The Effect of TRIPS Implementation on Indian Patent Law: A Pharmaceutical Industry Perspective: With Special Reference to Healthcare Industry

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Abstract

The Pharmaceutical Policy, 2002 of the Government of India emphasized upon diluting drug price control by suggesting criteria for price control that will reduce the basket of price control to a bunch of irrelevant or so drugs. The kinds of drugs that would be left under price control are mostly irrelevant to public health. The World Trade Organization (WTO) enacted the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to provide reasonable standards of protection for each of its Member Countries. The TRIPS Agreement is a basic standards agreement that gives Members the option to offer more comprehensive intellectual property protection if they so choose. Members are free to choose how to apply the Agreement's provisions in accordance with their respective legal framework and practices. Since India joined the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, the country's patent system has experienced substantial modifications. Product patent protection was made mandatory for developing nations in 1995. The TRIPS Agreement establishes basic requirements for patent protection, and when it was put into effect, the economic businesses underwent a significant transformation. Since its creation, the World Trade Organization's (WTO) member countries' intellectual property (IP) regime has changed and modified. Laws and organization rules are referenced in the TRIPS Agreement, making them enforceable for members.

Keywords: Pharmaceutical, Patent Law, IPR, Healthcare Industry, Legal Scenario and Policies.

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INTRODUCTION

Price regulation in the pharmaceutical sector is an important instrument of public policy for promoting equity in access to health care. At present about 65 per cent of the Indian population lack access to essential lifesaving medicines despite India being recognized as a global drug manufacturer. The Pharmaceutical Policy, 2002 of the Government of India emphasized upon diluting drug price control by suggesting criteria for price control that will reduce the basket of price control to a bunch of irrelevant or so drugs. The kinds of drugs that would be left under price control are mostly irrelevant to public health. Even the Drug Price Control Order of 1995 conspicuously omitted drugs for anemia, diarrhea, the majority of drugs for tuberculosis, hypertension and diabetes, and all drugs for cancer. The Trade Related Intellectual Property Rights (TRIPs) agreement has influenced drug pricing and policy in a negative way for India. The issue of drugs has shifted from the realm of health to the realm of trade- a situation made worse by the rise of multinational pharmaceuticals that are trying to control and own knowledge in the name of intellectual property rights. In reality, the provisions under the TRIPS agreement undermine some of the very processes that helped India become one of the leading countries in drug manufacturing with some of the lowest prices in the world. The effect is exemplified in the attempts of the government to reformulate the pharmaceutical policy and amendment of the Indian Drug and Cosmetics Act, 1948 to reduce the number of drugs under price control, and make space for clinical trials respectively in the name of liberalization. For India it would mean wiping out of the Indian public sector, small scale sector and overpricing of a large number of essential and lifesaving drugs and the already vulnerable population being exposed to the unethical experimentation by the drug companies. In short, we have reached a state of 'poor health at high costs'.

SCOPE OF THE STUDY

The World Health Organization (WHO) reported that one third of the world's population lacks reliable access to required medicines and the situation is even worse in

developing countries, which are finding it increasingly difficult to finance medicines as expenditure on medicines has been growing steadily. In India, over 80 per cent of health financing is borne by patients. Thus, the price of medicines is a crucial determinant of the health of citizens. Inadequate distribution systems also affect the availability of medicines. The pharmaceutical industry obtains higher profit with greater margins than other industries, and it has been argued that these margins are far beyond the sums required to finance research and development.

The Doha declaration affirms that the TRIPS Agreement does not and should not prevent members from taking measures to protect health. Health policies encompass a number of elements, from prevention to cure and access to drugs. While all elements are important, the question of access to drugs stands out in the context of the TRIPs Agreement.

Relevance (BS)

The Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference in November 2001, which affirms that the TRIPS Agreement should be interpreted and implemented so as to protect public health and promote access to medicines for all, marked a watershed in international trade demonstrating that a rules-based trading system should be compatible with public health interests. The Declaration enshrines the principle WHO has publicly advocated and advanced over the last four years, namely the reaffirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement to protect public health and enhance access to medicines. Article 31 (f) of the TRIPS Agreement stipulates that a compulsory licence must be issued predominantly for the supply of the domestic market of the Member granting the licence. Consequently, many countries without a significant pharmaceutical sector have not been able to take advantage of the compulsory licensing provisions of TRIPS. Although Members may issue compulsory licences for importation, they are restricted to importing goods from countries where pharmaceuticals are not patented, or where their term of protection has expired. As the sources for generic production of newer life saving drugs will increasingly run out after 2005, resolving this problem is of extreme importance to Members' efforts to secure access to affordable medicines to address public health needs. Consequently, Paragraph 6 of the Doha Declaration instructs the Council for TRIPS to find an expeditious solution to the problem faced by countries with insufficient or no adequate pharmaceutical production capacity in making effective use of the compulsory licensing provisions of the TRIPS Agreement.

