AN ANALYSIS OF THE TRIPS AGREEMENT AND THE TRIPS-COMPLIANT INDIAN PATENT REGIME

by

Soumyadip Panda & Anshu Singh

Abstract

The World Trade Organisation on Trade Related Aspects of Intellectual Property Rights has made it mandatory for the nations to establish the standards for protection of intellectual properties. The agreement came into force in 1995. The developing countries including India were required to fulfill the obligations mentioned in the TRIPS Agreement by 2000, whereas the developed countries were to by 1996. On the other hand, the time duration for the under developed countries was till 2005.

The TRIPS Agreement has indeed suggested a good market for nations like India, Brazil, China, South Africa, among others who have the capacity to manufacture drugs and other pharmaceutical products in their domestic environment. The Agreement also provides certain safeguards. It could definitely make India and other developing countries have a big victory in this sector.

The Indian Patents Act was amended under the TRIPS Regime. The amendments were made at three different stages, each stage introducing a new change in the Patents Act. The Authors through this study have tried to analyse the various amendments which were introduced in the TRIPS compliant Indian Patent Act. They have further tried to understand the impact of these amendments in the Indian society, both economically and socially. Finally, the Authors have concluded by saying that indeed the new Patent regime in the country has proved itself to be a growing economic hub for multinational companies.

KEYWORDS: World Trade Organization, Trade Related Aspects of Intellectual Property Rights, Intellectual Properties, Pharmaceutical Drugs, Multinational Companies.

INTRODUCTION

Patent is granted in favour of a person called the inventor, thereby conferring upon him the right to use it and exclude others from doing so.[1] It is granted for a fixed time period, i.e, a time period of five years if the product or process is related to foods or medicines and for a time period of fourteen years in case of other products. If the inventor is not able to use his invention by himself, he can grant a license to someone to use the invention for consideration or fees, known as the royalty.

A person who receives such a grant of license is allowed to make, manufacture, sell or use the invention along with the right to authorize others to do the same. If someone infringes a patent holder's right, he is liable to be restricted by injunction and is further liable to make compensation to the patent holder by making a payment of damages ascertained by the patent holder.

Amendments of the Patent Act in India under the TRIPS regime

The commitment of India to completely implement the TRIPS Agreement required amendments to the existing Patent law in three different sets. Though the developing countries were allowed to amend their patent laws for making it TRIPS compliant by an amendment before January 01, 2000, but India enjoyed a longer transition period for introducing Product Patents from January 01, 2005 because it already had a process patent regime in existence for pharmaceuticals and agricultural chemicals. However, there were also conditions attached with the longer transition period.

Article 70.8 and 70.9 of the TRIPS Agreement provides the provisions for "Transitional Arrangements"[2]. India was supposed to introduce two provisions in its existing patent law. Article 70.8 required India to provide a means for filing of product patent applications from 01 January, 1995. If the patent was granted for the products in these applications in any WTO

[1] Patents are granted as an exclusive right to any inventor for an invention which can either be a product or process. Such invention provides a different way for doing something or suggests a different technical solution to an existing problem.

[2] Transitional Arrangements refers to such arrangements which were granted by the TRIPS Agreement, to the countries depending upon their development levels for implementing the provisions of the Agreement in their domestic laws. The Developed countries were made to implement the Agreement in a year, developing countries were given the time period of five years, while the least developed countries were given eleven years to implement the same in their domestic laws. The provisions regarding the Transitional Period are discussed under Article 65 and 66 of the TRIPS Agreement.

member countries and marketing approval was obtained by the product in any WTO member country, then as per Article 70.9, exclusive marketing rights for five years was to be granted by India before grant or rejection of the patent product in the country.

The first amendment to the Patent Act through Section 5(2) introduced the requirements under Transitional Arrangements. This allowed filing of product patent applications. Further, Chapter IVA laid down the provisions for grant of EMRs.

On 01 January, 2000, a second amendment was introduced to bring the Patent law in conformity with substantive provisions of the TRIPS Agreement. However, the provisions related to product patents were outside the purview of this amendment. Redefinition of patentable subject matter, amendment of the compulsory licensing system, and increase in terms of patent protection to twenty years were the key issues which were included in the second amendment.

