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Flexibilities under TRIPS- An analysis of Indian patent regime in respect of section 3 (d)

Kakumani Kataky
Gauhati University, Guwahati, India

Abstract

The policy environment has now changed that TRIPS agreement of WTO is binding on all member countries of WTO basically aims at establishing strong minimum standards for intellectual property rights. Under TRIPS, all the member countries will have to provide product patent protection in all products including pharmaceuticals, within the time specified. In order to gain the economic and political benefits of participation in the WTO's trading system, India had no choice but to bring its patent laws into conformity with the WTO's intellectual property rules as set forth in TRIPS. Compliance with TRIPS was not the sole driver for the transformation of India's patents regime, however. Just as India made a deliberate choice in the 1970s to jump-start its indigenous generic drug manufacturing industry by prohibiting the grant of patents on pharmaceutical products, in 2005 it again made a deliberate choice to stimulate domestic innovation in new medicines and therapies. The famed section 3(d) of the Indian patent Act 1970 though amended by 2005 leads to so-called generic v/s innovators war. Its origin lies in generics-centered mind- set of the nation, as a whole; on the other hand, it has the 'seeds of innovation'.

Keywords : TRIPS flexibilities, Bolar provision, parallel imports, etc.

1. Introduction

Being a founding member of the World Trade Organization (WTO) and agreed to the requirements of the WTO intellectual property agreement, Trade-Related Aspects of Intellectual Property Rights (TRIPS) since in 1995 which mandates that all WTO members to adopt and enforce certain minimum standards of IPR protection. The developing countries like India did not provide for pharmaceutical product patenting when TRIPS came into force, it obtained a 10-year transition period, until January 2005 to put in place pharmaceutical patent protections.

During this transition period, India was required to provide a means for applications to be filed and assigned a filing date, a mailbox facility and exclusive marketing rights, the sole right to sell an invention for a specified time be provided for certain mailbox applications filed during the transition period. TRIPS accelerated the transformation of India's patent laws in a multi-phased manner that leads to three amendments to the Patents Act 1970.

Initially a mailbox facility was established, which allowed applicants to file pharmaceutical product patent application. Applicants were to be given exclusive marketing rights subject to certain conditions, to market the product for a period up to five years from the date of grant. The second amendment to the Indian Patent Act 1970 was made in 2002 which brought it into conformity with TRIPS on many issues, as it provided for a twenty year patent term, reversal of the burden of proof for process patent infringement and modifications to compulsory licensing requirements. By virtue of the third amendment in 2005, the 1970 law offered patent protection to pharmaceutical products as well as the process became substantially compliant with TRIPS.

2. Objective of the study

The author in this paper is trying to analyse the compliance of TRIPS into the Indian Patent Act. The

Corresponding author : kakukataki123@gmail.com
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impact of the TRIPS compliant Patent regime on access to medicine and prospect of generic pharma hub.

3. Methodology

The methodology applied here is the doctrinal one and based on secondary sources. The secondary sources comprises text book by authoritative writers on intellectual property law, IPR journal, websites, articles, etc.

The absence of product patent protection for pharmaceuticals and agrochemicals led many multinationals to limit their portfolios to patent expired products or a few selected patented products. This resulted in an erosion of their market share because local manufacturers introduced the unviable alternative of remaining completely outside the WTO system was forced to sign the TRIPS Agreement and join the WTO in 1995. Article 65.2 of TRIPS permits developing countries, a transition period of five years to implement the provisions of TRIPS. In addition, if a country did not provide the most advanced medicines through reverse engineering. Foreign firms were required to pay royalties for international drugs, while Indian companies could access the newest molecules from all over the world and reformulate them for sale in the domestic market. Thus, this resulted in the systematic weakening of patent rights for pharmaceutical products in India and led to the egression of several international research-based pharmaceutical firms. The purpose of the patent is to provide a firm of protection for the technological advances and thereby reward the innovator not only for the innovation but also for the development of an invention up to the point at which it is technologically feasible and marketable.

