



Whether Indian Patent Act TRIPS Compliant for Pharmaceutical Business: A Case-Based Approach

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Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was negotiated during Uruguay round and GATT was replaced by WTO. All the signatory countries had to abide to the norms of the agreement. They were asked to modify their national IP laws as per the requirement. India too incorporated the required changes and finally, Indian patent act became TRIPS compliant in 2005. Although, it was claimed that India has designed its action in a most exhaustive form still, Indian companies face lot of litigation suits concerning infringement of patented products. Issues were raised at international forums stating that Indian IP laws are not fully TRIPS compliant and lot of flexibilities are given for the domestic firms which creates an unequal platform for trade. In order to reach to the substantial-conclusion on the impact of TRIPS implementation on the functioning of Indian pharmaceutical industry (IPI) and the impact it may carry with respect to the socio-economic life of the citizens of India. The study considered some of the court cases related to the infringement of patents that were raised in Indian court by MNC's along with their decision. Through these cases and the judgements thereafter it was found out that Indian Patents Act is well in place and judiciary plays an important role in monitoring its effective implementation.

Keywords: Intellectual Property Rights, Indian Patents Act, WTO, TRIPS, Indian Pharmaceutical Industry, Innovation

The theories of international trade argue that no country is self-sufficient in producing each and every good. In order to fulfill the demands of their citizens we need to Import and Export with other countries and all classical thinkers were in the opinion to promote unhindered trade among the countries.^{1,2} The mercantilists advocated that the wealth of the nations may not be counted on the basis of gold they possess but the variety of goods and services which are enjoyed by the citizens of that country.³ This can be possible only through promotion of free trade. Later, this concept was propagated by the Ricardo, Hecksher-Ohlin, Reymond Vernon and other thinkers of their time which further improves trade between countries. As we know that the industrialisation took place earlier in the western countries and hence they started exploring to the global markets resulting in increase value and volume of trade across the nations. Seemingly, in the present era of globalization, cross-border movement of goods and services had increased drastically. As the trade increases, competition also increases and, in the race, to compete among companies, countries started protecting their domestic

firms by giving various subsidies, discounts and tax benefits⁴. In an effort to gain the maximum benefits from their research outcomes these companies spread their arms to all potential markets of developing countries. They tried to gain exclusive benefits from their innovations by securing patent protection for their intellectual outcome. In the process to achieve maximum gains they propagated the concept of IPR worldwide and all member countries of WTO had to abide to the minimum requirements of Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement.⁵ Based on the development stage and the present adoption of IPR laws among member countries, TRIPS Agreement take a balanced approach towards the interest of innovators and the general public. Therefore, member countries were provided with a permissible time limit to make their domestic IP laws TRIPS compliant and adopt minimum standards in all products, including Drug & Pharmaceuticals.

Interestingly, India, the founding member of WTO, must comply with the norms. However, patents were not new to India⁶, in the pre-independence period when India was under British rule both product and process patent were granted to the innovators in the

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category of pharmaceutical products which leads to the undermining the growth of Indian pharmaceutical industry. Even, it was observed that multinational firms were charging exorbitant prices from consumers for their patented products, making healthcare facilities unaffordable to poor citizens.^{7,8} After attaining independence, to address the affordability and accessibility issues of medicines for the poor and to make the country self-reliant in the sector of prime concern especially pharmaceuticals, the government came up with new norms to protect innovations. India came up with an Indian Patent Act in 1970⁹ where few changes were introduced including abolishment of grant of product patent in certain sectors including drug and pharmaceuticals. The decision comes up as a boon to the struggling Indian pharmaceutical industry as they were allowed to use the patented products through reverse engineering process. The representatives of developed countries strongly opposed the domestic laws and suggested one uniform code for the protection of IPRs. They proposed that the harmonisation of world trade will be badly affected if the countries have different norms to protect Intellectual Property Rights (IPRs). They also stated that the ineffective enforcement of these rights in different countries may increase trade of counterfeit and pirated goods and thus, destroy the genuine commercial transactions by the original manufacturer who holds or acquired the rights.