The third amendment was supposed to be introduced by 01 January, 2005. This amendment required introduction of product patent regime in various areas including pharmaceutical sectors which till date were covered by process patent. The amendment, even after having a narrow remit, allowed the Government to use the opportunity to review Patents Act once again. The opposition against grant of patent was the major issue which was involved in the third amendment.

A Perspective on Indian Patent Law being TRIPS-Compliant

Two out of the three amendments in the Patents Act in India were made as a result of global development. Developing countries had concern towards access to drugs and medicines at reasonable prices for their citizens to afford. This led to confabulations between the WTO member countries. The Ministerial Declaration adopted in 2001 after concluding the Doha Ministerial Conference on TRIPS Agreement and Public Health[3] resulted in the said confabulations.

At the outset of the Doha Declaration, it was stated that the TRIPS Agreement should not and does not restrict the member countries from taking such measures as are necessary for protection of public health at large. The ministers also held that the Agreement should be implemented and

[3] The member countries of the WTO Agreement adopted the special Ministerial Declaration in 2001. The Declaration aimed at clarifying the ambiguities which were existing in the system. It stated that the Governments are allowed to deviate from the provisions of the Agreement as per the flexibilities provided in the Agreement on TRIPS. But the deviation must be such that it is for the benefit of the public and for their right to health. The countries were allowed to take such measures which they feel was necessary for protecting and promoting public health.

interpreted in such a manner so that it can support the rights of the member countries of the WTO in protection of public health and specially ensuring that drugs and medicines are available to all. It was further emphasized that the members enjoy the right to use the provisions of the Agreement completely, for which flexibility is provided.

There were two issues critical to the Doha Declaration. The first being that the TRIPS Agreement must be read as is expressed in light of the purpose and object of the Agreement, i.e, its principles and objectives. The objectives enshrined under Article 7 of the Agreement provide that the enforcement and protection of the IPRs must be conducive to the economic and social welfare, and a balance between the obligations and the rights. Moreover, Article 8 instructs the WTO member countries to make such measures which are necessary for protecting nutrition and public health, while formulating new or amending the existing laws and regulations related to IP. Therefore, Article 7 and 8 of the Agreement requires that the WTO member countries ensure laws relating to all the forms of IPRs which are covered under the Agreement do give proper consideration to issues pertaining to protection of nutrition and public health and do not only serve the IP owner's interests.

The second focus area of the Declaration was the compulsory license, the instrument which played an important role in determining the possible future prospects of the pharmaceutical industry in India[4]. India had witnessed a strong development of this industry in the past few decades as the product patent regime was absent in the country. However, the product patent regime established itself in India post the amendments, and thus, the future of this industry was at stake because of the producer's ability to get licenses from the proprietary technology's owners. These producers were to depend upon the compulsory licenses for prevention of patent monopoly abuse.

The compulsory license is granted on the ground that the patent holder has refused commercial exploitation of the patent in the country which has granted the patent rights to him. The beneficiaries of this license must at the same time demonstrate their efforts in obtaining authorization from the holder of rights on commercial terms and conditions. Thus, such efforts were not successful in the reasonable time period.

[4] There are a set of conditions laid down under Article 31 of the TRIPS Agreement for grant of compulsory license on a patented product or a process

The Doha Declaration has in some ways gone beyond the Paris Convention. The Declaration provides that the member countries have the exclusive right of granting compulsory licenses and also the freedom for determining the grounds for such licenses to be granted. This implied that the Declaration allowed the WTO member countries to use the methods of licensing for understanding public interest objectives like medicines and drugs access.

In a country like India where a major area of concern is the access to medicines at reasonable prices, one needs to focus on the issue that adequate safeguards are provided for ensuring that the country doesn't witness high medicine prices caused due to the grant of IMDs on patent. This implies that strengthening the patent holder's rights, which is the cornerstone of the TRIPS Agreement, must be followed by including the provisions which address concerns of public interests effectively.

