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REGIONAL AND GLOBAL PERSPECTIVES ON THE PATENT REGIME AND THE RIGHT TO HEALTH

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ABSTRACT

The authors of this paper believe that by including a right to health viewpoint into patent disputes involving pharmaceutical goods, courts in poor nations may play an essential role in increasing access to health care in their country. Because iprs are still not civil liberties, the essay contends that they should never be permitted to override the right to health. The article looks at two prominent instances decided by Kenyan courts that show how important it is to incorporate a right to health viewpoint in order to improve access to medications.

Finally, the report outlines main reasons why courts in undeveloped countries cannot afford to overlook the right to safety when deciding issues concerning pharmaceuticals patent rights.

INTRODUCTION

"The concept of a better society is the one in which medical discoveries remain independent of patent and there is no profiting from death and life," Indira Gandhi proclaimed in India's stance. Where did this policy go? How did India, as the world's poorest country and a key producer of low-cost pharmaceuticals, miss the forest for the trees?[2]

The Indian government has proposed amending the Patents Act of 1970 to provide product patent protection for drugs, medicines, and foods. Within the 13th Lok Sabha, a Patent Amendment Bill was proposed to this effect, however, it expired owing to the collapse of the Lok Sabha.

The Cabinet agreed during the last week of August 2004 to send the Bill to a Group of Ministers (GOM) to investigate the implications of Bill's controversial issues. The recommended Bill's contents were similar to those of the expired Bill. This was a cause for worry since the Bill, in its current form, jeopardizes the accessibility and availability of medications, two crucial aspects of the right to health. The rights related to life and health is a not at any cost negotiable, basic right given to every Indian citizen.

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[2] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO) (1994), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

In 1999 and 2002, India modified the Patents Act to conform with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The establishment of product patents for pharmaceuticals and agro-chemicals seems to be the only TRIPS duty that has yet to be completed. Others are prohibited from manufacturing, using, selling the invention, purchasing, or exporting the patented product under the terms of the product patent.

As just a result, throughout the period of the patent, the licensor has a monopoly on the manufacture of the patented object (20 years). As a result, product intellectual property for pharmaceuticals and agrochemicals establishes a monopoly in the pharmaceutical industry and reduces competition.[3]

Drug firms frequently take advantage of their patent exclusivity to set excessive prices for patented medications. As a result of the establishment of product patents, medication accessibility and affordability have decreased.

The TRIPS agreement has resulted in high drug prices and, as a result, denied access to medicines to the impoverished throughout the world. Furthermore, it has resulted in a scenario in which medications needed to cure diseases that mostly affect the poor are not being investigated at all. Instead, medicines for "lifestyle" illnesses such as impotence, alopecia, obesity, and so on are being studied.

While the pharmaceutical industry argues that high costs are due to huge R&D spending, the fact is that the medications they are researching are unrelated to genuine medical requirements. Furthermore, the revenues generated by large pharmaceutical MNCs are indicative of profiteering rather than legal profit-generating.

Various contentions have developed concerning the influence of TRIPS[4] compliant Patent Laws upon local business - notably in developing nations - before the adoption of the WTO agreement, and in the subsequent ten years, both internationally and in the country.

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[3] See B. Lindstrom, *Scaling back TRIPS-plus: An analysis of intellectual property provisions in trade agreements and implications for Asia and the Pacific*, 42 JILP, 913,917 (2010).

[4]See G. DUTFIELD, INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCE INDUSTRIES: PAST, PRESENT AND FUTURE, 315–316 (2nd ed. Singapore: World Scientific Publishing, 2009).; E. Schiff, INDUSTRIALIZATION WITHOUT NATIONAL PATENTS: THE NETHERLANDS, 1869–1912 (NJ: Princeton University Press, 1971).

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1. Health and Patents

Health and Patents Health is amongst the most basic requirements that all people have. Basic human rights treaties recognize the right to "the greatest achievable level of psychological and physiological health" in practical terminology. From protection to cure and medicine availability, health policy includes a wide range of topics. While all of the aspects are critical, the issue of medication access shines out in the framework of the TRIPs Agreement.

