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IMPACT OF TRIPS AGREEMENT ON THE PHARMACEUTICAL SECTOR

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INTRODUCTION

Indian Patent regime has undergone major changes with TRIPs Agreement of WTO. New product patent regime replaced the age-old process patent regime in India. This required certain policy changes as part of the legal framework. Indian Patents Act (1970) was amended three times in 1999, 2002 and 2005. There were debates on complying TRIPs agreement, both in favour of and against the provisions. While the major pharmaceuticals companies have argued that this compliance would stimulate transfer of technology, expand Research and Development and encourage foreign direct investment (FDI) in this sector, certain civil society groups argued against the compliance as it would bring ill effects such as inaccessibility of medicines, impact on prices and survival problems to small and marginal pharma units of domestic industry1. It was believed by the government that the entry of Multinational Companies would push FDI and provide employment opportunities to Indian Youth. In addition, the active engagement of multinationals in Research and Development would create a viable clinical trials (Field Trials) sector that augments inventions and improvements. There are also optimistic views that Research and Development sponsored by big giants would facilitate technology transfer. In view of the above perceptions, certain issues like, impact of TRIPs agreement on policy framework, prices, generic medicines, availability and accessibility of medicines, Research and Development, growth of clinical trials sector, emergence of big giants in the pharma industry and influences on small and medium scale pharma units are to be studied.

IMPACT ON PRICES

Drug prices are monitored in India by the Drugs Prices Control Order (DPCO) of 1959 to prevent unilateral increases in prices. It also prevents monopolistic practices by the pharma companies in India. However, over a period of time, many medicines were kept out of control from the purview of this order. With the inclusion of Trait Value (royalty for a patent), the prices may go up for several times. As long as India had a process patent regime, the prices of medicines were at a lower level. The Drug prices control order used to prevent monopoly tendencies and regulate the prices. However, with the formulation of New Drug Policy (2002), the control of the government is highly restricted to only certain drugs. This New Drug Policy brought 35 drugs out from its jurisdiction based on criteria of turnover and others. Some of the drugs which were hitherto controlled by Monopoly Restrictive Trade Practices (MRTP) Act are also brought out from its purview. The prices of vitamins, aspirin and ciprofloxacin were also decontrolled. However, certain bulk drugs remained on the controlled list such as the anti TB drug Rifampicin, Betamethazone and Amikacin Sulphate. Companies that benefit from the developments are Ranbaxy, Pfizer and Glaxo. But other companies like Novartis, Knoll and German Remedies continue to remain under price control.

In other words, there has been a progressive decline in the number of drugs under price control from 347 in 1977 to below 50 in recent times. Deregulation of drug prices has contributed to increasing prices. Many vaccines and medicines related to anemia, cancer, oral rehydration salts, life-saving medicines, hypertension, diabetes, coronary artery disease, tuberculosis, malaria and many others are out of the purview of the price control order jurisdiction. As a result, there were demands for price control. The Draft pharmaceutical policy 2006 in Part A and Part B continued to identify 354 essential medicines for price regulation. Accordingly, a Committee is constituted by the Union cabinet with 14 members out of which 11 are from the Pharma industry, on price control. The industry argued that if price

regulation is implemented units will close down, spurious drugs will increase exports and R & D will decline and the country will face drug scarcities[2].

In fact, there has been a worldwide demand for cheaper prices and generic drug versions for poor countries[3]. Hundreds of people living with HIV from different parts of Asia particularly Indians reached to the office of the United Nations Special Reporter on Right to Health in New Delhi protesting against the adverse impact of trade agreements on their lives. This demonstration was organized by "Asia Pacific Network of Positive People"[4] The provisions of the TRIPs agreement and their impact on public health were widely debated. As a solution to this problem, Compulsory Licensing was facilitated to other pharma units to manufacture patented drugs by respective governments. If a dispute in this regard arises, the WTO settles it in an amicable manner[5].

