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TRIPs agreement and public health: Indian experience

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Abstract

This paper discusses briefly the recent problem associated with implementation of TRIPs agreement within the Indian Patent law. International obligation to protect Intellectual property right creates an everlasting conflict with the national duty to protect the public health. The far cries of the developing and least developed countries have been highlighted and reason behind their failure to apply compulsory licence provision has also been sought. Moreover, implementation of Para 6 of the Doha declaration and its outcomes have been discussed.

Keywords: TRIPs agreement, public health, pharmaceutical patents, Doha declaration

1. Introduction

The Uruguay Round of negotiation (1986-1994) was the turning point in the history of intellectual Property rights. The most important outcomes of the Uruguay Round of negotiation were TRIPs agreement and its came into force on 1st January 1995 and it's became mandatory for all the members of WTO. Therefore, India has to assent to the TRIPs agreement in 1995 and as a result it has to amend its existing patent law. Before, TRIPs Agreement came into being, product patent was not granted in pharmaceutical sector only process patent was allowed under the Patent Act, 1970. It was done intentionally so that the same pharmaceutical product can be produced by different process that lead to growth of generic pharmaceutical industry in India. Not only India, this practice followed by many developing and least developed countries to facilitate access to essential medicine at affordable cost to the large section of poor people.

However, due to TRIPs agreement India has to amend the Patent Law, 1970 three times in 1999, 2002 and 2005 and included the product patent in pharmaceutical sector also. The generic pharmaceutical industries are to be closed according to the international trade norms. That leads to unpleasant situation in India as well as all developing and least developed countries because, India is the major producer of generic drugs and also leading supplier of the generic drugs to other developing and least developed countries.

As a result life saving drugs become very costly and out of the reach of the poor patents. Thus, TRIPs agreement creates strong debate whether industrial interest shall be kept above the public health policy or vice versa.

2. India's obligation towards Public health

India is a welfare State and as a welfare state it has the obligation towards the public health of its citizens. The framers of the Constitution were well aware about the necessity to protect the public health. Therefore, they imposed duty of public health under the Article 47 of the Constitution. Under Article 47, the State shall regard the raising of the level of nutrition and standard of living of its people and improvement of public health as among its primary duties. As the Article 47 is included in Part-IV under the directive principle of state policy of the Constitution, it is not enforceable like fundamental right to the citizen but it is fundamental in the governance of the country.

In order to fulfill the above obligation India has to facilitate its citizen access to necessary medicines at affordable cost as the majority of the population in India are suffering with poverty and various diseases.

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3. TRIPs Agreement and its mandates

The main object of the patent law is to protect the exclusive right of the inventor of process or product and to encourage the inventor for fundamental research. If inventors are protected from the copying their process or product by others for a certain period of time, they shall get inspiration to invest their creative faculties towards the fundamental research.

Similarly, the main object of the TRIPs agreement is to reduce distortions and impediments to international trade and to provide effective and adequate protection of the intellectual property^[1].

TRIPs was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. Under Article 27 of the TRIPs agreement it is stated that patent shall be available for any inventions, whether products or processes, in all field of technology, provide that they are new, involve an innovative step and are capable of industrial application^[2]. Thus, all pharmaceutical products are included under the mandate of the TRIPs agreement and the duration of the patent has been fixed for 20 years including pharmaceutical products^[3].

Important factor is to be noted that TRIPs provides process as well as product patentability. Therefore, the similar product cannot be produced by application of different process. Thus, it provides the patent holder an exclusive right for producing and selling the patented product as there is no right for copying the product by using other production process.

The most debatable issues arise when it further restricts every developing nation on importing cheap generic version of the costly medicines from the other countries using the compulsory licence provisions. According to the Article 31(f) and 31(h), the importing countries must pay the adequate remuneration before using the said patented medicines^[4].