3. TRIPS Flexibilities drawn into the Indian patent law

The discussion will be how Indian Patent Act has made changes to become TRIPS compliant. While India made the necessary adjustments to its laws to satisfy the requirements of TRIPS, criticism and concern about the effect of pharmaceutical patents on domestic drug prices compelled the Indian government to retain legitimate means for balancing innovation incentives against the social costs of pharmaceutical product patents.

(a) Section 3(d) of Indian patent act 1970

A significant means by which the Indian government can limit the reach of product patent protection is section 3(d) of the Patents (Amendment) Act of 2005. Section 3(d) essentially provides a standard for securing patents more stringent than earlier patent. Companies that introduce new versions of their pharmaceutical products must demonstrate that the new versions are therapeutically more beneficial than earlier versions on which patents had expired.

Through Section 3(d), India is able to prevent ever greening which critics characterize as a common abusive patenting practice where pharmaceutical companies attempt to extend patent protection by making minor changes to existing drugs. Predictably, India's strict patent regime has constitute discontent among large multinational pharmaceutical corporations interested in tapping into India's growing market. Despite concerns on the limiting scope of Section 3(d) in the context of future drug discovery trends, what can be established with certainty is that since its inception, Section 3(d) has not resulted in discrimination against western manufacturers as is often claimed. India's novel approach to patent law has allowed it to successfully strike a balance between its obligations to TRIPS and its desire to discourage patent ever greening in the best interests of its citizens.

(b) Compulsory licensing

In addition to India's higher standards of patentability, another contentious aspect of India's patent regime is the compulsory licensing provision which is used against (usually foreign) innovators in the Pharma sector. It is one of the ways in which TRIPS attempts to strike a balance between promoting access to existing drugs and promoting R&D into new drugs. Compulsory Licensing is a procedure whereby a Government can allow any company, agency or designated person, the right to make a patented product, or use a patented process under license, without the consent of the original patent holder. Under section 84(1) of the amended Act, an application can be made for compulsory license three years after the grant of a patent. In the context of India's IPR regime, this issue came into the global spotlight in March 2012, when India's Controller General of Patents awarded Indian generic manufacturer NATCO a compulsory license for producing Bayer's blockbuster kidney cancer treatment Sorafenibtosylate, widely marketed under the name Nexavar.

(c) Bolar provision

The 'Bolar' provision or exception, as it is known in USA is also named as "early working" provision. It is important to understand the background of the Bolar

provision. Patents provide a monopoly to the innovator companies for a specified period of time. After the expiry of the patents, others can also produce and market the products. But it was found that before 1984, the entry of generic products was very slow in USA. Food and Drug Administration (FDA) estimated that by 1984, about 150 off-patent brand name drugs had no generic equivalents in the market. There were two reasons for this:

- FDA approval process and.
- Patent law.

Under the Federal Food, Drug, and Cosmetic Act, innovator companies seeking approval for a new drug are required to conduct tests including those on humans ("clinical trials") and to submit those results to the FDA with their new drug application (NDA). Before 1984, the generic producers also had to conduct their own studies and submit data about the safety and the efficacy of the product. The generic producers hardly had the resources to undertake such time consuming and costly studies. Moreover, under the existing patent law, they could start the process of testing and submitting data to FDA only after the patents have expired. The Drug Price Competition and Patent Term Restoration Act 1984 (commonly known as the Hatch-Waxman Act) - amended in 1984, the Patent Act of 1952 (35 USC) and the Federal Food, Drug, and Cosmetic Act (21 USC) to take care of both the problems. Under the Bolar provision of the Patent Act, non-patentees could start using the patented product for regulatory purposes even before the expiration of the patents. Moreover, generic applicants were no longer required to repeat the clinical studies to prove the efficacy and the safety of the product. They were permitted to rely on the innovator company's safety and efficacy data and could file only an Abbreviated New Drug Application (ANDA). The generic applicants were required to demonstrate that the generic drug product has the same active ingredient, route of administration, dosage form and strength and is bioequivalent (the rate at which the drug becomes available for absorption in the patient) to the relevant brand-name product. The Bolar provision is very important for generic entry. It permits generic entry soon after the patents expire and hence allows the consumers to benefit from competition and lower prices without delay. In the absence of it, generic companies will have to wait till the patents actually expire before they can start the tests necessary for getting regulatory approval.