Even with the continuous efforts and opposition throughout the world by the representatives of developing countries, the Agreement on Trade-Related Aspects of Intellectual property Rights (TRIPS) were negotiated at Uruguay Round (1986-1994). Finally, in the year 1995, GATT was replaced by WTO and the member countries were asked to sign the Dunkel draft. TRIPS laid down the minimum standard for the protection of intellectual property as well as the procedures and remedies for their enforcement.¹⁰ It established a mechanism for consultation and surveillance at the international level to ensure the compliance of domestic laws related to intellectual property for all the member countries of the World Trade Organisation (WTO) with respect to the standards established. The structure of the agreement was built on the existing international conventions dealing with IPRs¹¹. Its provision applies to all forms of intellectual property including Patents, Copyright and related rights, Trademark, Industrial design, Undisclosed information, Geographical Indications and Lay out design of integrated circuits.¹²

India also responded to the Agreement and amended its Indian Patents Act, 1970 in three phases (Year 1999, 2002 & 2005) to make it TRIPS compliant.¹³ Although, India claims that the Patents Amendment Act, 2005 is fully TRIPS compliant still, issues were raised at international forums stating that Indian IP laws are not following the international guidelines and lot of flexibilities were given to the domestic firms which creates an unequal platform for trade.

Although, it is claimed that India has designed its act in a most exhaustive form still Indian companies face lot of litigation suits concerning infringement of patented products. Within a span of 17 years since the adoption of patent regime lot of infringement suits were filed in various courts in the country. India has come across few landmark decisions while other is still pending in the court. Among all, *Novartis v Union of India* (2013) was one of the much hyped. Besides that, several other cases of patent infringement were filed by multinational companies against Indian pharmaceutical firms such as *Cipla v Roche* (2015), *Merck v Glenmark* (2015), *Bayer v Union of India* (2019), *Natco v Bristol Mayer Squibb Holding* (2019) and *Novartis v NatcoPharma* (2021).

The oppositions against the Indian patent act raised few questions such as; *Whether Indian Patents Act is TRIPS compliant? Whether Indian Patents Act will able to protect the interest of innovators? Whether the flexibilities in the patent act favour domestic firms?* Based on the research questions mentioned above and in order to reach to the substantial conclusion about the flexibilities in the Indian Patents (amendment) Act, 2005, the study considered all court cases related to the pharmaceutical patent infringement against Indian companies which were filed in Indian court by MNC's along with their decision. The criteria for selection of court cases are based on the date of filing i.e after 2005, as in this year Indian Patents Act become fully TRIPS compliant.

Cases of Pharmaceutical Patent Infringements in India

It is claimed that India has designed its Act in a most exhaustive form still Indian companies face lot of litigation suits concerning infringement of patented products. Within a short span of 16 years since the adoption of patent regime lot of infringement suits were filed in various courts in the country. India has come across few landmark decisions while others are still pending in the court.

Novartis v Union of India & Others

The argument related to the position of India towards incremental innovations filed for patent can be understood by the famous Novartis 'Gleevec' case. In an obligation to comply with the norms of TRIPS, India demolishes its Section 5 and introduced Article 70.8, through these changes 'Mailbox' transition was introduced. Novartis in order to secure monopoly position for 20 years to beta crystalline form of ImatinibMesylate (*Gleevec*) filed a patent application No 1602/MAS/1998 in India. It is worth to note that any patent which is filed before 1/01/1995 anywhere in the world is found ineligible for patent in India. Beta crystalline form of ImatinibMesylate is a typical case of prior disclosure where the base salt Imatinib is disclaimed before 1995. Since the Patent No 1602/MAS/1998 was filed during the transition phase, it remained in 'Mail-Box' till 2005. In lieu of that Novartis got exclusive marketing rights (EMR) for the *Gleevec*.¹⁴ After gaining EMR, Novartis obtained injunction orders to restrict other generic drug makers to manufacture market and distribute Imatinib. This results in an increase in prices of the product from 90 per 100 mg capsule of generic companies to 1000 per 100 mg capsule of Novartis. On the same time, another landmark amendment was made in the third Indian Patents (amendment) Act, 2005, which is related to Section 3 (d), where the concept of "efficacy" was introduced.¹⁵ This results in the immediate filing of pre-grant opposition against the Novartis patent application by Cipla and other NGOs. They argued that the patent does not beg any novelty and inventive step rather it is just a new form of the known substance. Novartis had already granted a patent for Imatinib in U.S.A. in the year 1993. During the argument, the opposing parties claimed that the crystalline form of Imatinib does not differ in terms of efficacy. Therefore, it should be considered same substance. On the basis of pre-grant opposition, the patent controller did not grant a patent to Novartis in January 2006. In response to this Novartis filed a petition challenging the constitutional validity of Section 3(d) claiming that it is not TRIPS compliant. The Madras high court upheld the constitutional validity of Section 3 (d) and the appeal was rejected. Further, the High court defined the term efficacy as 'therapeutic efficacy' in healing the disease and having a good effect on the body. The company produced the affidavit showing 30 per cent increase in bioavailability as compared with the Imatinib base, but it was rejected on the ground that the comparison