Therefore, the production of generic version of the costly medicine is prohibited under the mandate of the TRIPs agreement. The main problem of those mandates of the TRIPs agreement are that the developing and least developed countries are highly depended to their indigenous generic pharmaceutical industries to facilitate access to essential medicines at affordable cost to the large section of the poor people. Sometime, developing countries like India and Thailand has promoted the growth of the generic pharmaceutical industries without protecting new pharmaceutical invention for the public health purpose^[5]. However, that development has to be stopped or reduced as per the mandates of the TRIPs agreement which will increase the cost of necessary medicine in unprecedented manner. It will deprive the poor patient of developing countries to afford the costly medicine for which they have previously used cheap generic version.

4. Impacts of TRIPs Agreement on Indian Pharmaceutical Sector

India has its own patent law since 1970 and it excluded all pharmaceutical products from the patentability. Further, under the earlier Patent Act, 1970 only process patent are granted, not product patent. Moreover, the process patent could be granted only for seven years. The inner motive behind this lenient patent law in India was to encourage

generic pharmaceutical industries to facilitate the poor inhabitants' access to cheap medicines^[6].

As a result of this, the production of generic drugs became the paramount in the country. Indian generic pharmaceutical industries not only supply generic drugs to the domestic levels but also supply to the other developing and least developed countries. In the 1970, Indian pharmaceutical companies not only dominate domestic markets but also to the foreign markets, as well^[7].

India provides a supportive patent system for the generic drugs for a number of reasons. India is a leading example of a low-income country that did not recognize pharmaceutical product patents at the time the TRIPs agreement went into effect. In fact, during the Uruguay round of negotiations, India led the opposition to the TRIPs articles mandating pharmaceutical product patents. In terms of the structure of demand, India is an admittedly low-income country with a large number of poor households and for whom health insurance coverage is non-existent. As a result, they have to meet all medical expenses out of their own pockets.

Moreover, the domestic Indian pharmaceutical industry, which as of 2002 was the largest producer of generic drugs in the world in terms of volume and also supply to many middle-income countries^[8].

However, due to international pressure India has to sign TRIPs agreement and as a result India needs to amend its national patent law to make it consistent with the TRIPs agreement.

Under the new amendment of the Patent Act in 2005 product patent of the pharmaceutical product has been granted^[9]. This creates three types of problems in India pharmaceutical sector. *Firstly*, they cannot produce generic version of drugs, as a result their business goes down. As well as revenue coming to the Indian Government though the foreign export of the generic drugs has come to an end. *Secondly*, the price of live saving drugs become very costly and goes out of the rich of the poor Indian citizens. *Thirdly*, the Multi-National Companies create monopoly market and take control over the Indian pharmaceutical market. Those MNCs became the controller of health sector of India. Nowadays, the survival of the generic pharmaceutical companies comes in question and they are struggling for their survivals.

5. Conflicts between TRIPs Agreement and Indian Public Health Policy

As a welfare state India has to develop a sound balance public health policy to save its citizens from any kinds of diseases and epidemic. Further, the maximum populations of India are poor and they cannot effort the costly medicines. Therefore, government must take some initiatives to protect the interest of the common people.

Pharmaceutical and agricultural chemical products were not included under the original Patent Act, 1970 because such inclusion may contrary to the public health policy of the country^[10].

Unfortunately, due to TRIPs agreement the existing Indian patent law had to be amended. Pharmaceutical product has been patented for the term of 20 years in the latest amendment of 2005. As WTO makes compliance to the TRIPs agreement mandatory for its membership India has nothing to do but to assent to the TRIPs agreement.

Therefore, the Government of India has nothing to do because under the new international patent regime TRIPS agreement is to be complied strictly.

According to some scholars, under the TRIPs agreement there is sufficient scope for the national Government to manipulate their national law according to their economical and social development. However, even after assenting the TRIPs agreement Indian Government still has the right to manipulate their national law according to their economical and social development and it is permitted under Article 8 of the TRIPs agreement. Article 8 of the TRIPs said that members may during the formulation or amendment of their national laws and regulations; adopt necessary measures to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.