Drugs must be available and affordable in order to be accessible. As a result, there is a significant connection between economic hardship and drug availability. According to a recent report by a collection of international organizations, only around 10% of HIV/AIDS patients in poor nations have anti-retroviral treatment. The HIV/AIDS epidemic has decimated whole nations throughout the world, notably in Africa.[5]

The epidemic has brought attention to the inhumane behavior of multinational pharmaceutical MNCs, which continue to sell HIV-AIDS medications for 20-50 times their true cost by claiming refuge under TRIPS-mandated regulations. In reality, it was left to Indian pharmaceutical companies like Cipla to supply these medications at drastically reduced costs, providing some relief to HIV-AIDS patients.

However, there is widespread agreement that domestic legislation must make full advantage of the TRIPS agreement's "frameworks" while being TRIPS compliant. The WTO Doha Declaration of TRIPS Agreement for Public Health (2001), which said, among other things, that nations have the sovereign authority to adopt laws that protect domestic interests, reaffirmed this in clear terms.

It acknowledged the seriousness of public health issues in developing nations and said unequivocally that participating countries seemed to have the right to safeguard public health and encourage universal access to medicines.

The behaviour of these MNCs has also sparked an outpouring of public opinion throughout the world, notably in the United States and the European Union, challenging

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

their justifications, particularly in the field of public health. Organizations such as Médecins Sans Frontières (Doctors Beyond Borders)[6] have offered a forceful voice to this rise, and have quickly grown into a global force opposing the current IPR regime's justification.

These events eventually led towards the Doha Declaration on the TRIPS Partnership as well as Public Health (November 2001), which aimed to mitigate the harm caused by the TRIPS agreement as well as its underlying ideology to some extent.

Novartis AG has been awarded an Exclusive Marketing Right (EMR) by the Controller of Patents for the medication Gleevec, which is used to care for patients with Chronic Myeloid Leukemia (CML), an experience type of cancer. EMR is given as a temporary measure before actual patent protection is obtained. Novartis AG sells Gleevec costs Rs. 1,20,000 per monthly. Patients with CML might get synthetic medicines of medication for Rs 9,000-12,000 per month. If the EMR is implemented, the generic form of Gleevec will be removed from the market.

As a result, the vast majority of patients in India who are diagnosed with CML each year would be refused entry to this life-saving medication.

1.1 To ensure access to medications, consider including a right to health approach

There was no local patent legislation in Kenya prior to 1989, and the Patents Clone Saga was the sole way to register innovations nationally (enacted in 1962). Only licenses awarded in the United States were allowed to be registered in Kenya within this procedure. The Industrial Property Act from 1989 was meant to replace the Patents Civil Rights act in order to create an autonomous patent system.

Kenya was a foundation member of the World Trade Organization (WTO) in 1995[7] and a signatory to the Model Law. The 1989 Industrial Property Law was promulgated to make it in conformity with the TRIPS Deal's provisions, as required by the TRIPS Agreement. The United States patent and trademark Act dated 2001 was enacted as a result of this procedure.

[6] E. M. Anderson, *Unnecessary deaths and unnecessary costs: Getting patented drugs to patients most in need*, 29(1) TWLJ, 1, 85 (2009).

[7] H. Brennan, R. Distler, M. Hinman, and A. Rogers, *A human rights approach to intellectual property and access to medicines*, 1 GHJP, 1, 1 (2013).

The Kenyans Industrial Property Legislation conforms with the TRIPS Agreement's standards in terms of patent protection. It also includes provisions for obligatory permits, research exceptions, and parallel importing, among other things.

A Kenyan High Court issued ground-breaking rulings in 2012 on the connection between the right to education and copyrights. 45 Prior to this case, nevertheless, it appears that Kenyan courts had never addressed the possible effects of patent rights implementation on the right to education. The Kenyan Foreign Investment Tribunal's ruling in a previous dispute between a global multinational pharmaceutical firm and a generic drug business in Kenya exemplifies this.