Effects of TRIPS on Indian Patent Law

The World Trade Organization (WTO) enacted the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to provide reasonable standards of protection for each of its Member Countries. The TRIPS Agreement is a basic standards agreement that gives Members the option to offer more comprehensive intellectual property protection if they so choose. Members are free to choose how to apply the Agreement's provisions in accordance with their respective legal framework and practices. Since India joined the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, the country's patent system has experienced substantial modifications. Product patent protection was made mandatory for developing nations in 1995. The TRIPS Agreement establishes basic requirements for patent protection, and when it was put into effect, the economic businesses underwent a significant transformation. Since its creation, the World Trade Organization's (WTO) member countries' intellectual property (IP) regime has changed and modified. Laws and organization rules are referenced in the TRIPS Agreement, making them enforceable for members. The TRIPS Agreement's second key component is enforcement. These clauses stipulate that member nations must have policies and regulations in place for protecting intellectual property rights and that there must be legal remedy available in the event that these rights are violated. Countries that are party to this agreement shall abide by a set of general guidelines for protecting intellectual property rights. Several provisions deal with different aspects of enforcing intellectual property rights:

A. For administrative and civil levels, there are remedies and procedures.
B. Special rules for border procedures.
C. Measures that are only transient.

The process for resolving disputes is the third key component of the TRIPS agreement. WTO processes will be used to resolve any disputes between WTO member states involving the obligations of the TRIPS agreement. In addition to this fundamental principle, other rules, such as the most-favored-nation clause, may be in effect. There are also regulations in place to ensure that the TRIPS Agreement's intended advantages are not offset by the challenges associated with acquiring intellectual property rights.

All member states are equally obligated by the agreement's requirements, however developing and least developed nations were given more time to comply with them. Special transitional procedures can be employed if a developing nation does not provide pharmaceutical patent rights. Until the developing nation has completely complied with the TRIPS Agreement and starts granting patents, these agreements may offer patent protection.

It's crucial to realize that the TRIPS Agreement only specifies minimal requirements. As long as they have complied with the requirements of the agreement, member nations have the option to provide stronger intellectual property protections, but they are not compelled to. The member nations' implementation of the necessary provisions is not specified in the TRIPS Agreement. Instead, member states are free to implement these clauses in a way that best complies with their

own legal systems. It only counts that the nation conforms with the minimal TRIPS requirements.

After India ratified the TRIPS agreement, the Indian Patent Law was updated to comply with the agreement. Numerous multinational corporations started investing in India as a result. Additionally, MNCs began their research and development activities in India, which helped the country's economy flourish. Moreover, India is welcoming more multinational corporations to invest and begin their R&D in India as it will strengthen and enhances the economy of India through India's economy will grow in this way. As many multinational companies invested and began their research and development process in India after the year 2005, the India has increased economy saw a boom, especially in the pharmaceutical industry from 6 billion US dollars to 30 billion US dollars during the past 10 years.

On 1st January 2005, India incorporated the product patent in the pharmaceutical sector under its Patent Legislation. Following India's requirement to reinstate product patents, several extremely big pharmaceutical firms, or "Mega pharma corporations," joined the Indian market with the aim of targeting the nation with the second-largest population in the world. These large pharmaceutical firms began doing R&D and producing their patented goods after filing patent applications with the IPO. [1] This has made the Indian Pharmaceutical Industry the 3rd highest producer in terms of volume of pharmaceutical drugs in the world.