Thus, the TRIPs Agreement is the main reason behind the basic changes brought about in the patent law of the country by legislative action. However, the legislature and Indian judiciary several times have expressed their concern about the outcomes of the patent protection to pharmaceutical and agricultural chemical products and they have an apprehension that such drastic step may cause life-saving medicines beyond the reach of a very large section of poor people. The Indian legislature addressed this concern while harmonizing the patent law in the country with the provisions of the TRIPs Agreement and tried to balance its obligations under the international treaty and its commitment to protect and promote public health considerations, not only of its own people but in many other parts of the world (particularly in the Developing Countries and the Least Developed Countries).

Indian legislature tries to apply the mandates of TRIPs agreement on pharmaceutical and agricultural products in lenient manner. Under Section 83 of the Patent Act, 1970 it is clearly reflected when it states that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest, especially in sectors of vital importance for socio- economic and technological development of India ^[11].

It further states that patents granted do not in any way prohibit Central Government in taking measures to protect public health ^[12].

The conflict between the TRIPs agreement and Indian Public health policy best can be illustrated in *Novartis Ag v. Union of India* ^[13] case, Novartis, an USA based MNC invented an anti-cancer drug under the brand name of Glivec/Gleevec. Novartis never applied for patent before 2005, after TRIPs agreement came into enforced it applied for product patent in India.

However, patent registration office rejected the said application according to the provision of Section 3(d) of the Patent Act, 1970, under the said Section patent cannot be granted for a mere new form of a known substance for which patent cannot be granted ^[14].

Therefore, the patent office rejected the application of Novartis on the ground that it did not satisfy the efficacy criterion of Section 3(d).

The Supreme Court held that the Indian Parliament had done an absolutely unenviable task by balancing TRIPs agreement within the Patent Act, 1970. Indian Government realized that implementation of the TRIPs Agreement had

aroused grave concerns about its impact on public health. India had learnt from experience the inverse relationship between product patents and the indigenous pharmaceutical industry, and its effects on the availability of essential drugs at affordable prices.

The Apex Court further stated that after the patent system in India barred the grant of patents for pharmaceutical and chemical substances, the pharmaceutical industry in the country scaled great heights and became the major supplier of drugs at cheap prices to a number of developing and under developed countries. Hence, the reintroduction of product patents in the Indian patent system through the TRIPs Agreement became a cause of alarm not only in this country but also for some international agencies.

Rejecting the said patent application the Supreme Court strongly upheld that, while fulfilling its commitment under the TRIPs agreement, the Government must not bring in a patent regime where all the gains achieved by the Indian pharmaceutical industry are dissipated and large sections of Indians and people in other parts of the world are left at the mercy of giant multinational pharmaceutical companies.

6. Conclusion

After the TRIPs Agreement came into force some scholars argued that there were sufficient flexibilities under the TRIPs for protecting interest of the generic industries so as to achieve the goal of providing necessary drugs at affordable cost. The flexibilities include freedom to determine the scope of subject matter for product patent protection ^[15], to determine the grounds on which compulsory licence could be issued ^[16], in identifying exceptions to patent ^[17], providing provisions for parallel import ^[18], and protection of test data ^[19], etc. Countries adopted various approaches to implement the TRIPs obligations and tried to protect public interest of providing access to affordable drugs. However these measures were not sufficient for the developing and least developed countries. Probably, Indian representative at the Uruguay round of negotiation could not understand the true consequence of it.

However, soon it was realized that it is difficult to provide access to new and costly drugs to poor inhabitants if TRIPs Agreement is to be followed strictly. Many developing and least developed countries could not even enjoy provisions for compulsory licence due to lack of manufacturing capabilities. These forced countries like Brazil and South Africa ^[20] are completely depended to the mercy of the MNC and other developed countries ^[21].

Moreover, research and development in the pharmaceutical sector is a time consuming process; at least 9 or 13 years may pass until a new drug becomes suitable for the human consumption after it is invented from the a molecule. Such long term research work is not affordable for the developing and least developed countries ^[22].

This leads the developing countries to bring the health care issues into the international attention and demand for amendment of the TRIPs provisions dealing with health care at Doha Round of negotiation. At the Doha Round of negotiation it was agreed that the member of WTO must find an expeditious solution of the problem of developing countries which have no such infrastructure to utilize the compulsory licence provision of the TRIPs agreement ^[23].