Pfizer Inc. v. Cosmos Limited was a 2008 lawsuit in which Pfizer claimed that Cosmos had infringement on its trademark on a medical substance known as "naproxen sodium dihydrate."

Cosmos, on the other hand, claimed that the property was not in operation from 2003 and 2006 (when the accused infringing occurred) since Pfizer failed to pay the intellectual renewal costs. The adjudication, on the other hand, found that there has been no proof that the claim had ever been revoked or been withdrawn from either the patent database. Kenya was one of the designated jurisdictions for the claim, which was issued by the Kenya National Un (ARIPO), of which Kenya is a participant.

According to Section 59 of the Kenyan Foreign Investment Act, “a patent issued by ARIPO by virtue of the ARIPO Convention in terms of which Kenya is a recognized state would have the same force in Kenya as a claim obtained under this Act.”

A court that understands the critical necessity of ensuring access to healthcare would never allow patent rights to be enforced in a way that obstructs access to healthcare. The Kenyan tribunal's reasoning in the *Pfizer v. Cosmos*[8] issue basically put patent owner rights well above right to care of women in need of vital medications.

The Special Rapporteur concurred with the plaintiffs that the Act might jeopardize the right to safety since generic medications are not excluded. 62 Generic drugs are defined by the Special Rapporteur as prescription medications that "have always had the same chemistry and encapsulate the same substances as invention formulations from same opiates, and are practically identical reproductions [that] may be used for same specific purpose as their quel predecessors" (as mentioned in the court's ruling).

[8] Pfizer v. Cosmos, case no 49 of 2006; State of Punjab v. Mohinder Singh Chawla, (1997) 2 SCC 83.

It should be observed, nevertheless, that the eventual determination of the conflict between patent rights and freedom to health may vary from case to case. In some situations, enforcing patent rights does not necessary obstruct access to medications, and patentees' rights do not need to be respected. Inside the South African decision of Aventis v. Cipla, for example, the South African Supreme Court issued an injunction to prevent the infringing of a drug patent (Docetaxel) upon determining that the stay would not inevitably restrict access to the medicine.

2. Human Rights and Patents

Patents And Human Rights The connection between human rights and intellectual property has to be clarified. On the one hand, there is little instruction in intellectual property law about its connections to other areas of law. Human rights accords, on the other hand, demonstrate that patent holders' concerns are recognized but not as basic rights and that the population's values come first.

TRIPs were enacted as a hold agreement, with no discussion of the potential consequences, such as in the sphere of health. WTO members who are also signatories to human rights treaties, however, are unable to write legislation to execute WTO requirements without taking into account the compatibility of the law with other international responsibilities, including such human rights obligations.

In reality, the UN Committee on Financial, Social, and Contributes To a number has said explicitly that governments should not commit to initiatives that are plainly incompatible with their prior international legal commitments in the context of the right to education.

Even if the worldwide definition of the right to health is ambiguous, it provides a broad structure within which health policy should operate. As a result, it requires governments to gradually ease medication access. Because medication patents tend to raise prices, governments must guarantee that the establishment of patented products does not threaten drug availability.

States should not only avoid adopting any actions that restrict medication availability, and they should also work to improve access over time. In this regard, it's debatable whether the 1970 modification to the Patents Act can withstand examination under international human rights accords. With particular public health aims in heart, the 1970 Act[9] imposed a set of rules on the extent of patents holders' privileges.

[9] 3 S. JOSEPH, TRADE AND THE RIGHT TO HEALTH, 360 (Ruffer & Rub, 2009).

As is commonly accepted, the 1970 Act's measures did not address the problem of drug access, but they did help to improve it. Dismantling the entire regime entails a significant reduction in drug accessibility. This appears to be even more important in the field of the HIV/AIDS pandemic since certain current medicines are often only available at prohibitively high costs for the wider populace.