The amended Patent Act in India provides for Bolar exception. Under Section 107A(a), use of a patent for development and submission of information for regulatory approval will not be considered as an infringement of the patent right. Thus in the new patent regime, as innovator companies introduce new drugs in India and enjoy exclusive patent rights, such Bolar provisions can be used to introduce generics immediately after the expiry of patents.

The "Bolar exemption" was included in the Second Amendment of the Indian Patents Act, 1970. Section 107A(a) of the amended law contains the relevant provisions: "Any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required for the time being in force, in India or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product". Although in its essentials, Section 107A(a) mirrors the provisions of the Canadian Patent Act, it has one significant difference. Included in the exception to the rights is the act of importation, which the Canadian Patent Act does not provide. The implications of including the act of importation as a part of the "Bolar exemptions" are not immediately obvious. Nor is it clear as to how this exemption may in any way affect the applicability of Section 107A(b) that provides for parallel imports.

(d) Parallel imports

Under Article 28 of TRIPS, the patent owner has the exclusive right to prevent others not only from making, using or selling the invented product or process in the country, but also importing from other countries. This is however subject to Article 6 on "exhaustion." What it basically means is that the patent holder in a country cannot legally stop imports of patented products offered for sale in another country. Such imports of patented products without the consent of the patent holder in the importing country are known as parallel imports. This is very important in the pharmaceutical industry because the same patented medicine is often sold at different prices in different countries and hence parallel imports permit a country to shop around for the lowest price. The underlying justification of allowing parallel imports is that since the innovator has been rewarded through the first sale of the product, its patent rights have been "exhausted" and hence it should have no say over the subsequent re-sale. Under Article 6 of TRIPS as clarified by the Doha Declaration (paragraph 5(d)), each country is "free to establish its own regime for such exhaustion

without challenge."

Under the original 1970 Act, importing was not mentioned as an exclusive right. This has been amended (in Section 48) to conform to TRIPS. But unlike Article 28 of TRIPS, Section 48 of India's amended Patent Act provides no qualification about exhaustion of patent rights. Instead another section (107A(b)) has been inserted which says that "importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product shall not be considered as an infringement of patent rights."This does permit parallel imports but only in some cases. As the Indian Drug Manufacturers Association (IDMA) has pointed out, the phrase "duly authorized by the patentee" may cause delay and difficulty. In accordance with the spirit of Article 28 of TRIPS, any import from any legitimate source even if not specifically authorized should be permitted.

(e) Limiting data protection

As we know to get marketing approval for a new drug developed, innovator companies are required to submit test and clinical data relating to safety and efficacy to national health authorities. The current practice is that when generic companies apply for approval of their drug, they are not required to conduct their own studies and submit independent data. They can rely on the safety and efficacy data submitted by the innovator company and get marketing approval for their products. But if the law of a country provides for data exclusivity, i.e., grants exclusive rights to the innovator company to prevent subsequent applicants from using the data submitted, then generic companies cannot use such data till the data exclusivity period ends.