Article 7 of the TRIPS Agreement states that "The protection and enforcement of intellectual property rights should [be] to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". By defining the extent of patentability and introducing the compulsory licencing system, the patent law in India was able to implement the purpose of the upper regulation and balance the interests of the patent holder with the responsibilities of the public interest. This is been majorly controlled by Section 3(d) of the Indian Patents (Amendment) Act, 2005 which acts as a special safeguard clause. It says that:

"(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

The establishment of this clause has had a considerable impact on the Indian pharmaceutical regime since it has rejected several big patents that have been approved in several international nations. The Novartis Gleevec Law Suit was a landmark case in which the company presented their anti-cancer medicine Gleevec, which was rejected by the Indian Patent Office in 2006. In 2007, the appeal was denied by the Intellectual Property Appellate Board on three key grounds. This included the invention being predicted by prior publication, obvious to a person skilled in the art, and failing to meet Section 3 (d) requirements. This agitated Novartis to taking the case to High Court of Madras under two contentions. First being Section 3(d) of the Patents Act, 1970, was inconsistent with Articles 1(1) and 27 of the TRIPS Agreement and second that Section 3(d) was unconstitutional being vague, arbitrary and violative of Article 14 of the Constitution of India, which guarantees equality before law. However, the Madras High Court clearly stated that the purpose of amending the Patents Act and introducing Section 3(d) was simply to put a stop to evergreening; that is, to provide citizens with easy access to life-saving drugs and to discharge the Constitutional obligation of providing good health care, thus not also violating Article 14. Evergreening or re-patenting something to run in circles was an obvious infringement of the welfare purpose, and the Madras High Court dismissed the appeal on these grounds as well.

After several rejections, debates, and appeals, the issue reached the Supreme Court in 2013, where Novartis asserted patent protection as a new product with a technological development that was not obvious to a person skilled in the art. However, the Supreme Court refused it because it did not meet the criteria of "enhanced efficacy." It also acknowledged the decision of the High Court as well as IPAB, on the points that Novartis' claims were not in compliance with section 3(d). It said "section 3(d) of the Patents Act, 1970 clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds."

On March 12, 2012, the Controller General of Patents, Designs and Trademarks, for the first time in India, issued a compulsory license against Bayer, a German pharmaceutical company, over Nexavar (sorafenib), an anti-cancer drug for liver cancer, thyroid cancer, and a type of kidney cancer. Bayer obtained a patent for Nexavar in India in 2008. The company was selling Nexavar in India at Rs. 284,428 (US$5,500) for a pack of 120 tablets, equivalent to a month's dosage. The Controller General of Patents, Designs and Trademarks on March 12, 2012 issued a compulsory license against Nexavar and asked Natco, an Indian domestic pharmaceutical firm, to manufacture and sell its sorafenib at Rs. 8,880 (US$175) (for a month's treatment) after paying Bayer a 6% royalty on net sales.

The addition of Section 3 (d) to its patent legislation has worked as planned; the Indian pharmaceutical industry has

had strong, healthy growth, and there have been no unexpected influx of items manufactured by foreign-owned firms into the Indian market. The manufacturing capabilities of international businesses with affiliates in India, however, are increasingly being employed to meet domestic demand rather than to a large extent for exports. The affiliates of some of the biggest firms in the world's industry, such GlaxoSmithKline and Pfizer, who have decreased their exports from India since the middle of the previous decade, stood out for this pattern.

Despite the strictness of Indian Patent Law in the pharmaceutical industry, the Annual Reports from the Controller General of Patents, Designs, and Trademarks reveal that the number of patent applications in India has been steadily increasing since 2005. Currently, over 55,000 applications are filed each year, with a 15-25% increase in the areas of Bio-Medical and Biotechnology. Its high-quality, low-cost strategy has propelled it to the third-largest pharmaceutical business in terms of volume.

TRIPS Implementation and Pharmaceutical Patenting

One augmentation of the TRIPS that has caused a lot of criticism is the patents on pharmaceuticals, which were introduced to achieve an equilibrium between the long-term social goals of establishing incentives for future inventions and the short-term social objectives of allowing people to use established inventions and creations. On another aspect for patent protection, pharmaceutical patent holders have a strong market dominance and can restrict the rates of medicines. As a universal human right, the right to health involves access to medicine; consequently, signatories to human rights treaties must protect, preserve, and execute the right. If patent holders raise drug prices, access to drugs will be hampered. This brings the attention to developing countries, which argued that treatment options with them were limited. This was also a focus point of the Research and Development (R&D) capabilities of developing and undeveloped nations in comparison to the industrialised nations with well-established R&D centres. Despite diverse responses, the TRIPS Agreement continues to exert a considerable influence over the pharmaceutical business, governing patent acts worldwide for all signatories.

