

**TRIPS AND ITS IMPACT IN INDIAN PHARMACEUTICAL INDUSTRY**

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ABSTRACT

The Uruguay Round (1986 – 1994) was the turning point in the history of Intellectual Property Rights. This round included the Agreement on Intellectual Property Rights under which minimum uniform laws are to be carried out. The Agreement on TRIPs came into force on 1 January 1995 and is to be implemented over a six-year period ending 31 December 2000 for developed countries and over a ten-year period ending 31 December 2004 for developing countries India has always remained committed to the WTO and in every sphere; it has stood by those commitments. Going by such commitments to the WTO, India has amended its Intellectual Property Laws. Apart from meeting WTO obligations India has placed this new regime due to its economic rational. It enables pioneering firms lead time to recoup sunk cost on research and development.^[1] India is ranked as the fastest emerging economy and a major global player in the years to come. The country has the largest scientific and technical human resources among top five countries in the world. India cannot afford to remain in isolation, disregarding the norms of international intellectual property rights convention. A careful consideration is equally essential in the future interest of macro-level development.^[2] TRIPs was one of the most contentious issues in the Uruguay Round of multilateral trade negotiations, which was concluded in 1994 at Marrakesh. As a member of the World Trade Organisation (WTO), and having signed the General Agreement on Tariff and Trade (GATT), India has agreed to comply with all the instruments and annexes of GATT, including Trade Related Aspects of Intellectual Property Rights (TRIPs). Because of WTO, India has to amend its intellectual property laws .India was forced to comply with the TRIPs agreement. After the formation of WTO in 1995, the India being its member has to implement the TRIPs agreement in toto. The commitment under TRIPs agreement compelled India to amend its intellectual property laws. India has implemented the TRIPs by amending its intellectual property laws mainly patent thrice.^[3]

KEYWORDS: The Uruguay Round, Organisation toto.**INTRODUCTION**

In a democratic country, like India, it is not easy to shift the policy against public interest. India was in the difficult situation of protecting people's interest on the one hand and fulfilling the WTO's agreement of TRIPs at the other. A successful patent policy of any developing country is one that strikes a clear balance between protecting the rights of innovators & services at affordable prices to the population. India's patent policy so long has been, infact, protecting the interest of public more than that of the monopoly rights. The question is that whether the amendment to the Indian Patents Act, 1970 has taken advantage of the provisions available under the TRIPs agreement, and look at the exemption, exception and compulsory licensing provisions in Pharmaceuticals.^[4] Intellectual Property rights have generated strong impact on the modern day life. Therefore, the impact of IPR is enormous and on the modern day life. These IPRs were promoted in an ever seen manner by the TRIPs agreement. The TRIPs agreement has mandated its members states to implement the provisions of the agreement in order to promote and

protect IPRs. Members states are asked to provide protection to different IPRs by making necessary adjustments in their existing laws or enacting new laws. India, being a member state to the TRIPs agreement brought changes in its IPRs laws. The preceding fifteen years have seen many new IPR enactments. With globalization, liberalization and privatization, the ambit of IPR has grown multifold and its importance has amplified, having a profound impact on commercial interests.^[5]

IMPACT ON EXISTING LEGAL FRAMEWORK

The agreement on TRIPs prescribes norms and standards in respect of copy rights, Trade Marks, Industrial Design, Geographical Indications, patents etc. It was the impact of the TRIPs on India that India brought changes in its IPRs laws. The preceding fifteen years have seen many new IPR enactments. With globalization, liberalization and privatization, the ambit of IPR has grown multifold and its importance has amplified, having a profound impact on commercial interests.^[6] IPR have generated strong impact on the modern day life. These IPRs were

members' states to implement the provisions of the agreement in order to promote and protect the IPRs. Members' states have been asked to provide protection to different IPRs by making necessary adjustments in their existing laws or by enacting new laws. In order to fulfill such obligations, member's states have amended their laws or have brought up new legislations. India being a member state to the TRIPs agreement brought changes in its IP Laws in fulfillment of its obligations under the agreement⁸. The TRIPs agreement brought changes in the existing framework on the IPRs, which had impact on the entire world. The TRIPs agreement unifies and rationalizes all the existing international agreements on different areas of IPRs. It provides for the blue print for the protection of all the different forms of IPRs.^[7]

IMPACT ON COPYRIGHT LAW

The Copyright Act, 1957^[8] has been amended to include computer program as literary work as required by Article 10 of the TRIPs Agreement.