Many countries have been utilizing the provisions of TRIPs agreement to issue Compulsory Licenses to Domestic Companies for the production of patented drugs of other companies. For example, with the outbreak of Anthrax scare, already Canada decided to break the patent and licensed Apotex to produce ciprofloxacin and doxycycline. Originally, the drug was patented by Germany's Bayer Company. The US, and Switzerland which are homes to the highest pharma companies along with Germany and other countries oppose this violation. However, the less developed countries led by India and Brazil insist upon their right to Compulsory Licensing.

IMPACT ON AVAILABILITY AND ACCESSIBILITY OF MEDICINES

The Indian Patents Act (1970) promoted the domestic pharmaceutical sector very rapidly and this is resulting in the production of generic medicines at a large scale. However, with draft Patent law amended in 1999, 2002 and 2005, the availability and accessibility of these medicines became scarce due to the process patent system replaced by the product patent system. As a result, the government invoked Section 84 C, Section 92 and Section 92 A to issue compulsory licenses on patented drugs to domestic enterprises only to meet the market demands. Due to these measures, the pharma industry continued to supply medicines as per the requirements. Thus these sections of Indian Patent Act encouraged the production of medicines from non-patented pharma units[6].

During the initial years of TRIPs agreement, it was apprehended that the availability of new drugs from indigenous sources would be totally out of question. It was imagined that dependence upon on imports would go up as it has been happening in some Latin American Countries, Canada and Italy, who had changed their patent laws and India might also face similar phenomenon in the coming future[7].

But these apprehensions were proved as un-substantiate and India continues to produce medicines in adequate quantity and quality with relatively cheaper prices to make the industry more accessible to people and medicines available to people. The Report of the Task Force on strategy for increasing Exports for pharmaceutical products of the Ministry of Commerce and Industry stated. In the context of pharmaceutical exports, because as shown by the examples of Thailand and South Africa, there are situations when patented pharmaceuticals became too expensive for developing countries and consequently they import cheaper copies of these drugs. Indian companies such as Cipla and Aurobindo have been at the forefront of exporting drugs in these situations. It is an acknowledged fact that India has requisite manufacturing capacity, internationally approved quality and regulatory infrastructure in several companies. Diseases like AIDS etc. are national emergencies. Since India is one of the countries which has significant manufacturing capacity as well as the past record of providing for such situations, an important opportunity, as well as special responsibility emerges. For example, India has offered various ARVS (Antiretroviral) such as NRTIs, NNRTIs, PLs at a breathless speed and at affordable price. Various international organizations and governments which did not dream of providing medicine except for campaigning prevention could benefit from India and are able to provide relief to millions in Africa etc. A simple look at WHO approved ARVs or PEPFAR approved ARVs clearly illustrates the undeniable contribution of India in controlling AIDS internationally at an affordable cost. Indian Organizations like Aurobindo have been felicitated at White House and UN for such contributions.[8]"

In fact, there were serious efforts at different levels to make the medicines in general and life saving

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drugs in particular, more accessible and available to people. In the WTO itself, the African countries vehemently appealed for import of cheap copies of the patented drugs to fight killer diseases such as AIDS, Malaria and Tuberculosis. A body of 146 diplomats met in Geneva for 6 days under WTO guidance and clinched a deal on cheaper drugs for poor nations.

The WTO General Council formally approved this agreement. The Director General of WTO, Supachai Panitchpakidi described this agreement reached on 31st August 2003 as "historic agreement for the WTO." This agreement allows the poorer countries to make full use of the flexibilities in the WTO's Intellectual Property rules in order to deal with the diseases that ravage their people".[9]

In India, the Industries Ministry prepared a discussion paper emphasizing the need for capping certain limits on Foreign Direct Investment (FDI) in the Pharma Sector and widening the options for introducing compulsory Licensing.[10] Subsequently, the Central Cabinet approved the issuance of compulsory licenses for the production of various life saving medicines.