should be made between alpha and beta forms and not with the base formula. The final decision came on April 2013 by the honourable Supreme Court stating that the beta crystalline form of ImatinibMesylate fails the test of the invention and patentability criteria under Section 2(1) Clause (j), (ja) and Section 3(d), respectively.

The decision got a mixed response from various organizations worldwide, some had welcomed the decision on the ground that this will help poor as it will improve the accessibility and affordability of drug. On the other hand, few companies had shown their anger by stating that the decision is a setback for patents as it will hinder the progression in the medical field, as companies will withdraw their investments in research and development.¹⁶ From the above case, it can be interpreted that most of the patent application which was related to the incremental innovations of the already patented product are likely to be challenged through pre-grant opposition and Section 3(d). This would have positive implications for the Indian generic drug manufacturers as it further prevent the grant of patent and will result in breaking of monopoly pricing of the patentee and in turn benefits the consumers as there will be a widespread availability of product at a relatively low price. Lastly, we can conclude that although the decision proves to be a roadblock for innovators, but it will certainly help the poor to afford the medicinal cost in developing and least developed countries.

The judgement of Madras high court had given a jolt to Novartis and other MNCs operating in India who want to secure their monopoly position by restraining Indian firms to produce generic version of their off-patented product through incremental innovation. In a similar fashion another landmark judgement made India's position clear towards the issue related to affordability and availability of drug for the poor.

Bayer v Natco

Another news which had created ripples in pharmaceutical industry in India, was related to the issue of first compulsory licence in the post TRIPS period. The compulsory license was granted by the controller general of patents for the anti-cancer drug Sorafenib a patented product of Bayer which is marketed under the brand name of Nexavar. This drug is used for the treatment of Renal and Hepato-cellular carcinoma. The rationale for the grant of compulsory license for Nexavar was in line with Section 84 of

Indian Patents Act, 1970,¹⁷ where compulsory licence can be granted to the third party in case it is found the patent holder's inability to meet the demand and the extraordinarily high price charged which raises the issue of affordability among people as compared to what is offered by generic manufacturer, Natcopharma. A compulsory license is granted to Natco pharmaceuticals against the Patent No 215758 which was granted to Bayer Corporation in the year 2008. The issue started in on 6 December 2010 when Natco approached Bayer for a voluntary licensing on reasonable terms; a reasonable term can be defined as "paying 3 per cent royalty amount of net sales". Bayer refused to grant a voluntary licence to Natco. On that ground Natco filed an application for issue of compulsory licence under Section 84(1) of Patents Act, 1970. The Section 84 of the act states that, any generic drug manufacturer can approach the patent owner for voluntary CL after completion of 3 years of patent grant on reasonable terms. Natco justified its appeal on three basic issues (1) reasonable requirement of the public has not met, it was reported that the drug is accessible to only 2 per cent of the patient, (2) that the patented product is not available to the public at a reasonable price, Bayer charged Rs. 2,80,000 for a month long therapy, and (3) the invention is not worked in India. After a two year long hearing it was reported that Bayer could not able to supply the appropriate amount of drug in comparison with the renal and hepatic cancer cases reported in the country. The controller general of a patent issued CL to Natco, the major terms and conditions set are; the price of the drug should not exceed Rs. 8880 for a pack of 120 tablets, the licensee will maintain a proper record of sales and furnish the report to the controller general and the innovator company, the licensee will manufacture the drug by his own and does not outsource, the license is non-exclusive and non-transferable, the licensee will pay 7 per cent of net sales in the form of royalty to the parent company and the licensee do not have the right to export the drug to another part of the world.