IMPACT ON TRADE MARK LAW

The Trade and Merchandise marks Act was passed in the year 1958. Since then it has been amended several times. Moreover in view of developments in trading and commercial practices, need for simplification and harmonization of trade mark management system, it was necessary to bring out a comprehensive legislation on the subject. Accordingly the Trade marks Act 1999 was passed.^[9] The Trade and Merchandise Marks Act, 1958¹³ has been replaced with the Trade Marks Act, 1999^[10] which includes protection of well-known marks, certification marks and collective marks. It now provides for registration of trade mark for services as well. This is in compliance with Article 16 of the TRIPs Agreement.

IMPACT ON INDIAN PATENT LAW

Changes into the Indian patent laws have been necessitated by India's accession to the world Trade Organisation, as one of the founder members, in January 1995. The Agreement helps India to introduce the changes at three different stages. To satisfy the first set of obligations, the Patent (Amendment) Act, 1999 was enacted after India lost the dispute with USA in WTO¹⁶. In pursuance of the TRIPs agreement negotiated during the Uruguay Round, the Patent Act, 1970 was first amended in March 1999 to introduce the transitional mailbox facility from 1 January 1995 to receive and hold product patent applications in the field of pharmaceutical, agriculture and chemicals until 1 January 2005. The second amendment to the act was made in June 2002 to meet obligations under the TRIPs agreement relating to modifications in the provisions concerning among other issues, term of patent protection, rights of patentee and Compulsory licensing. This included changes in patentable inventions, grant of new rights, extension of the term of protection, provision for reversal of burden of proof in case of process patent infringement and conditions for compulsory licenses.^[11]

The third amendment required to meet obligations under TRIPs agreement introduce product patent protection in all fields of technology. The Patent (Amendment) Act, 2005 make the Indian patent Act fully compatible.^[12] Other recent legislations include the Geographical Indications of Goods (Registration and Protection) Act, 1999, The Designs Act²⁰, 2000 and The Protection of Plant Varieties and Farmers' Rights Act, 2001. Online International Interdisciplinary Research Journal, {Bi-Monthly}, ISSN2249-9598, Volume-III,

IMPACT ON FOOD SECTOR

The food sector in the country will also have to face new challenges in the new patent regime. Different processes and products will become patentable. Therefore, there is need to document all the traditional processes as well as products with a view to reduce the number of controversies over claims for patent rights.^[13] One of the serious implications of the treaty is that when the industrial countries could strengthen their control over global agriculture by keeping their food security intact, developing countries are called upon to dismantle their food security system.^[14]

INDIAN CONSUMERS

Fears have been raised in several quarters, including consumers and industry on the possible impact on them, particularly the pharmaceuticals. Consumer fear the product patent may lead to price hike, making medicines unaffordable to the poor. However, government has clarified that the law is prospective and covers an insignificant percentage of medicines.^[15] With the introduction of product patents, the inventor will try to maximize his profits and therefore price of drug higher than if there were no patents. Correspondingly, the consumption of the drug will be lower. This represents an indirect welfare loss to Indian consumers because of higher prices associated with introducing product patents. In addition to this are the direct costs of administering the patent system and enforcing patentee rights through the courts in case there are infringing disputes.^[16] Thus patented products would be sold at monopolistic prices devoid of any competition resulting in still high price for the consumers.

IMPACT ON INNOVATIONS

Many countries of the world, including India, The implementation of TRIPs worldwide represents a step in the opposite direction have achieved self-sufficiency in knowledge intensive sectors by allowing for a loosely defined intellectual property rights (IPR) regime and its impact on the production and innovative capacity of developing countries in knowledge intensive sectors is not at all clear. Taking India as representative of a technologically advanced developing country, and the biotech based segment of the pharmaceutical industry as an example of an emerging knowledge intensive sector, we examine the possible impact of TRIPs on the incentives and ability to innovate. The conclusion is that TRIPs is not likely to have a significant impact on