The patents law aims to bring India into conformity with its TRIPs commitments. It does so by removing some of the most important aspects of the present legislative framework, which, when combined with other instruments like the Drugs Price Control Order, historically benefited the public effectively.

It is likely to result in a legal environment that is less favourable to the citizens of this country in terms of drug availability. TRIPs do not give much flexibility in how it may be implemented, which was one of the reasons for presenting the law in this manner. As the cases from South Africa demonstrate, this is no longer the case.

There is currently room for interpretation within TRIPs. TRIPs, on the other hand, cannot be executed in isolation. India also has a variety of additional international responsibilities, notably in the area of human rights.

The right to health, as defined by UN human rights organizations, requires governments to gradually take constructive efforts toward improving access. India's duties under the Covenant on Financial, Social, and Contributes To a number may be violated if the 1970 regime is dismantled. There are so significant reasons to rewrite the patents law in a way that does not jeopardize the country and its people or risk violating human rights.[10]

So far, we've looked at arguments for why India's patent policy must be kept out of the realm of pharmaceuticals. Now we'll take a look at the whole debate from a global viewpoint. It may be divided into the following categories:

2.1 United Nations

The right of people to access vital medicines at reasonable costs, as well as how patents and the WTO's TRIPS Deal's intellectual property rights system are undermining this right, was a major topic during the UN General Assembly's Committee Hearing for Social Cohesion.

[10] S. P. MARKS, ACCESS TO ESSENTIAL MEDICINES AS A COMPONENT OF THE RIGHT TO HEALTH, 90 (Clapham and Robinson, 2009).

After tense negotiations, ministers agreed that they'll be allowed to freely exercise options just now available to them because of international trade deals to defend and advance entry to life-saving and indispensable medicines at the close of the 24th Meeting of the United Nations General Meeting Special Session (UNGASS) in Vienna. There hasn't been much progress in terms of meeting the needs of developing countries and ensuring that impoverished people have access to life-saving medications. A lot has been accomplished in means of attracting to light the activities of certain industrialized governments in advancing the agenda of pharmaceutical firms.

2.2 The Declaration of Doha on Health

The Declaration makes no changes to the TRIPS Agreement and does not create a guideline for creating countries to connect their patent and health laws. The Patents (Amendment) Act, 2002, strongly resembles TRIPS and eliminates sections of the 1970 Act, which were India's approach to the issue of granting exclusive media rights. It an area concerned with meeting fundamental health requirements.

The 1970 act's provisions, as well as comparable legal systems in other developing nations, have been the subject of several complaints from the pharmaceutical industry in industrialized countries. The pharmaceutical industry in the United States believes that it now loses $1.7 billion per year due to India's lack of copyright protection. The Doha Declaration is indeed a direct result of the numerous patent-related disputes in the health-care sector, notably in the setting of the HIV/AIDS pandemic. Its significance stems from the realization that the existence of patent rights in the health industry does not preclude the implementation of public health safeguards. TRIPS should be "perceived and constructed in a manner conducive of WTO members' right to safeguard public health and, in especially, to ensure universal access to healthcare," according to the statement.[11]

This enhances the hand of nations seeking to take benefit of TRIPS' existing openness. In other words, the statement does not create new channels inside TRIPS, but rather supports the legality of measures that attempt to use TRIPS' inherent flexibility to the greatest extent feasible. The statement focuses mostly on issues surrounding patent implementation, such as tight regulation. Copyright law has been used to restrict its exclusive rights granted by patents for a long time. In the case of health, the logic is to

[11] UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, 126 (Cambridge University Press, 2005).; C. M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT 103 (Oxford University Press, 2007).

ensure that the presence of a patent does not result in a scenario in which a protected drug is unavailable to the general population due to non-health-related reasons.

The Patents Act of 1970 established a complex system that comprised both compulsory and voluntary licenses. The TRIPS Agreement does not eliminate the concept of compulsory licensing, but it does offer a more limited framework than the existing regime in place in the United States. The Doha Declaration's acknowledgment that TRIPS signatory can use the deal's flexibility to establish the grounds as to which work permits are issued, for example, must be interpreted in the context of an extremely strict world patent regime.