By looking into the last case it cannot be concluded that any company who wishes to take compulsory licence of the patented product will be allowed to do so in India. It is worth mentioning here with the help of another case of BDR Dasatinib where some irregularities were found and CL application was rejected.

BMS v BDR

Bristol Myers squibb, a global biopharmaceutical company filed a suit of infringement against BDR for their patented product Dasatinib Patent No IN203937 marketed under brand name Sprycel which is used to treat case of chronic myelogenous leukemia and acute lymphoblastic leukemia. The issue started in the year 2008 onwards when BDR asked for voluntary compulsory licencing from BMS for Dasatinib. While replying to the mail BDR was asked to reply certain query raised by the innovator company, which the applicant did not furnish. Besides that BDR filed a CL for Dasatinib in the year 2013 citing the extraordinarily high price charged against the innovator company. In reply to this, BMS filed two separate cases of infringement CS (OS) 2303/2009 and CS (OS) 679/2013. After a long hearing finally, the application was rejected as the authorities found that the process followed by BDR was not appropriate and had not acted in good faith during the proceedings for application during the negotiation for voluntary licencing. Initially, it was in the news that ministry of health is interested to grant compulsory licencing for Dasatinib under section 92 of the act. This act allows the central government to issue compulsory licence in the condition of national emergency, extreme urgency and public non-commercial use but also seems to fade off.¹⁸

This decision may be considered as an example to the rest of the world which considers India as a country with weak patent enforcement. Such type of judgements show that court always tries to maintain is a balance between the benefits of innovators and generic drug manufacturers. Still, issues of affordability of drug to the public should always remain a priority for every country. Through, another case of infringement filed by Roche against Cipla, it is evidently clear that the implications of Section 3(d) applies to both Indian and foreign origin firms.

Roche v Cipla

Another landmark case that took place between Switzerland based multinational company 'Roche' and Indian generic drug manufacturing company 'Cipla'. The issue come in the light when Cipla announced the launch of its generic version of Erlotinib a cancer drug of Roche which is patented in India (Patent No. 196774) after screening of patent filed under Mail box method.¹⁹ Cipla started manufacturing and marketing the polymorph B of Erlotinib whose patent was rejected in India on the

grounds of Section 3 (d). They launched the product with the perception of non-infringement of Roche Erlotinib as it was not identically similar. Roche filed an infringement suit against Cipla. This case can be viewed from two aspects through the orders of Delhi High court. Usually, the decision came either in favor of the defendant or the plaintiff, but the judge gives special consideration to the third party i.e. public. In his argument, he states that Cipla is selling its generic version at a price which is one-third of the patented product. The therapy costs rupees 46000 for Erllocip as compared to 1.42 lakhs of Roche. Depriving of the generic version will lead to the shortening of lives of people suffering from cancer. This decision was seen as a 'Judge-made compulsory licence'. Court directed Cipla to maintain fair record of sales figure of Erllocip in order to compensate the innovator. Roche further filed an appeal before the division bench against the orders. The Division Bench dismisses the application in the public interest. Rather Roche was fined 5 lakhs to be paid to Cipla. The Court claimed Roche for not disclosing proper information as a requirement under full disclosure. Roche filed SLP in Supreme Court against the order, as the civil suit was pending in the High Court; Supreme Court did not interfere in the matters but recommends expediting the trail as possible without any further delay. The honourable judge rejects the Cipla claim related to the validity of patent under Section 3 (d) and concludes that the patent is valid. Although, Roche could not prove that Erllocip which is the polymorph B form of Erlotinib in any way infringe its patent IN774. The case was further taken to the division bench where it went in the favor of Roche. The Judge states that the process for manufacturing B polymorph of Erlotinib hydrochloride results from recrystallization of Erlotinib hydrochloride, therefore any polymorphic version will certainly infringe the patent. Finally, Cipla announced that it had ceased all patent litigation cases against Roche through out-of-the-court settlement. This case is considered as the first pharmaceutical patent case which got closed in the post TRIPS period. Similarly, another infringement case was filed in the court of law this time it was Merck.