Before the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) in 1995, the pharmaceutical industry saw significant transformations. In the 1930s and 1940s, the pharmaceutical business underwent one of its greatest revolutions with the introduction of sulpha medicines and penicillin to the market. Since then, there has been an expansion of Research and Development, which has led to successive discoveries and advancements. However, it is crucial to notice that before the TRIPS Agreement, there was hardly any universal regulation that could regulate the protection of pharmaceutical intellectual property. This not only contributed to the development of a uniform model for protection but also brought about considerable changes in the economic relationships between nations. The rationale for this is that the Agreement compelled countries to implement patent laws compatible with TRIPS without differentiating between economically established and developed nations and developing or undeveloped nations. Contrary to widespread assumption, the sector expanded throughout the post-TRIPS period, despite expectations that reverse-engineered or export pharma manufacturing would halt. As a result of the TRIPS Agreement, the pharmaceutical industry has become more transnational. The pharmaceutical Global Value Chain (GVC) has been reorganised and is now being expanded into emerging countries. GVC participation is conducive to technology transfers and technological upgrading.

Developing countries and transition economies were allotted five years, till the year 2000. For pharmaceutical patents, the least developed countries got 11 years until 2006, which was then extended to 2016. Economically developed countries, led by the United States, demanded that WTO members abandon liberal compulsory licensing practices in favour of patent protection regimes that are equivalent to those of the United States and Europe in most significant areas. These requirements have been addressed by developing countries' demand for improved access to affordable drugs and medical technology developed in economically developed countries. The debate over patentability and compulsory licensing are fuelled in part by opposing perspectives on whether patent protection in developing countries is a required incentive for optimal medication development and distribution. In addition to that, the 2001 Doha Declaration on TRIPS and Public Health addressed and clarified the concerns of developing nations about pharmaceutical patents. The 2003 ruling made it possible for nations who are unable to produce their own medications to import those that are produced under a compulsory licence. According to the Doha Declaration, the TRIPS Agreement's clauses should be interpreted to support "access to affordable medicines for all." This statement emphasises the ability for a country to take use of the TRIPS Agreement's flexibilities, such as compulsory licensing, and it committed to extending the scope of the exceptions to preserve pharmaceutical patents for least developed countries by 2016.

Nexus of Healthcare and Pharmaceutical Patenting

In 2001, WTO Members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In particular, concerns had been growing that patent rules might restrict access to affordable medicines

for populations in developing countries in their efforts to control diseases of public health importance, including HIV, tuberculosis and malaria. The Declaration responds to the concerns of developing countries about the obstacles they faced when seeking to implement measures to promote access to affordable medicines in the interest of public health in general, without limitation to certain diseases. While acknowledging the role of intellectual property protection "for the development of new medicines", the Declaration specifically recognizes concerns about its effects on prices.

The Doha Declaration affirms that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health". In this regard, the Doha Declaration enshrines the principles WHO has publicly advocated and advanced over the years, namely the re-affirmation of the right of WTO Members to make full use of the safeguard provisions of the TRIPS Agreement in order to protect public health and enhance access to medicines for poor countries. The Doha Declaration refers to several aspects of TRIPS, including the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of intellectual property rights. The TRIPS Agreement allows the use of compulsory licences. Compulsory licensing enables a competent government authority to licence the use of a patented invention to a third party or government agency without the consent of the patent-holder. Article 31 of the Agreement sets forth a number of conditions for the granting of compulsory licences. These include a case-by-case determination of compulsory licence applications, the need to demonstrate prior (unsuccessful) negotiations with the patent owner for a voluntary licence and the payment of adequate remuneration to the patent holder. Where compulsory licences are granted to address a national emergency or other circumstances of extreme urgency, certain requirements are waived in order to hasten the process, such as that for the need to have had prior negotiations obtain a voluntary licence from the patent holder. Although the Agreement refers to some of the possible grounds (such as emergency and anticompetitive practices) for issuing compulsory licences, it leaves Members full freedom to stipulate other grounds, such as those related to non-working of patents, public health or public interest. The Doha Declaration states that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Parallel importation is importation without the consent of the patent-holder of a patented product marketed in another country either by the patent holder or with the patent-holder's consent. The principle of exhaustion states that once patent holders, or any party authorised by him, have sold a patented product, they cannot prohibit the subsequent resale of that product since their rights in respect of that market have been exhausted by the act of selling the product. Article 6 of the TRIPS Agreement explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system. The Doha Declaration has reaffirmed that Members do have this right, stating that each Member is free to establish its own regime for such exhaustion without challenge.