Analysis of the Amendments

The above discussion proves that various issues needed careful consideration while India implemented a patent regime which was TRIPS compliant[5]. Some of the key issues which were given consideration are discussed below:

Scope of Patentability

It is important to note here that for defining the scope of patentability, as many countries, especially the developing ones, adopted open ended definitions which had undesirable consequences, for instance, on IMDs grant of patent. Further, the examination process of product applications in mailbox also revealed that granting patents on IMDs was a threat which needed to be addressed by the stakeholders in a concerted manner. The mailbox provision was introduced by the 1999 Amendment Act which required the country to accept applications in areas of agrochemicals and pharmaceuticals for product patents. According to Article 70.8 of the Agreement, the purpose of mailbox was providing inventors a means to file applications for the pharmaceutical product patents until January 2005, which is regarded as the transition period. On terminations of the said period, applications on mailboxes were examined. As per Article 70.8 of the Agreement, the mailbox has an effect similar to a legal fiction, according to which, the three areas of patentability criteria, novelty, industrial applicability and inventive step must be applied after the end of transition period, if they were to be applied on the priority date or the filing date.

[5] Fathima Mehendi, An Analysis of the Development of the Patent Law in India: A Look at the Three Amendments to the Patents Act, 1970, (22 Oct, 2021, 11:30 AM), https://www.legalbites.in/analysis-of-the-development-of-patent-law-india/

An invention's novelty is preserved even though the product is made available to the public for some time.

The mailbox provision had attracted more than nine thousand applications for product patent, which was indeed a significant proportion in the sector of pharmaceuticals which needed to be examined as per the provisions of the amended Act. It has also been stated that at the time between 1995 and 2003, marketing approvals were granted to only 274 new chemical entities by the US Federal Drug Administration. This also implies that the majority of the applications of the mailbox covered IMDs.

If the scope of patentability is narrowed down, especially in respect of the pharmaceutical sector, the first step was to ensure that IMDs don't get rights on patents in India. Thus, there was a need for the amended law to provide definitions and/or clarifications for the three criteria which are used to assess whether an invention is patentable or not, which are novelty, industrial application and incentive step. It is imperative to note that the TRIPS Agreement does not lay down any strict definition of any of the three criteria which implies that the WTO member countries are free to decide and adopt the definitions as they feel suitable for their nation.

Two issues are found to be mentioned here as crucial. They are related to the elaboration of the patentability criteria and patentable subject matter's issue. There were amendments made to the existing Patent Act. Some of them are discussed herein.

The first one dealt with the elaboration of the "Inventive Step" definition. It was considered that the earlier version of the Patent Act was coterminous with non-obviousness. As per Section 2(ja), inventive steps denotes such feature of an invention which involves technical advances when compared to any existing knowledge or which has economic significance or can be both. The interpretation of the Patent Office for this definition can be seen on two counts. Firstly, the extent of technical advances that would be considered sufficient for granting rights may depend majorly on the patent examiner's subjective judgment. Patent examiner will require a set of clear guidelines for ensuring that the incremental innovations of such kinds which the IMDs represent do not get patent rights. Secondly, assessing the inventive step on the basis of economic significance of that invention may lead to erroneous outcomes. This problem might have arisen due to exaggerated claims about the economic value of the invention which the patent applicant would have been tempted in making so as to take advantage of the provision.

The second amendment in this genre required a re-look in introducing a new definition of pharmaceutical substance. Post amendment, Section 2(ta) of the Act defines pharmaceutical substance as any new entity which involves one or more than one inventive steps. In case narrowing the scope of patenting pharmaceutical products was the real intention of the definition, then as per the legal scholars, it has failed to meet this objective. Instead, the existing definition incited frivolous claims in this area. It was further argued by the legal scholars that the term "chemical" must have been inserted. The definition would then have included "any new chemical entity" as well. This suggestion having a consideration may be inferred from the manner in which the FDA dealt with it. As per FDA, new molecular entity (NME) or new chemical entity (NCE) connotes a drug containing no active moiety which had already been approved by the FDA in any application which had been submitted before it in accordance with Section 505(b) of Federal Food, Drug and Cosmetic Act. An active moiety means an ion or a molecule responsible for pharmacological or physiological action of drug substance. It excluded the appended portions of the molecule which made the drug a salt (including one with co-ordination or hydrogen bonds), esters or any other non covalent derivatives of the molecule such as chelate, clathrate or complex.