Though the government is initiating many measures for the production of medicines, Price Regulation and price control of essential medicines become a point of debate. Pharmaceutical policies of successive governments do not particularly emphasize on price control. As a result, the largest numbers of people are suffering from inadequate access to essential medicines. Price regulation is in no way incompatible with the TRIPs Agreement. In fact, the flexibilities under the TRIPs agreement of WTO can be properly utilized to protect Public Health[11].

Thus, the availability and accessibility of essential medicines depend on many issues such as the production of drugs, Research and Development, Clinical trials, regulation of new drug approvals, drug quality, drug promotion, availability of unbiased drug information, removal of unsafe and irrational drugs and such others. In the TRIPs Agreement of WTO, certain flexibilities are provided to issue Compulsory Licensing. Hence the government needs to motivate the Pharma industry to engage in production. The government also needed to regulate price anomalies for the same molecules between the Pharma Companies.

IMPACT ON RESEARCH AND DEVELOPMENT

Indian Pharmaceutical Industry relying on a process patent system before 1995 and was not concentrating on Research and Development. The Intellectual Property System under TRIPs after 1995 posed a challenge of its survival to Indian Pharma. Certain Pharma giants like Dr. Reddy Labs led the industry in reorienting towards Research and Development and stood as a model enterprise. Drug Discovery Programmes were initiated and many awareness programmes on product patents were undertaken. This is followed by other units that have set up Research facilities of global standard. According to the Task Force Report of Ministry of Industry, out 596 Indian Pharmaceutical Companies, 151 Companies invested in Research and Development Activities during the first decade of 21st Century with an outlay of 2,973.20 Crores of Rupees. Among the pharma giants that invested in Research and Development (R&D) include, Ranbaxy Laboratories, Dr. Reddy Laboratories, Sun Pharmaceuticals, Cipla Ltd., Cadila Health Care Ltd., Lupin Ltd., Wockhardt Ltd., Torrent Pharmaceuticals Limited, Panacea Biotech Limited, Aurobindo Pharma Ltd., Matrix Laboratories Ltd., Orchid Chemicals and Pharmaceuticals Ltd, USV Ltd., Ind-Swift Laboratories Ltd., Biocon Ltd., Glenmark Pharmaceuticals Ltd., Strides Arcolab Ltd. and so on[12]. In spite of huge investments in Research and Development, companies are worried about the Data Protection which is necessary to claim supremacy over other units in claiming patents. Data generated by a company in the course of its research or clinical trials is not subjected to unfair commercial use. In fact, Article 39.3 of the TRIPs agreement requires the countries to enact data exclusivity laws. In other words, the TRIPs agreement makes the member countries to protect the data against unfair commercial use. Article 39 (3) of the TRIPs agreement recommends a five year period for data exclusivity. Indian Patent Law has section 107(A) that provides for Research Exemption. This is in accordance with Article 30 of TRIPs agreement which provides its member nations to include exemptions to the Exclusive rights conferred through patents. The condition for this Article 30 is that exemptions do not unreasonably conflict with a normal exploitation of patents and do not unreasonably prejudice the legitimate interests of the patent owners.

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There is also a lot of criticism against this position of W.T.O. The US pharmaceutical research companies were concerned that a deal to allow countries to import generic drugs would be abused by generics manufacturers and could also lead to drugs being smuggled back into rich countries. Though the production of generic medicines is a humanitarian issue, the pharma companies my subvert the patents of other companies for their advantage. However, the core group of negotiations among W.T.O. the ministerial conference, including the U.S., Brazil, India, Kenya and South Africa finally agreed to balance research interests and generic drug manufacturing[13].

The impact of TRIPs Agreement of W.T.O. is particularly visible in the Indian Pharma Industry. The Post 1995 TRIPs regime has been a spurt of allocations to Research and Development in many pharma giants. Further, Article 30, 39 (3) and others are utilized to use patented data for Research purposes. But, contrary to the provisions of TRIPs, India has not taken any significant initiative in matters of data protection and data exclusivity.