incentives for innovation creation in the biotech segment.^[17] The strengthening of the IPR regime world wide as part of the TRIPs agreement might adversely affect the technological activity in the developing countries by choking the spill overs of knowledge from industrialized countries to developing countries.²⁶ The provision of product patent on many industrial products might affect adversely the process of innovative activities in the developing countries enterprises. It is true that the development of many products is beyond the capability of most developing countries in view of huge resources involved.^[18] The TRIPs agreement was born to protect the interests of the industry, trade and services. Whereas the higher standard of protection is relatively advantageous for the developed economies which are ahead of the developing countries in terms of innovations and research and development among developing countries it is less advantageous for those where the domestic industry is not very strong to invest in R and D to pursue new product development or process development skills.^[19] The increase in the period of the patent protection and a stricter enforcement of patenting rules and regulations would increase the cost of technology acquisition for Indian industry.^[20] Impact of TRIPs on Indian Pharmaceutical Sector The most adverse impact of the TRIPs Agreement is going to be on the health sector of the developing countries. The role of patent in maintaining monopoly and restrictive practices in Pharmaceutical industries was identified by the UN Agency like UNCTAD in the 70's itself. It was this realisation which prompted the developed and developing countries to deny or limit Pharmaceutical patents till recently. India is a glaring example in this regard. After denying product patent under the 1970 Act, the Indian domestic Pharmaceutical industry became an export surplus industry. The 40000 crore domestic industry fears that increased competition, import surges and MNCs would lead to a non level playing field. So far, the pharmaceutical industry was covered only by process patent, which allowed them to reverse engineer drugs and market them at very low prices. Now with a product patent in place this will no longer be possible.^[21] The post Patent Regime opens up vast opportunities for Indian pharmaceutical firms. India will emerge as a leading country in the world pharmaceutical market. Presently, many Indian companies have begun international operations as well as acquisitions which will make a significant contribution to their turn over. Export will be the major thrust of the industry, in the post Product Patent regime.^[22]

IMPLICATIONS FOR DRUGS PRICES

A strong Patent system under TRIPs will establish a sort of monopoly. Drugs prices in India are very low when compared to t A product patent of 20 years in medicines under the TRIPs Agreement will give rise to patent monopoly. In condition of monopoly, a high price can be charged, as these prices have no considerations with the buying capacity of the consumers in developing countries like India, the countries where product patent is

recognized. The fear that prices of medicines will spiral is unfounded. 97% of all drugs manufactured in India are off patent, and so will remain unaffected. these cover all the life savings drugs, as well as medicines of daily use for common ailments. In the patented drug also, in most cases there always alternatives available.^[23]

IMPACT ON AVAILABILITY OF PHARMACEUTICAL PRODUCTS

In addition to high prices, the lack of availability of essential drugs will be affected. The TRIPs Agreement does not require a patentee to manufacture an invention in India. Under TRIPs, patents be shall available and patents rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. Before enactment of the Patents Act, 1970, the Colonial patents and Designs Act, 1911 permitted foreign countries to block India's access to the latest antibiotics and to critical therapeutic discoveries. Between 1947-1957, 90% of drugs and pharmaceutical patents in India were held by foreign citizen and less than 1% were commercially exploited in India. The three amendments to the Indian Patents Act were made alongside intense debates which emphasized that with the rights of the patent holders strengthened under TRIPs, there is an urgent need to balance this situation with more effective instruments so as to ensure that the public interest issues, as for example, access to medicines at affordable prices are also addressed. The global community took a major step towards bringing about a balance through the 2001 Doha Declaration on TRIPs Agreement and Public Health. While the third amendment of the Indian Patents Act takes steps to address some of the more difficult issues in TRIPs, there remains a need to revisit the key provisions of the Patents Act keeping in view the imperatives of access to medicines.^[24]

IMPACT ON RESEARCH AND DEVELOPMENT

In the field of R&D, with no Indian pharmaceutical company being equipped to take a potential drug from the investigational stage to the stage of final market launch, collaboration with multinational corporations is the norm, resulting in biases in the choice of therapeutic areas towards lifestyle-related diseases³⁴, like malaria or TB etc. These diseases kill millions of people each year in developing countries like India. The medicines used today were invented about 30 years ago. The change in patent laws may encourage many firms in India to undertake more research for inventing more drugs rather than continuing to those drugs once invented by developed countries in the past.^[25] Indian industry has never seriously considered in house research and development or indigenously developed technology as a source of new technologies. It has depended mostly on imports to provide technologies for new products and processes. However in the changed environment, the benefits that would accrue to companies that invest in R& D capabilities would be quite substantial. Strong patent protection would enable Indian firms to exploit