The third amendment made an attempt to exclude discoveries or a novel use of a known substance from patenting. However, here again the language had left a lot of space for ambiguity. Exclusion of a mere discovery of an existing substance's new form which does not result in enhancing the efficacy of the substance from patentable invention is a good example for this.

While answers to many issues may have been settled through disputes which also included the ones in the opposition's nature for grant of patent, there was still a need of getting legal certainty on the contentious issue. Therefore, the Government of India in April 2005 had set up a Technical Expert Group of Five Members on Patent Law Issues. Dr. R. A. Mashelkar headed it. He was the director general of the Council of Scientific and Industrial Research. The terms for reference given to the group were as follows:

1. Whether it would be compatible with the TRIPS Agreement to put a limit on the grant of patent for pharmaceutical substance to new medical or chemical entity which involves or more than one inventive step; and

2. Whether it would be compatible with the TRIPS Agreement to exclude micro organisms from the ambit of patenting.

The reports of the group were as follows:

1. Regarding introduction of the term "new chemical entity" or "new molecular entity", the group observed that the former one has for the first time found a place in the international IP Agreement under the TRIPS, Article 39.3. When the members require a condition for approving marketing of agricultural or pharmaceutical chemical products that uses new or novel chemical entities, then in such cases, the submission of some undisclosed data must be protected, especially the ones whose origination has involved efforts against any unfair commercial use. If it is necessary for protecting the public or if the steps are taken for ensuring that the data remains protected against any unfair commercial use, then it may be disclosed. On the other hand, "new molecular entity" has not been defined or even used in the Agreement. From the point of view of the National Interest Perspective the group recommended efforts to be made for preventing evergreening practice which is used by pharmaceutical companies to extend the patent life by making claims on changes which are trivial. The authority must be given powers for determining what is patentable and constituting those trivial changes without any significant improvement is not patentable.

Thus, the group concluded that limiting grant of patents to new chemical entities only for pharmaceutical substances would violate the TRIPS Agreement. It will amount to exclusion of the technological field. However, efforts should be made to ensure that drugs and medicines are made available to the citizens at reasonable prices. Also, a check must be put on grant of frivolous patent as well as evergreening of patent. Indian Patent Office must formulate and use guidelines to examine patent applications in pharmaceutical sectors for elimination of all kinds of granting of frivolous patents.

2. Regarding exclusion of microorganisms from the ambit of patenting, the group observed that Article 27.3 of the TRIPS Agreement excludes animals and plants from getting patented but also treats micro-organisms as different from them. Natural microorganisms though don't qualify to be patented, but ones with human utility and intervention become a subject matter of patent under the Agreement, if they meet the criteria.

Thus, the group concluded that exclusion of microorganisms from patent protection would violate the provisions of the TRIPS Agreement.

As for the patentable subject matter, the main change which got introduced was the mandatory requirement of removal of process patent alone for chemicals. This resulted in removal of

Section 5(1) of the Act which laid down the provision for process patent. This meant that from 01 January, 2005, applications for product patents were being examined after acceptance. The applications made since the introduction of the mailbox provision in 1999 were also included in these product patent applications.

It is imperative to note that the definition of pharmaceutical industry and the scope of patentability have been laid down clearly and unambiguously. This has resulted in decrease of patent litigations which were increasing at an alarming rate. The targets back then were the patents which were being used for treatment of various diseases such as HIV AIDS, TB, etc.[6]

Future of the Producers of Generic Drugs

The third amendment of the Patent Act, 1970 had one contentious issue to address; the Indian generic producer's future who were producing the generic products and whose application for the grant of product patent was in the mailbox. If the patent was granted to such products, it would have led to cessation of operations of these producers.