Data exclusivity provisions have implications for generic entry and hence competition and prices. A patent is taken immediately after a new drug (new chemical entity) is developed. But usually it takes several years of clinical trials and other testing and drug development before a drug is approved for marketing. Thus a drug discovered and patented in 1995 may actually be approved for marketing in 2005. In developing countries, it may be introduced even later, for example in 2010. With a 20 year patent term under TRIPS, the monopoly patent rights are supposed to expire in 2015 and generic companies can enter the market. But if the developing country provides for data exclusivity for 10 years, then generic companies cannot use the test data before 2020 because generic companies typically do not have the resources to conduct such time consuming and costly studies. As a result data exclusivity effectively extends the monopoly beyond the patent term. Article 39.3 of TRIPS is being interpreted by the MNCs and some developed countries, particularly USA to mean that WTO member countries are required to grant data exclusivity for a specified period of time. Article 39.3 does require governments to provide protection to marketing approval data under certain conditions. Article 39.3 requires countries to protect data against "unfair commercial use." . Again data protection to be provided under Article 39.3 is subject to certain qualifications. Protection is not necessary if regulatory authorities do not require the submission of such data for marketing approval or if the data are already public. Protection is required only for new chemical entities. Countries have considerable discretion in defining what is "new," and may exclude the different formulations based on the same chemicals. Thus even if test data are required to justify a new formulation, Article 39.3 does not require any protection of such data. India's Drug and Cosmetics Act 1940, which regulates the marketing approval of new drugs as well as the Patents Act, 1970 the three amendments (including the Ordinance of 2004) carried out till date to comply with TRIPS do not contain any provisions relating to test data protection. Thus India has been able to use an important TRIPS flexibility with positive implications for generic competition and prices. But India has been under tremendous pressure from MNCs and the US government to introduce data exclusivity provisions. Government officials admit that it is not a TRIPS obligation but feel that a re-consideration by India may be necessary. In the USTR 2004 report, India has been targeted as a "priority watch list" and points out that "the United States is encouraged by the Indian Government's recent statements concerning implementation of data exclusivity regulations "

(f) Government use

Article 31 of TRIPS dealing with compulsory licensing provides for special provisions "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." Public use of patents or "government use" is a standard feature of patent laws in many countries. Under 28 USC Sec 1498 of the US patent law, the US government can use a patent or authorize third parties to use patents for virtually any public purpose and the government has actually made good use of it as we

have mentioned above. For any such use, the government is not required to negotiate with the patent owner. Nor is the latter provided any injunctive relief. All that it can expect is payment of compensation for the use.

Following the British Patent law, the Indian patent law also provided for government use of patents and much of these have been retained in the recent patent amendments. The central government or anyone authorized by it may use (i.e., "make, use, exercise or vend") an invention or acquire an invention for the purpose of the central government, state Governments or a government undertaking on payment of adequate remuneration or compensation (Sections 99 to 103). Except in circumstances of national emergencies, extreme urgency or public non-commercial use, the government need not even inform the patentee about such use. The patent owner, however can challenge such a use or the terms of such use. Any such disputes are required to be judicially settled at the level of the High Court. Under the Act of 1970, the right to use included "the right to sell the goods." In the amended Act, the right of the government is restricted to the "right to sell, on non-commercial basis." This is an important difference. But still, in the amended Act, the government has wide ranging powers to make drugs more affordable. If the patented drugs are too expensive, then the government can produce or authorize others to produce and distribute these through public clinics. As the World Bank (2003, p. 39) has pointed out, even if the government recovers the cost of such drugs fully or partially, such an arrangement will be consistent with TRIPS so long as the government does not seek to make a profit out of it. In the absence of product patent protection in pharmaceuticals in the previous patent regime, government was not required to and in fact did not use such special provisions.

As a result unlike in USA, there is no history of such use. The ability of the government to use such provisions to enhance affordability of drugs will crucially depend on whether proper administrative and judicial systems are put in place. If as in the case of compulsory licenses discussed above, any patent holder can oppose such a use by government and can indefinitely delay or prevent the use, then obviously such provisions will remain ineffective. But if a government of a poor country tries to do anything close to it, they would put to intense diplomatic and economic pressures from developed countries, even if the public health crisis is more severe and extensive. Government use will ultimately depend on how such pressures are tackled.