The research in private and public sectors was concentrated in developing process technologies in pre-1995 period in India. In the present WTO framework of TRIPs after 1995, the research and development have to focus on product technologies. Moreover, Indian pharma industries have to acquire new infrastructure and technologies to carry on Research and Development. In these circumstances, many of the units may not embark on various programmes of basic research. Many of the domestic companies leave alone a few; will never be able to match with Multinational Companies in Undertaking Research and Development to claim product patents. Only certain pharma companies can engage in a substantial manner in Research and Development.

In the Research & Development front, India plays another crucial role in stopping multinational companies from making false claims on Traditional knowledge sources. Some of the Indian Scientists have noticed a new trend of "bio-prospecting" of natural remedies by MNCs abroad. It is found that around 5000 patents are issued on medicinal plants and traditional systems. To counter this trend, Indian Scientists made researches on Traditional Indian Systems. Dr. Vinod Kumar Gupta who heads the Traditional Knowledge Digital Library prepared a database of around 2,00,000 treatments with 200 researchers for eight years by translating all the ancient Indian Texts. The work of this project is presently used by the European Patent Office to check against bioprospecting. Many of the Indian medicinal plants such as Brahmi (Bacopa monnieri), aloe vera, neem, turmeric and so on. After battling for 10 years, the patent on neem was revoked. Likewise, Indian Yoga, Ayurveda, Unani, Siddha and so on were patented by European and American Scientists. Many Indian Scientists and concerned citizens took up research to make these illogical patents lifted[14].

As a result of these constant efforts by Indian Scientists, the World Intellectual Property Organization (WIPO) decided that too science journals brought out by[15] the Council of Scientific and Industrial Research (CSIR) namely Indian Journal of Traditional Knowledge (IJTK) and Medicinal and Aromatic Plant Abstract (MAPA) are to be made mandatory reference literature. Patent offices across the world must compulsorily refer these two journals before granting any patent. This would effectively block any misappropriation of India's traditional knowledge. The scientists and departments in India need not have to spend enormous amounts to challenge patents granted abroad on products and process based on Indian knowledge already available. In fact, CSIR had to mount a costly litigation a few years ago before it could make the US Patent Office revoke a patent it had granted for use of turmeric for healing wounds. Under the Patent Cooperation Treaty (PCT), the WIPO had issued a list of 85 Journals, including 2 from India. These Journals are included in the test of minimum documentation.[19]

There are also other few points on the role of research and development in Intellectual Property regime that indicate significant increases in the rates of returns of MNCs and their affiliates compared to the local or domestic Industries. In the pharmaceutical sector, an analysis of post 1995 scenario reveals that profits of domestic companies are in sharp decline while those for the American MNCs and their affiliates operating in the Indian market are rising steeply. The United Nations Conference on Trade and Development (UNCTAD) report calls for stronger measures to protect domestic sectors against the undue domination of large companies particularly in high profit sectors

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such as Pharmaceuticals, media and ICT. The report identifies Patents as an instrument of unfair market power across markets and calls for protection for domestic industry[16].

SMALL AND MEDIUM SCALE SECTOR:

The WTO agreement on TRIPs has shown a serious impact on small and medium scale industrial units in the pharma sector. India was a home for many medium and small scale pharma units. But these units witnessed crisis due to competition from multinational companies, inadequate allocations for Research and Development and ever increasing investment costs. There was hardly any possibility to take up new products. Even for the existing products, the newly established patent regime created difficulties to market their products. As the existing infrastructure become redundant due to new technology, many of the small and medium scale units are either closed down or liquidated in the competition environment. Some of the units have become auxiliary units for making supplementary products of the multinational companies.