not just but global market as well.^[26] The development of new drugs is an extremely expensive exercise since the entire cost of developing a new drug and bringing it into the market has to be borne by the firm developing it. It is estimated that it takes twelve years and about 200 to 300 million dollars for a US firm to develop a new drug and introduce it into the market.^[27] Process research would be severely affected as there would be no immediate use of process technologies for the new drugs in the product patent regime. Research and development expenditure as percentage of pharmaceutical sales is as low as 1.8% in India when compared to USA where it is 16%. India companies neither have adequate funds nor infrastructure to conduct basic research. The majority of patent filing are from residents of industrialized countries and there is strong relationship between the volume of patent filings and level of GDP and investment in research and development. China, Japan and U.S.A. are the top three ranked countries in terms of GDP and R& D. In 2007, about 59.2% of world patent filing are filed in these three countries.^[28] Indian Pharmaceutical sector has moved into post-product patent regime, putting end to the long era of launching and manufacturing re-engineered generic drugs in India. The transitional period to reintroduce product patent regime has elapsed but the transitional period for transformation of domestic Pharmaceutical industry to face the challenges in post-product patent regime is still underway, it fails to protect the public from the aggressive monopolies that patents confer on the right holders.^[29] Thus the implication of the TRIPs Agreement for the Indian Pharmaceutical industry is going to be enormous. The TRIPs Agreement will affect drug prices, their availability, and competition. Research and Development are very existence of the Pharmaceutical industry in India. The ultimate result would be higher prices for the consumers in India. Drugs and medicines are essential products which should be made available at affordable prices, especially in a poor and developing country like India, where as it is, decent health care is out of reach of majority of population. A uniform patent protection in vital sector like Pharmaceuticals as applied in developed and industrialized countries with a very high level of economic development will have enormous economic and social costs in countries like India and will further aggravate the suffering of the people. Once the country accepts patenting products, administering prices through the existing government machinery will be difficulty, as there are no comparable standards. Monopoly MNCs claiming high prices on the pretext of recouping their huge outlay in R&D and long clinical trials cannot be effectively countered. There is no doubt that India is considered as one of the largest pharmaceutical industry in the world. Nearly 90% of the domestic demand for pharmaceutical in India is generally satisfied through indigenous protection. At the same time, imports are limited to very few drugs, precisely life saving drug. One of the important consequences had been seen in the rise of the prices of drugs. Of course there is applicable only to those medicines which have been invented only after

the new product laws came into operation i.e. since 2005. So, it is expected that it would affect only a small proportion of the drugs available in India. The TRIPs convention is not going to improve the incentives for investment in the finding of treatment for new diseases. Therefore, the impact of TRIPs will be restricted to an elimination of the production of patented products. It will not have a deleterious or a positive impact on their levels of inventive activity. Even more importantly, TRIPs is not likely to create any incentive to increase technological knowledge or create innovations other than that provided by the national system of innovation. TRIPs is not likely to increase incentives for multinational Pharmaceutical firms to invest in, or to collaborate with research and production unities based in developing countries. By putting a universal minimum standard, India which till now was supporting the developing countries by offering the cheapest generic version of the medicines under its process patent regime would not be in position to export these medicines after adopting 'product patent regime' under the TRIPs. It is among the few Pharmaceutical industries from the developing countries, posing the capacity to meet out such unforeseen challenge by taking recourse of flexibilities offering under the TRIPs and hence ensuring an access to the medicine to the poor peoples. A country having agreed to be a party to the TRIPs and to WTO regime is bound to legislate in harmony with the international agreements phasing out the pre-existing IP legislations. These new laws not only call for the change in the existing IP laws but also in many cases take up the need for setting up new and modernized institutions. Many Intellectual Property laws are at times just rushed through without giving due weightage to the long-term implications of the new provisions. To utilize the WTO benefits, India has complied with the TRIPs, agreement, otherwise India has to face the problem. Significant impact has been felt in India since the establishment of the WTO. In the wake of the things, several aspects both beneficial and adverse are discussed here. Efforts have been made to find out what exactly has happened in India as a whole and especially to the most important sector, namely, the pharmaceutical sector. The WTO regime has created excellent opportunities for the developing countries to increase their exports. However, the developing countries have to improve the quality of products upon their international standards set up by the WTO organizations.

CONCLUSION AND RECOMMENDATIONS

At last, I want to say that it will take years to truly evaluate the full impact of India's new patent regime on the Indian industries. It is clear that it will change, and has already changed, the businesses of the indigenous generic Pharmaceutical industry. With regards to foreign investment in Pharmaceutical research and development, however, it is less clear whether the recent growth can be primarily attributed to the new patent regime, or whether it is more the result of India's low-cost, highly skilled scientific human resources. Indeed, many multinational

Pharmaceutical companies (MNCs) have not been entirely satisfied with some of the new laws and feel that several of the provisions still require further development. The new patent incentives in India are likely to be at least a significant factor in spurring foreign investment. If India did not respect Pharmaceutical product patents at all and if they were not even attempting to protect intellectual property, it would be much less likely that MNCs would be investing in India to the degree they have been.

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