(g) Access to medicine

Growing concerns in developing countries regarding access to medicines at prices that their citizens could afford led to considerable confabulations amongst the WTO members. The outcome of this process was the Ministerial Declaration adopted at the conclusion of the Doha Ministerial Conference held in 2001 on TRIPS Agreement and Public Health (henceforth, Doha Declaration). The Doha Declaration unequivocally stated at the outset "that TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" (emphasis added). The Ministers further stated "that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and in particular to promote access to medicines for all". It was emphasised that the WTO Members have the right to use to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose. Two critical issues were particularly emphasised in the Doha Declaration. The first was that the provisions of the TRIPS Agreement should "be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles". The objectives of the Agreement on TRIPS provided in Article 7 states that the protection and enforcement of intellectual property rights should among other things be "conducive to social and economic welfare and to a balance of rights and obligations". Furthermore, Article 8 of the Agreement directs WTO Members to adopt measures necessary to protect public health and nutrition while formulating or amending their laws and regulations relating to intellectual property. Thus, Articles 7 and 8 of the TRIPS Agreement require that WTO Members must ensure that the laws relating to all forms of intellectual property rights covered by the Agreement give due consideration to issues like protection of public health and nutrition and do not merely serve the interests of the owners of intellectual property. The second area of focus of the Doha Declaration was compulsory licences, the instrument that could have a vital role to play in determining the future prospects of the Indian pharmaceutical industry. Over the past few decades, India witnessed the development of a strong pharmaceutical industry largely because of the absence of the product patent regime. However, with the product patent regime establishing itself following the adoption of a TRIPS-consistent

patent regime by India, the future of the pharmaceutical industry in India would critically hinge on the ability of the producers to obtain licenses from the owners of proprietary technologies. For obtaining the licenses, these producers would have to depend on compulsory licenses, an instrument that has been embedded in the patent system for preventing abuse of patent monopoly. The grounds for the grant of compulsory licenses include the refusal of the patent holder to exploit the patent commercially in the country granting the rights.

A number of new medicines that are vital for the survival of millions are already too costly for the vast majority of people in poor countries. In addition, investment in Research and Development (R&D) towards the health needs of people in developing countries has almost come to a standstill. Developing countries, where three-quarters of the world population lives, account for less than 10% of the global pharmaceutical market. The implementation of TRIPS is expected to have a further upward effect on drug prices, while increased R&D investment that aims at addressing health needs in developing countries, despite higher levels of intellectual property protection, is not expected.

One-third of the world population lacks access to the most basic essential drugs and in the poorest parts of Africa and Asia, this figure climbs to one half. Accessto treatment for diseases in developing countries is problematic either because the medicines are unaffordable, have become ineffective due to resistance, or are not sufficiently adapted to specific local conditions and constraints. Many factors contribute to the problem of limited access to essential medicines. Unavailability can be caused by logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, and prohibitive prices. Despite the enormous burden of disease, drug discovery and development targeted at infectious and parasitic diseases in poor countries has virtually leads to a standstill because drug companies in developed and developing nations simply cannot recoup the cost of R&D for products to treat diseases that is bound in developing countries.

Of the 1,223 new drugs approved between 1975 and 1997, approximately 1% (13 drugs) specifically treat tropical diseases. The implementation of TRIPS, initially scheduled for 2006 by all WTO Members, is expected to impact the possibility of obtaining new essential medicines at affordable prices.

Médecins sans Frontières (MSF), together with other non-governmental organizations (NGOs), formulated the following concerns related to TRIPS:–

Increased patent protection leads to higher drug prices.

The number of new essential drugs under patent protection will increase, but the drugs will remain out of reach to people in developing countries because of high prices.

As a result, the access gap between developed and developing countries will widen.

Enforcement of WTO rules will have a negative effect on local manufacturing capacity and will remove a source of generic, innovative, quality drugs on which developing countries depend. It is unlikely that TRIPS will encourage adequate R&D in developing countries for diseases such as malaria and tuberculosis, because poor countries often do not provide sufficient profit potential to motivate R&D investment by the pharmaceutical industry. Developing countries are under pressure from industrialized countries and the pharmaceutical industry to implement patent legislation that goes beyond the obligations of TRIPS. This is often referred to as "TRIPS plus." TRIPS plus is a non-technical term which refers to efforts to extend patent life beyond the twenty-year TRIPS minimum, to tighten patent protection, to limit compulsory licensing in ways not required by TRIPS, or to limit exceptions which facilitate prompt introduction of generics. Industrialized countries and World Intellectual Property Organization (WIPO) offer expert assistance to help countries become TRIPS-compliant. This technical assistance, however, does not take into account the health needs of the populations of developing countries. Both of these institutions are under strong pressure to advance the interests of large companies that own patents and other intellectual property rights.