The proclamation has been praised as a significant step forward in the effort to make the TRIPS Agreement better relevant to the requirements of developing nations, particularly those who cannot afford the high costs of patented medications. In reality, it tackles a number of critical concerns surrounding medicinal patent compliance.

However, it neglects to address the much more key problems of patentability and patent length in the health industry. For two major reasons, the Doha Declaration continues to be a major instrument in India. To begin with, on a government level, India was one of the most outspoken emerging regions at the ministerial meeting, advocating for the interests of underdeveloped nations. Second, the proclamation was passed while the working group of Parliament was working on its final report.

2.3 WTO Negotiations to Come

At this time, the WTO is still a long way from offering a comprehensive answer to developing countries' health-care requirements. The Doha Declaration only gives a short reprieve in a few key areas. The proclamation makes no mention of whether or not the next round of trade talks will inevitably result in a reduction of TRIPS restrictions in this area. Indeed, the medical industry's recent harsh rhetoric appears to indicate that considerable lobbying for additional hardening of patent laws is likely to occur in the future.

Overall, the Patents (Amendment) Act, 2002 strongly resembles TRIPS and eliminates parts of the 1970 Ordinance in the process. To begin with, no formal change in the policy underpinning the Patents Act has occurred to justify such severe revisions. Second, India's domestically and internationally obligations to all people's basic right to health have remained unchanged throughout the last decade.

Third, it looks that the establishment of patented products in 2005 will have a negative impact on millions of people's access to medications. One element that may have

pushed the authorities in this approach was a desire to promote its own private medicines business.

However, it is remarkable that there is no unity among the industry's stakeholders, which is still mostly or entirely domestic. Some large companies that primarily produce generic medicines have been adamantly opposed to alterations towards the 1970 Patents Act[12], while others that have established considerable Distribution network believe that the new government may go to them for a chance to grow internationally. Small businesses, on the other hand, appear to have realized that they are not powerful enough to have a con Develop policy-making.

CONCLUSION

In India, the inclusion theory is followed. This implies that a treaty is not legally binding until it is adopted by Parliament.[13] The joint congressional inquiry mostly on Patents (Second Amendment) Bill, 1999 completed its report in December and delivered an updated version of the changes to house during the WTO ministerial meeting. As a result, the recently enacted law must be evaluated in light of the Asian Declaration Convention and Public Health, as well as other pertinent issues. India is willing to sacrifice its autonomy by placing greater emphasis on WTO deadlines than on democracy. The World Trade Organization (WTO) is not the only pact with which India must comply.

Many civil liberties have been immediately incorporated into the life and liberty provisions of Article 21, notably the right to heath, as a result of Supreme Court judgments culminating in and after Vishakha's case (1997)[14]. Such obligations are not negotiable by the WTO. India's autonomy, position, prestige, and duties are also jeopardized by acting in this manner. It is unacceptable to practice medicine without regard for social and economic justice.

Patents aren't a free pass for pharmaceutical corporations to abuse their position. Despite the fact that the Patents (Amendment) Ordinance has recently been passed, the argument over the impact of healthcare patents on medication availability is unlikely to die down anytime soon. This means that the ultimate solution to TRIPS in the healthcare sector will take several years longer to be decided.

[12] *Id*, at 108–109; WTO, *The Doha Declaration on the TRIPS Agreement and Public Health*, WT/MIN (01)/DEC/2 (November 20, 2001).

[13] Emmanuel Kolawole Oke, *Incorporating a right to health perspective into the resolution of patent law disputes*, 15(2) HHR, 1, 6 (2013), https://www.hhrjournal.org/2013/12/incorporating-a-right-to-health-perspective-into-the-resolution-of-patent-law-disputes/.

[14] Vishakha V. State of Rajasthan, (1997) 6 SCC 241.