Since many patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of lower priced patented products. Parallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences between the same pharmaceutical product sold in different markets.

The Doha Declaration also extended the transition period for LDCs for implementation of the TRIPS obligations from 2006 to 2016. However, the extension is limited to the obligations under provisions in the TRIPS Agreement relating to patents and marketing rights, and data protection for pharmaceutical products. Thus, LDCs are still obliged to implement the rest of their obligations under the TRIPS Agreement as of 2006. From a public health perspective, this extension of the transition period for LDCs is of significant importance. It is a recognition of the implications of patent protection on public health, and thus, it is recommended that all LDCs adopt the necessary measures to use the 2016 transition period in relation to pharmaceutical patents and test data protection.

While access can be affected at the practical level by the introduction of patents on medicines, there are more general issues concerning the compatibility between human rights and intellectual property. Intellectual property law has traditionally dealt mainly with technical issues related to scientific and technological development. Treaties such as TRIPs thus hardly envisage patents in relation to other fields of law. There is, for instance, no attempt in TRIPs to delineate the relationship between patents and the human rights to health. Patent treaties only recognize that there should be a balance between the rights that are conferred to an inventor and the broader interests of the society in having access to the results of scientific advances. Equally, human rights treaties have not devoted significant attention to the impacts of intellectual property on the realisation of specific rights such as the right to health. However, the relationship has been considered in general terms.

Access to drugs generally requires their availability and affordability. There is thus a strong link between economic poverty and access to drugs. A group of international organisations recently estimated that less than 10 percent of people living with HIV/AIDS in developing countries have access to antiretroviral therapy. The HIV-AIDS epidemic across the globe, and particularly in African countries, has devastated entire countries. The epidemic has served to focus on the inhuman conduct of global pharmaceutical MNCs who continue to sell drugs to treat HIV-AIDS at 20-50 times their

actual cost by seeking shelter under laws mandated by the TRIPS agreement. In fact it was left to Indian companies like Cipla to offer these drugs at vastly reduced prices and thereby provide some to those affected by HIV-AIDS. The conduct of these MNCs has also led to an upsurge of public opinion the world over, including in the US and EU, questioning its rationale, particularly in the area of public health. Organisations such as the Medecens Sans Frontieres (Doctors without Borders) have provided a powerful voice to this upsurge and soon became a global force contending the rationale of the new IPR regime. These developments ultimately resulted in the Doha Declaration on TRIPS Agreement and Public Health (November 2001) seeking to limit, to some extent, the damage done by the TRIPS agreement and its underlying philosophy.

India follows the incorporation theory. This means that a treaty does not become law until enacted by the Parliament. Following the WTO ministerial conference, the joint parliamentary committee on the Patents (Second Amendment) Bill, 1999 finalized its report in December and submitted an amended version of the amendments to parliament. The recently passed legislation must therefore be analyzed in the context of the declaration on the TRIPS Agreement and public health (Doha Declaration) and other relevant factors. By giving greater credence to WTO deadlines than democracy, India is prepared to jeopardize its sovereignty. The WTO is not the only treaty that India has to comply with The Supreme Court decisions culminating in and following have directly imported many human rights into the life and liberty provisions of Article 21, including the right to health. The WTO cannot over-ride these obligations. India this way is also putting its sovereignty, status, prestige and obligations at risk. Medicine without social justice is unacceptable. Patents are not a gift for drug companies to exercise power without responsibility. Given the importance of the issues at stake, the debate concerning the impact of medical patents on access to drugs is unlikely to subside in the near future even though the Patents (Amendment) Act, 2002 has just been adopted. This still leaves several years for further open debate concerning the final response to be given to TRIPS in the Health sector.

Conclusion and Viable Solutions

To make sure that no essential drugs are patented for an excessive amount of time, Section 3(d) must be used properly. Governments must loosen up national patent laws. Additionally, they must adopt rules that guarantee the poorer sections of the nation's population have access to pricey but necessary medications. In order to respect the rights of patent owners and ensure that they receive a fair amount of royalties for their ideas, the government must also be flexible when giving compulsory licences.

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