Merck v Glenmark

The battle between innovators and generic drug manufacturers had stepped one step ahead from antiretroviral and anti-cancer drugs to anti-diabetic therapy. In another infringement case which is similar to the above mentioned Roche and Cipla issue, this

time Merck and Glenmark goes head-on with each other in an infringement suit related to the Sitagliptin a molecule from Gliptin family used to cure type 2-diabetes. The issue come in light when Glenmark had launched the generic version of the patented drug of Merck in India. Before going into the detail of the case we must understand that Merck is manufacturing and marketing Sitagliptin with a brand name of Januvia which is surrounded by two patents in India 'IN209816 and IN 219148'. The previous patent protects Sitagliptin and the later one is granted to the process intermediaries which are used to manufacture Sitagliptin. Merck had filed another Patent Application No 5948/DELNP/2005 covering the phosphate form of Sitagliptin. The patent application related to the phosphate form of Sitagliptin was rejected following pre-grant opposition on the grounds of Section 3(d). Based on these rejection grounds Glenmark announced Zita and Zita-Met tablet and argued that since Sitagliptin and Sitagliptin phosphate are two different products considered by Merck and the patent application was rejected for the later, they can manufacture and market the phosphate form of Sitagliptin, the court rejected this appeal. The court further stated that Sitagliptin phosphate monohydrate cannot be prepared without manufacturing the active molecule i.e. Sitagliptin. In the 2 yearlong dramafinally, court issued a permanent injunction and restrained Glenmark from manufacturing, marketing and selling of any product claimed by Patent No IN209816. Although, the court did not find it fit to fix damages against the loss of profit as it was not demanded by Merck but they ordered Glenmark to pay the attorney's cost incurred by Merck in carrying out the proceedings. Court further gave time to Glenmark pharmaceuticals to liquidate its inventory.

This case also proves that "at risk strategy" which was described in few articles in the past no more remains valid in India in the present context. Finally, it may be concluded that the developed countries especially US will welcome the decision and change its perception towards Indian legislature which he earlier believes that they are biased against innovators.

While going through the infringement cases filed against Indian generic drug manufacturers in India it has been found that there was a mixed response towards the interpretation and outcome of the amendments made in the Indian Patents Act, 1970. Although, it was claimed that the Indian Patents Amendment Act, 2005 is fully TRIPS compliant still, voices were raised to make it more stringent. Before

jumping onto the conclusion we must understand that the agreement itself talks about the minimum standard a country must adopt, beyond this it is the government and the situations which will decide. It is the country's responsibility to take the advantage of the flexibilities in the agreement in order to make a balance between the rights of innovators and the users of the technology. While going through the TRIPS Agreement, Article seven and eight itself states that the objective of the agreement is to promote free trade through transfer of technology to balance the rights and obligations in order to generate social and economic welfare. Further, article eight of the agreement suggests countries to amend their laws in the way it protects public health and nutrition at least to the sectors which are of vital interest such as pharmaceuticals. Therefore it has become imperative on the part of the government to make a balance. Even the Article 27 of the Agreement states that any patent must qualify on the parameters of novelty, inventive step and industrial application before grant. In extension to that Article 27 (2) also talks about the circumstances in which patent application could be rejected. Section 3 of Indian Patents Act incorporated the suggestions and introduced 3(d) Clause, this helped India to restrict 'abuse of patent' by restricting patent of incremental innovations thus limiting the monopoly of multinationals such as Novartis and other through 'Evergreening'. This seems favourable for developing countries like India where affordability is still an issue. This can be visibly seen in the case of Novartis where patent application of beta crystalline form of Imatinib Mesylate (Gleevec) was rejected on the ground of enhanced efficacy.