Section 11 of the amended Act protects the generic producer's interests whose business may get affected in the new product patent regime. The section entitled the patent holder to receive adequate royalty from enterprises, who are making investments and producing and marketing the products prior to 01 January, 2005 and further continue manufacturing products which are covered by the patent on the date of its grant. The section further provides that against these enterprises, no proceeding in relation to infringement gets instituted.

This section was though expected to help these producers, still a number of imponderables were be faced by it. Firstly, the threshold for assessment of investment levels whether to be considered as "significant" or not was not clear. This lacuna in the definition of significant posed threats relating to infringement suits as any definition of "significant investment" may be challenged by the patent holder proposed for extracting high royalty payments.

Another problem may have been faced while attempting to define the term "reasonable royalty"[7].

Compulsory Licensing

An important issue in the context of changing the patent regime was the system of compulsory licensing which is indeed an essential pillar of the system of patent. It is well recognized that compulsory licenses play an important role in prevention of abuse of patent rights which may

[6] *Ibid.*
[7] *Ibid.*

have arisen when the holder of the patent using his statutory rights attempts to make a pre-empt entry of competitors.

If we look at a more functional perspective, an opportunity was provided by way of compulsory licensing to the technological users, especially the developing countries for gaining access to proprietary technologies. By not taking reverse engineering as recourse the system of compulsory licensing may have been immensely useful for Indian pharmaceutical firms as they could have met their technological requirements.

Implementation of the system of compulsory licensing may have resulted in different outcomes, as the owners of the patent and the users of the technologies patented have indeed given contradicting interpretations of the functioning of the system of compulsory licensing that was TRIPS consistent. The provisions were given a narrow interpretation by the patent community. They were of the opinion that compulsory licenses must be used only in exceptional circumstances. Whereas, the developing countries has time and again tried to use the system of compulsory licensing in such a manner to allow domestic enterprises to engage in production as this was an aspect of promotion of access to medicines.

Developments in the years after the implementation of the TRIPS compliant patent regime indicates that developing countries and their point of view was getting better support from the community at global level. In 2001, the Doha Declaration effectively removed the legal uncertainties regarding use of the provisions of compulsory licensing for public health. The Declaration unequivocally granted rights to the members for granting compulsory licenses as well as freedom for determining grounds on which licenses are to be granted.

The compulsory licensing system even after the above mentioned developments may not have completely met the requirements of the pharmaceutical industry's requirements in India after the amendment to the Patents Act. This view was a result of some reasons explained herein below:

The Indian Patents Act enumerates that an application regarding grant of compulsory license can be made after three years from the date of grant of patent only. There are exceptional circumstances such as national or extreme emergency that may be used for justification of grant of license prior to the said period of three years. Thus, the grounds for grant of compulsory licenses are:

- Reasonable requirements of public in regards to patented invention not being satisfied;
- Patented invention not available at affordable and reasonable prices to the public;

- Patented invention not being worked upon in the Indian Territory.

The above mentioned conditions for compulsory license's grant may be seen as facilitating the license's grant, the Act further stipulates the authority to give proper consideration to additional four factors before granting the license. The first one being the nature of invention, the time lapsed since patent sealing and measures taken by licensees or the patented to completely use the invention. The second factor is the applicant's ability to work the invention for the advantage of the public. The third factor is the capability of the applicant for taking risks for working the invention and providing the capital. The final factor is the efforts of the applicant to obtain license on reasonable terms and conditions from the patentee and those efforts not yielding any successful results within a reasonable period.

Considering these factors while granting licenses raises a lot of problems. Firstly, the procedural requirements result in delay as they are too onerous. Secondly, it is unclear whether on refusal of a patentee on issuance of voluntary license on commercial terms which are reasonable lead to grant of compulsory license. Thirdly, the grounds for determining anti-competitive practices are not clearly provided in the Patents Act nor in the Competition Act. Finally, no ceiling is provided on remuneration which is payable to holders of the patent which inevitably will lead to unnecessary litigations and excess royalties being demanded. The last problem is capable of blocking the way in the system of compulsory licensing.