In the TRIPS Council, developing countries argued for complete freedom to introduce changes in the patent law to overcome health crisis^[21]. Though this was opposed by the developed countries they were forced to agree for a unanimous declaration on TRIPS Agreement and Public Health, using compromising words in the Doha Round of Negotiations^[22].

As a result of Doha Declaration the WTO extended the period of the obligation of the least developed countries to implement the product patent regime till 2006. Further, an attempt has been made to give a waiver to the predominant domestic supply requirements under Article 31 (f) and the adequate remuneration requirement under Article 31 (h) of the TRIPS Agreement. To convert this as a permanent decision and part of TRIPs obligation, Article 31bis has been drafted as a proposed amendment for incorporating the provisions in the Para 6 of the Doha declaration^[24]. The proposed amendment is left for the acceptance of two third members of WTO.

However, the outcomes of the Doha declaration is not very fruitful, the requisite numbers of members have not assented. The time period for acceptance of the amendment was extended up to 2013. Unfortunately, within the stipulated time requisite numbers of members have not assented the proposed amendment. That leads the international public health issue in the deep trouble.

7. Reference

1. See. Preamble of the Trade-Related aspects of Intellectual Property Rights (TRIPs).
2. See, Article 27 (1) of the TRIPs Agreement.
3. Article 33 determines the term of protection which shall not end before the expiration of a period of twenty years counted from the filing date.
4. Ibid, Article 31 (f) and 31(h).
5. Gopalakrishnan NS. TRIPs Agreement and Public Health: An Overview of International Issues. *Journal of Intellectual Property Rights*, 2008; 13:395-400.
6. Barton JH. TRIPs and the global pharmaceutical market. *Health Affairs*, 2004; 23:146-154.
7. Cullet P. Patents and medicines: the relationship between TRIPs and the human right to health. *International Affairs*, 2003; 1:139-160.
8. Chaudhuri S, Goldberg PK, Jia P. Estimating the effects of global patent protection in pharmaceuticals: A case study of Quinolones in India. *American Economic Review*, 2006; 5:1477-1514.
9. Rajeev Dhavan. GATT-The Final Solution Fraud Twice Confounded, *Lawyers Collective*, 1994, 4-6.
10. Under section 3 of the original Act, 1970 such provisions were enacted and afterwards those provisions underwent the amendments with effect from January 1, 2005.
11. The Patents Act. Section 1970, 83(d).
12. Ibid, Section 83(e).
13. 2013, 6 SSC 1.
14. Section 3 (d) states as followings:
The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process,

machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation. -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

15. Article 27 of the TRIPs used the standards of novelty, inventive step and capable of industrial application to identify inventions for grant of patent. But since these terms are not defined the countries have the freedom to determine the level of inventive step required to satisfy patent protection. This it is felt will help countries to prevent ever greening of patents in the field of pharmaceuticals if the domestic legislation is properly structured. Various amendments introduced in the Indian Patent Act particularly Section 3(d) are considered as one of the approaches to achieve this.
16. Article 31 of the TRIPs gives the freedom.
17. Article 30 identified three steps to determine the limitation and exceptions to patent.
18. Article 6 of the TRIPs makes it clear that 'for the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights.
19. Article 39.3 deals with this, also see, Gopalakrishnan N S and Kadavan Benoy K, *Study on Testdata Protection in India*, Eastern Book Co, Lucknow, 2005, 75-77.
20. South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997.
21. www.sarprn.org.za/ContryPoveryPapers/SouthAfrica/april2002/berger/berger.pdf.
22. Beata Udvari. *The TRIPs Agreement and Access to medicines: who are the main losers?* *Studies in International Economics and Finance*, JATE Press, Szeged, 2011, 157-179.
23. Under paragraph No 6 Doha Round of Negotiations is stated as followings:
We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
24. General Council, Amendment of the TRIPs Agreement, Decision of 6 December, 2005. WT/L/641, dated 8 December 2005 http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm