to protect public health…and to promote the public interest in sectors of vital importance".* In addition Article 30 indicates that "*Members may provide limited exceptions to the exclusive rights conferred by a patent"* cognizant of the interests of third parties. And perhaps most significantly, Article 31 of TRIPS grants the use of patents by legitimate authorities *without the authorization of patent holders* in the case of national emergencies (such as the HIV/AIDS pandemic).[ix]

In brief, both parties agreed on the substantive fact that there was a dire medical need, but the main issue was whether the insertion of *Section 15C* to the MRSCA contravened TRIPS as evident in the lawsuit. However, on April 19, 2001, 39 members of the pharmaceutical Trans-national Corporations (TNCs), dropped the lawsuit against the South African government. The European Union and WTO supported the SA position, and later, SA pledged to comply with TRIPS agreements.[x]

In summary, the SA government successfully contested its case within the scope of international laws such as TRIPS because HIV/AIDS was indeed a *health emergency* covered under the agreement. Also, the promulgation of MRSCA, in particular Section 15C, circumvented patent laws within the scope of the constitution. It was therefore not surprising that South Africa (and allied southern African countries) became the architects in drafting the agenda leading up to the Declaration on the TRIPS Agreement and Public Health (the *Doha Declaration*), which reaffirmed patent protection as well as the public health challenges facing developing nations. Both the United States and Canada also expressed their willingness to use the *Doha Declaration* to override Bayer's patent to manufacture *Ciprofloxacine* (Cipro) in case of a hypothetical outbreak of anthrax which could constitute a case of national emergency. The SA legal case therefore has become significant in clarifying and reaffirming WTO TRIPS. There are many ethical principles gleaned from the legal precedents above, and I intend to focus on some of these issues in the next section.

Utilitarian Perspective

One of the major contentions in patent infringements is that they serve to provide immediate, affordable, and accessible pharmaceuticals for more people in health emergencies such as pandemics. This line of thinking and justifications seemingly aligns with the ethical principle of utilitarianism. Jeremy Bentham posited an important question as to whether something is utilitarian by asking "What is the use of it? The theory or the *principle of utility* suggests that when one is confronted with moral choices or liberties, one has to choose an action that leads to the highest or maximal amount of pleasure or good for a greater number of people while concurrently minimizing any harm as much as possible. For utilitarians, an action is ethical if it is "useful"; hence the principle of utility. But utilitarianism is both quantitative and qualitative. Bentham further noted that an action is ethical if it maximizes the greatest amount (qualitative) of pleasure and minimizes pain by testing these actions against the "pleasure-pain calculus". Mill added a quantitative component to Bentham's theory by suggesting that an action is ethical if it brings about the greatest amount of pleasure for the greatest number of people. In brief the end justifies the means.[xi]

Juxtaposing these strands of views on utilitarianism, it could be inferred that patent infringement is justified because it brings about a greater good for a greater number of people especially in the wake of the HIV/AIDS pandemic. This may be accentuated by the fact that ordinarily, most patients in South Africa and Brazil could not have afforded the pricy anti-retroviral drug. By breaking the patents, these two countries were able to provide enough and affordable medications to their patients. Had the patents not been infringed, most probably, *very few people* could have afforded the anti-retroviral drug to the exclusion of the majority.

Furthermore, by infringing on the patents, *many lives* were saved and thus quantitatively, the anti-retroviral drug was made available to many people and maximizing a useful purpose. Less "harm" was caused as many people (presumably) benefited from breaking the patents. Furthermore, physical pain in the form of diseases were minimized and curtailed while optimizing some pleasure or happiness by improving the lives of the patients and their families. Economically, these nations have saved substantial amounts of their budgets on health care and could use these resources in other sectors of their local economies. Moreover, by producing these medications locally, they have also created some jobs for the local population. In brief, patent infringement under the aegis of the principle of utility may be deemed justified.

Counter Arguments

One of the major arguments against utilitarianism is that it is too reductionist with the tendency to cause the Lake-Wobegon effect. That is, it has the proclivity of reducing ethical choices to mere "pleasure" and "pain". Overtly emphasizing the maximization of pleasure does not address the specific circumstances in each ethical decision. It dehumanizes morality. In the case of patent infringements, the principle of utility does not take into account the inventors and the companies who owned these patents and have invested substantial amount of time and resources in research and development. Most of them chose to work hard and endured

lots of "pain" in order to obtain these patents. The question herein is, should society inflict pain on them by depriving them of their happiness as well? Would these inventors and investors be willing to sacrifice their resources in inventing other novel technologies and pharmaceuticals for the common good if their inventions are not incentivized? In brief, justifying the breaking of patents under the expediency of the principle of utilitarianism is fundamentally flawed and has the inherent tendency to truncate innovations and deny patents owners their rights.[xii]

The second counter argument to the principle of utilitarianism is deontology. Deontologists such as Kant suggest that morality should be based on the set of universal normative principles that impose a categorical imperative on moral agents.[xiii] In evaluating a course of ethical action, one has to adhere to universal principle akin to a call to duty such that anyone, anytime, and anywhere may make the same ethical decision. As Kant summarizes:

When I think of a *categorical* imperative I know at once what it contains. For, since the imperative contains, beyond the law, only the necessity that the maxim be in conformity with this law, while the law contains no condition to which it would be limited, nothing is left with which the maxim of action is to conform but the universality of a law as such ... There is, therefore, only a single categorical imperative and it is this: *act only in accordance with thatmaxim through which you can at the same time will that it become a universal law.*[xiv]

In addition, the principle of deontology imposes an obligation on all people to never use another human being as a means to attain an end. In other words, the end does not justify the means. Hence, in dire humanitarian crises such as the HIV case, by breaking the patent, the government of these countries "used" the intellectual property of these patents to attain their own local or national needs. One cannot use the larger interest of the population to the exclusion of the investors or patent holders who have rights as well.[xv]

In brief, patent infringements under the aegis of a national health emergency may be justified depending on what ethical principle one uses. But each position also has some weaknesses that need to be addressed from the ethical perspectives. Breaking a patent will obviously infringe upon the rights of patent holders even in such emergencies. The question then arises as to how to find some common grounds such that the larger humanitarian health needs are met while the individual and equally important rights of inventors are protected. But is that possible? This then begs the question of justice which will be the focus of the next section.[xvi] [xvii]

Justice[xviii]

Some proponents of patent infringements in humanitarian health crises contest that justice demands expeditious availability and accessibility of essential medical interventions to serve vulnerable populations. Justice as fairness means that legitimate governments have fiduciary responsibilities towards ensuring that the most vulnerable such as the victim of the HIV/AIDS pandemic have essential and life sustaining drugs even if it means temporarily interfering with rules governing patents. After all, no human life is replaceable; hence

every measure to preserve life must and ought to be taken.[xix] It is important to note at this juncture that according to the *Universal Declaration of Human Rights*, "Everyone has the right to life, liberty and security of person".[xx] Everyone is guaranteed an equal protection of "life" which implicitly includes access to health care even in humanitarian crises such as an pandemic or the flu. Furthermore, the WTO TRIPS (Article 31) anticipated such emergencies and therefore stated among other things "…in situations of national emergency or other circumstances of extreme urgency, the right holder[of a patent] shall, nevertheless, be notified as soon as reasonably practicable". Clearly, breaking patents has saved many lives; if countries in such health emergencies had not taken any action, the harm would have been egregiously high.[xxi]

Another justified reason for patent infringements within the law may be construed around the cost for generics and in particular biologics. Currently, the pricing of biologics are very high and patents on biologics entail twelve years of exclusivity. For instant, Cerezyme is estimated to cost more than $ 150,000 per year per patient. This and the cost of many other biologics prompt many in the international community to suggest that breaking the patent to make biosimilars under the aegis of justice may be deemed ethical.

Counter arguments[xxii]

Patent infringement is a transgression of the rights of patent owners. In other words, patent owners and inventors have "equal" protections under the law, which includes according them justice for the use of their intellectual property. Equal protection under the auspices of justice as fairness means that society must ensure adequate compensation to patent owners as well. But in most of the cases, such as in South Africa, Brazil, and Thailand, patent owners have not been compensated even though their patents and innovations have been used in making pharmaceuticals and therapies to save lives. Essentially, they have been deprived of their legal rights to their ingenuity and inventions. It is ironic that violators of patents make a claim to justice and yet refused to accord the inventors their concurrent claim for a just use of their intellectual property. One wonders if this is actually fair.

It is important to distinguish "actual demonstrable existential" and "good" reasons for breaking patents. In the case of the HIV/AIDS pandemic, it clearly posed existential threat to both patients and the global health at large. Breaking a patent may be justified in this circumstance. However, we see in the case in Thailand, that their "good" reason was only to advance their own parochial economic need rather than existential public health crises. Such (mis)conduct cannot be justified under the expediency of justice.[xxiii]

Non-maleficence& Beneficence

One of the justified ethical reasons for patent infringements is the ethical principle of beneficence and, implicitly, non-maleficence. [xxiv] First is the issue of cost. As noted in my exposition so far, many of the pharmaceuticals made in developed countries are very expensive with many years of patent exclusivities without the generic versions. Consequently, without even a national emergency, there is always the temptation of breaking some of these patents for the benefit of the local population. This is evident in the

case of Thailand and India, where pharmaceutical companies question the very logic of patenting if patented drugs are not generally and reasonably affordable. This is why some of these patents have been broken with impunity. In the case of the HIV/AIDS pandemic, it was demonstrably evident that many patients could not afford $12,000 per year, especially in developing countries with abysmally low wages of $1 or less per day. Without breaking a patent, it is hard to see how these essential lifesaving drugs could have been afforded and accessed by those in dire need.

In an ethical conundrum, risk ought to be shared to the extent that the most vulnerable are insulated.[xxv] Breaking a patent and making these drugs available should be weighed against the risks of losing these patients. The risks of not breaking a patent in a hypothetical case of anthrax could be higher and possibly catastrophic.

This then leads to the third element, 'benefit'. Who are the beneficiaries in such national emergencies? Are they the most vulnerable? Who determines and defines vulnerability? For the most part, countries like SA that have broken patents have seemingly justified their actions by arguing that their most "vulnerable" people were victims of HIV/AIDS. In addition, breaking a patent means that the cost of the generic versions would be reasonably low and therefore beneficial to all patients.

Counter Arguments

It may be argued that the world risks losing innovators if they should opt out from patenting their innovations and keep them private as trade secrets. If this occurs, it means that the larger society may not have access to valuable knowledge and these could be costly in the wake of humanitarian health crises. For instance, if scientist X decides to hide an essential therapeutic formulation that could potentially save many lives, it means that during a potential humanitarian crises, the larger society could pay dearly for it. In view of this, some have proposed that innovators should be "reasonably and properly" compensated after their patents are broken.

Another counter argument is that patent infringement to develop generics does not and will not necessarily benefit the general public. A classic example is the case of Thailand, which has broken many patents for non-emergencies such as in the case of Plavix. The Thai government issued compulsory licenses for the importation of these pharmaceuticals from India, as well as for the production of the generic versions locally by invoking the TRIPS agreement (Article 31). Obviously, heart diseases are not diseases of national emergencies of epidemic proportions, but the Thai government broke the rules with impunity. This is why, it has been suggested that breaking patents or allowing local governments to issue compulsory licenses on patents could be a bad precedent.

Another counter argument is on counterfeits and issues of safety. Breaking of patents means most patent owners might not be able to monitor counterfeits on the open market. In addition, most developing countries might not have the facilities to safely produce these pharmaceuticals compared to the patent holders, and could potentially compromise the safety of patients as well.

The ethical argument of beneficence is important because it seeks to balance risk allocations, costs, and benefits to the most vulnerable in society among others. Circumventing patent protection in order to provide lifesaving therapies could be justified especially as in the case of the HIV/AIDS case in South Africa. As the US and Canada have both indicated, they will break patents on *Cipro* in emergencies in order to save lives.

Some Perspectives and Conclusion

Inventors are granted certain exclusive protections by national and international laws such as the US Patent Laws as well as WTO's TRIPS.[xxvi] Nonetheless, the TRIPS grants some exemptions for circumventing patents in the case of national emergencies such as epidemics. In the wake of the HIV/AIDS pandemic, TRIPS laws became a bone of contention between international pharmaceutical companies such as GlaxoSmithKline and the government of South Africa, resulting in a subsequent lawsuit. Even though the lawsuit was later withdrawn, the case became a litmus test for breaking international laws on patents, as well as charting the path for the *Declaration on the TRIPS Agreement and Public Health* (the Doha Declaration). This paper has argued that patent infringement is legal within the context of international laws.

In addition, this piece has analyzed patent circumventions through many ethical principles such as utilitarianism, the question of justice, and beneficence with allusion to non-maleficence. This analysis makes the case that it is possible to set aside stringent patent laws in the wake of emergencies. But it is important to ensure that inventors are properly compensated when such emergencies subside. If possible, tariffs could be imposed on all pharmaceuticals and given to WTO TRIPS oversight committee so that in the case of such emergencies, patent holders could still recoup some of the costs of research and development. In the case of exclusivities of twelve years on biologics, this paper contends that it may be prudent to reduce in order to prevent the likelihood of patent infringements under TRIPS. Furthermore, patents should be protected but each attempted infringement should be analyzed based on specific needs, and infringers (as in the case of non-emergency situations) should be sanctioned under the laws.

In brief, the case of the HIV/AIDS pandemic throughout the world and especially in SA reverberated with a sense of urgency and emergency. I believe the actions of patent infringement within the context of Section 15C of MRSCA and the patent provisions of WTO was justified as millions of lives were saved. Scientific innovations and the law are geared toward improving the lives of every human being and the world – this is the human factor. And the human factor is the humane factor.

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[iii] South African Department of Health, National Drug Policy for South Africa 3 (1996).

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[v] *See* Notice of Motion in the High Court of South Africa (Transvaal Provincial Division), Case No. 4183/98

[vi] Notice of Motion in the High Court of South Africa (Transvaal Provincial Division), Case No. 4183/98

[vii] See www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm

[viii] See Naomi A. Bass, Note, Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century in Geo. *Wash. Int'l L. Rev.* 191, 210 Vol 34 (2002). Also Marjorie Cohn, The World Trade

[viii]Organization: Elevating Property Interests Above Human Rights, in *Ga. J. Int'l & Comp.* L. 427, 435-37 Vol. 29 (2001).

[ix] It is important to point out that here that the TRIPS agreements especially on circumventing patents in the wake of national emergencies were reaffirmed in the *Doha Declarations*

[x] Rachel Swarns, Drug Makers Drop South Africa Suit Over AIDS Medicine in *The New York Times* (New York April 20, 2001)p. A1

[xi] Jeremy Bentham, *An Introduction to the Principles of Morals and Legislation*

[xii] William W. Fisher et al. See also Lissett Ferreira Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations in Fordham Law Review Volume 71(2002)

[xiii] Immanuel Kant Kant's *Grounding for the Metaphysics of Morals* (1985)

[xiv] Kant *Groundwork* 4:420-1

[xv]Tom Beauchamp et al. *Principles of Biomedical Ethics* (Oxford University Press: London, 2009). See Marjorie Cohn, The World Trade Organization: Elevating Property Interests Above Human Rights, 29 Ga. J. Int'l & Comp. L. 427, 435-37 (2001)

[xvi] Beauchamp et al. 197

[xvii] Ibid. See also Theodore C. Bailey, Note, Innovation and Access: The Role of Compulsory Licensing in the Development and Distribution of HIV/AIDS Drugs, 2001 U. I11. J.L. Tech. & Pol'y 193, 202-04.36

[xviii] Beauchamp et al p197. Also Norman Daniels *Justice, Health, and Healthcare* in American Journal of Bioethics, (December 7, 2010) p2-16. John Rawls, *A Theory of Justice*, (Harvard University Press, Massachusetts; 1971) p6

[xix] Ibid

[xx] Article 3 of the *Universal Declaration of Rights*

[xxi] Theodore Bailey. 202-04

[xxii] Beauchamp. P197-198

[xxiii] Ibid

[xxiv] Ibid

[xxv] Ibid

[xxvi] U.S. Patent Laws, Regulations, Policies & Procedures