In implementing the system of compulsory licensing, royalty payments were a critical issue at that time. Besides the problems discussed above, there was proof and evidence of developing countries not being able to afford proprietary technologies as a result of high cost for acquiring them. This situation was a result of the fact that owners of the technology were indeed able to use their position of superior bargaining for seeking terms which would have suited their interests. At a time when patent thickets i.e, web of patents which covers a single product was becoming common, it was often required that multiple licenses get negotiated before commencement of production by any industry. Patent thickets have also led to royalty stacking.

India's experience with the agreements on licensing of technology provided scope for an interesting reading. According to the previous trends, the licensors even when not transferring proprietary technologies were capable of securing their payments for the technologies. Surveys conducted for three decades on foreign collaboration agreements by RBI have revealed that only in fifty percent of the total cases, the proprietary technologies were indeed transferred.

The above mentioned problems are not addressed by the Indian Patent Act. Section 90, in fact states that the perspective of the patentee would be taken into consideration by the remuneration. This includes the patentee's expenditure he has incurred, for making and development of the invention and for obtaining the patent and keeping it in force. It can be argued that the considerations for determination of all the remuneration and royalties will enhance the existing bargaining position of the patentee and these will need to be tempered with considerations on public interest as well. [8]

Opposition Proceedings

The third amendment was introduced in the year 2005. It dealt with another issue which was of considerable significance, i.e, the issue of opposition for the grant of patent. The Ordinance brought up in December 2004 ignored the provisions related to pre grant opposition and the post grant opposition was introduced. However, the legislation after amendment restored the ground for making pre grant opposition. India thereby became the only country to provide in its domestic legislation, both pre and post grant opposition. But by doing this, India has indeed put the applicant in a position which is disadvantageous.

2.8.1 The Two Exemptions

Two notable exemptions are discussed under Section 107A of Patents Act, 1970[9]. Bolar Exemption is the first exemption while the second exemption attempts at defining contours of Parallel Imports.

1. Bolar Exemption

Bolar exemption is a less focused area of the amended Act. It was introduced by the second amendment for creating conditions for manufacturers of generic drugs to introduce their products immediately after drug lapses on a patent. The leading firms of the Indian Pharmaceutical Sector showed dynamism in a few years after amendment.

According to the provision, an act of making, selling, constructing, importing or using an invention which has been patented for uses related to submission and development of information required, either in India or any other country, for regulating construction, manufacture, sale, import or use of a product.

2. Parallel Imports

[8] *Ibid.*
[9] *Ibid.*

The TRIPS Agreement allows parallel imports but has not defined the circumstances when they can take place. According to Section 107A(b), parallel imports are the imports of a product which has been patented by a person from someone who has the authorization of law to sell or distribute the product. For ensuring that the patent products were made available to all the consumers at a cheaper rate, the provision of parallel imports was introduced.

For establishing a balance between public's interests and rights of the holders of the patents, the attempt was made to make the Indian Patent Act TRIPS compliant by way of the amendments. These amendments strengthened the rights of the patentees to a great extent, but the interests of the public were ignored to some extent. A balance between the two was not established properly. Space was provided for the firms to grow and expand by exploitation of various provisions of the TRIPS Agreement.

CONCLUSION

For reaching global standards and achieving economic development, patent law is among those intellectual properties which can be considered to be efficient. Grant of patents for pharmaceutical products along with methods and processes has indeed impacted economic growth to a large extent. By each passing year, the number of applications being filed for the grant of patents is increasing which is thereby aiding the growth of the economy. Today, the MNCs established in India are itself proof of the growth of Indian economy.

The MNCs were earlier not keen to take up Research and Development as a process in India due to the problems in regard to the implementation of intellectual property laws and infringement risks involved in the initial stages. After the amendments which were introduced in the Patents Act for compliance with the TRIPS Agreement, India witnessed an increase in the number of patent applications being filed as a result of investment by the MNCs and their interest in undertaking research and development in the Indian Territory. This change is the result of the better implementation of laws and proper definitions of various legal terms.

Investments by the MNCs have indeed increased the employment opportunities in India along with the increase in the amount of tax being paid every year. It is presumed that an increase in the number of employees helps in economic growth.