4. Conclusion

As per TRIPS, it is mandatory for all member countries of WTO to provide patent protection for all products including pharmaceuticals. But the protection of the rights of the patentees is not the sole concern of TRIPS. TRIPS provides flexibility for governments to strike a balance between the private rights of patentees and the socio-economic needs and objectives of its people.

The costs of high prices resulting from product patent protection can be tackled by:

(i) resorting to parallel imports or granting compulsory licenses during the patent term and

(ii) ensuring that the entry of generics is not delayed after the expiry of patents.

The recent amendments to India's patent regime provide for parallel imports and hence the country can import cheaper alternatives, if available. But looking to the present scenario which the generic companies so called pharma hub India have achieved, what is of greater importance in India is a proper compulsory licensing system. In a product patent regime, a proper compulsory licensing system is of vital importance in promoting competition while ensuring that patentees get compensation through royalties. In fact compulsory licensing is one of the ways in which TRIPS attempts to strike a balance between promoting access to existing drugs and promoting R&D into new drugs. But India has not been able to take full advantage of the compulsory licensing provisions. The compulsory licenses procedure is not amenable to easy interpretation and is not operationally useful. The procedure is cumbrous and time consuming. The process is much more legalistic than what TRIPS requires. It provides opportunities to the powerful patentees to manipulate the process by litigation to prevent others from getting such licenses. Even in cases of special provisions relating to national emergency, extreme urgency or public non-commercial use, adequate care has not been taken to put in place a proper structure to prevent delay due to litigation. India's pharma hub can produce low cost drugs, has particular significance from the point of view of supplies to countries with no manufacturing capacities like least developed countries. Care has not been taken in the patent amendments to facilitate such exports. In the absence of compulsory licensing, generic companies can enter the market only after the expiry of the patents. But the entry of generics depends on patent and other legislation. India has incorporated the Bolar provision. This will permit the generic producers to use the patents even before the expiry to get regulatory permission and hence to enter the market as soon as the patent expires. India has also not yet provided data exclusivity. Hence lack of access to test data may not prevent generic entry after the expiry of patents. But multiple patents can be taken to effectively extend the patent term. While deciding on the inventions eligible for patents, the terms "new", "inventive" can be defined to grant patents only for new drugs which represent significant therapeutic advances. Modifications of existing chemical entities, which do not involve clinical improvements, can be excluded. This would restrict the number of patents and prevent the delay of generic entry. Such qualifications have not been provided in the patent amendments carried out in India. If the bias in the Patents Act 1970, which did not provide product patent protection in pharmaceuticals, was in favour of the non-patentees, the bias in the amended Act is clearly in favour of the patentees. No time limit has been specified for processing of compulsory licensing applications and a compulsory license can be used only after the appeals against the grant of such a license by the Controller of Patents are turned down following a detailed procedure. But in the case of applications for product patents, time limit has been specified and patents can be granted even before it is convincingly settled that it can be granted. Unlike in the case of compulsory licenses, full scale opposition proceedings can start only after the grant of patents. India has effectively provided a more extensive protection to patentees than what is required under TRIPS.

The concern for securing access to affordable drugs is also a real one and there are strong moral arguments for why increasing patent protection for the products of powerful MNCs works only to hurt the common man. However, in reality, the protection of intellectual property rights provides the corporations with the much needed incentive to invent and manufacture the drugs on which patients around the world rely, whether branded or generic. Patent is an essential component of the framework for developing countries like India to magnetize foreign investment and faster technology transfer. India could continue its present path where its generics industry simply reverse-engineers the patented pharmaceuticals that are researched and developed elsewhere. But if India desires to grow into its role as a major scientific and technological powerhouse, then it must work to protect intellectual property rights, as opposed to doing the bare minimum to ensure compliance with TRIPS. To strike a balance between both the need of the poor patients not amenable to access costly drugs and benefit the domestic industry.

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