Article 30 of the TRIPS Agreement gives liberty to the member countries to practice certain exception to the exclusive rights of the patentee considering the affordability and accessibility issues of product to the poor. In line with the recommendations of the agreement, Indian patent act introduced Section 84 which permits the government to issue a compulsory licence under certain circumstances such as; patent not worked in the territory, prices are too high or the product is not fulfilling the requirement of public. Through the case it is found that the ground for first compulsory licence which was granted in India in the post TRIPS period to the generic drug manufacturer Natco pharmaceuticals for the cancer Drug 'Nexavar' was on the basis that the product was not made available to the public in the desired quantity and even the prices were not reasonable. On the other

hand, while analysing the case of compulsory licensing between *BDR v BMS* the court rejected the application as it was found that the process followed by BDR was not appropriate. This decision shows that India does not have weak patent enforcement. Rather, the judgement indicates that court always tries to maintain is a balance between the benefits of innovators and public as issues related of affordability of drug to the public always remains a priority for every developing country and India is one among all. Not only this, through another case of infringement filed by Roche against Indian pharmaceutical firm Cipla, it is evidently clear that the implications of Section 3(d) applies to both Indian and foreign origin firms. Similarly, in case of *Merck v Glenmark* the Court issued a permanent injunction and restrained Glenmark from manufacturing, marketing and selling of Sitagliptin as the product infringes the parent patent and thus protect the interest of innovator.

In extension to this, Article 31 of the agreement gives liberty to the member country to grant compulsory licence even without the authorization of the patent holder even without expiration of three years to grant of patent in the country under certain conditions of national emergency, extreme urgency or public non-commercial use. On the same guidelines Section 92 of the Indian Patents Act defines that compulsory licence can be granted to the third party or government itself for free distribution of drugs to the hospitals, dispensary or other dispatch centers to overcome such situations. Although, no such case has been reported in India in the post TRIPS period under Section 92 of the Act. But the member countries have a liberty to practice.

Article 32 of the TRIPS agreement also seems important for Indian businesses in the post TRIPS period. This Article states that if any person found that the patent granted to the product is frivolous or it is known earlier to the public, then they can file a review against the granted patent. Section 25 (1) and (2) of the Act deals with pre-grant and post-grant opposition. Earlier post acceptance opposition was allowed in the Indian Patents Act, 1970. Later on in the third amendment of the agreement pre-grant opposition was introduced. There are several cases which were reported in India related to pre-grant opposition. This process can delay the exclusive right of the patent holder although this 'at risk strategy' does work no more in India presently but it was initially used as a tool against the patent. Few successful cases were also reported for post-grant opposition as well.

Conclusion

It has to be understood that the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement laid down the minimum standard for the protection of intellectual property and countries have to abide to the norms as per their domestic requirements. It was established with intent to balance the interest of both innovators and the users of the technology. India being a country with approximately 138 crores people and where it is still struggling with providing primary healthcare facilities to the masses, we need to understand the significance of controlling the prices of products so that nobody is deprived of life saving drugs. Through this paper while analysing the court cases against pharmaceutical firms, we come to the conclusion that the Indian patent act is fully TRIPS compliant and the interest of both innovators and the users of technology is protected. The judgements of the court indicated that no company will be allowed to exploit the patented invention of any innovator against his will, although it is observed that compulsory licences were granted to the companies if they had followed a reasonable approach for generic manufacturing and the government feels that it is in the interest of general public.

Through the findings of the study it is further recommended to the policy makers to formulate more stringent laws against the infringers so that we could able to restrict the cases of patent infringement in India. Although, utmost care is been undertaken to bring in light all the infringement related cases against Indian pharmaceutical firms but it is too early to jump into the conclusion about the completeness of Indian patent act as India is still in a formative stage to educate and implement IPR related issues in all forms. Therefore, time remains a limiting factor. The findings of the study have far reaching implications for the industry. Through the analysis of judgement of the court cases it was found that firms will not be allowed to copy or infringe the patented products of the innovators any more. Therefore 'collaborate' is one of the best strategies for survival. Further, to carry out the research forward a comparative study may be conducted among BRICS nations to understand their interpretation towards the agreement and how they are coping up with the problem related affordability and accessibility of drugs to the poor.

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