The TRIPs regime of the WTO enabled the big pharma companies to spend huge investment in Research and Development and clinical trials. In fact, many of the big pharma companies are competing with each other in higher allocations for Research and Development and successfully launching new patents with existing legal framework. On the other hand, the companies with meager or dismal allocations for clinical trials and Research and Development have to close down their units for want of new technology, skilled manpower, Research equipment and other tools. This has also resulted in large scale unemployment in pharma related sectors.

Taking advantage of this adverse situation, the multinational companies also resort to forceful mergers and acquisitions. There are numerous reasons for these mergers and acquisitions. These included expanding the product range for building a good product portfolio, gaining access to approved facilities outside India, access to distribution channels and gaining market presence, pressure by governmental agencies, insurance companies, various countries to reduce the cost of medicines and so on.

CLINICAL TRIALS

With the entry into new TRI's regime of WTO, certain ancillary sectors like clinical trials sector have gained momentum. With the protection of product patent system and formulation of legislation pertaining to Trade Related Intellectual Property Rights, many companies in general and Multinational Companies, in particular, has been engaging in Research and Development (R&D). Research and Development gravitate to countries with large domestic markets for the resulting products[17]. India has an enthusiastic population to participate in clinical trials. This offer an opportunity to capture the global R&D market for clinical trials, data management, testing etc., According to the Report of the Task Force, on "Strategy for increasing Experts of pharmaceutical products", India is slowly picking up in clinical trials sector. The costs of clinical trials in India are around one-tenth of their levels in the USA. Hence major drug industries including Pfizer, GSK, Eli hill, Astra Zeneca and Novartis are spending huge amounts in the clinical trials sector as part of the Research and Development Programme. India is also experiencing a growing number of collaborations between Indian and Foreign firms involving the biotechnology sector. This is part of Collaborative Research and Development including drug discovery and clinical trials[18].

For successfully undertaking clinical trials, the country needs to employ a greater number of proficient Institutional Review Boards (I&RB), strict laws and other regulations. The clinical trials also require proper approvals from the Government. These are also certain outsourcing agencies to undertake certain chemical testing as part of the clinical trials.

India is currently following certain International guidelines on clinical trials developed by International Conference on the Harmonization of Technical Requirements for Registration of Pharmaceuticals for human use (ICH) and the principles contained in the Declaration of Helsinki on the "Ethical Principles for Medical Research Involving Human Subjects" of 2004. Clinical Trials sector also use good Laboratory practice (GLP) guidelines. These guidelines are used as Good Clinical Practice (GLP) has already been included in Schedule 4 of the Drugs and Cosmetics Act, 1940.

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As part of a safer and more transparent clinical trials regime, fourteen notifications governing various aspects pertaining to a clinical trial were released during the year 2014. Later these notifications are further developed to evolve a strict code of regulations for clinical trials.

Thus, the clinical trial industry is developed as an offshoot of the pharma industry, the multinational companies are competing with each other in acquiring patents and resorting to unethical means in the process of clinical trials. There are allegations that innocent people are victimized to undergo clinical trials. In the process, there are certain reported deaths with negative effects. Many innocent people from remote villages are chosen for making clinical trials by pharma companies and resorting to unethical means.[23]

The WTO agreement on Trade Related Intellectual Property Rights (TRIPs) facilitated the developed of the pharma sector. This sector, in turn, contributed to the development of other auxiliary sectors like the clinical trials sector. But this sector is alleged to have been following certain means which are detrimental to the lives of innocent people[19].

IMPACT ON GENERIC MEDICINES

Indian Pharmaceutical Industry has an important component known as Generic Drugs Industry. Generic Drugs are often referred to as unbranded formulations. According to the Report of the Task Force on "Strategy for increasing Exports of Pharmaceutical Products (2008)," Generic drugs are, "copies of off-patent brand name drugs that come in the same dosage, safety, strength and quality and for the same intended use. These drugs are then sold under their commercial names as both over the counter and prescription forms[20]."

The Indian Patent Act (1970) is amended for three times in 1999, 2002 and 2005 and Section 47(3) and 107(A) of the Act are invoked to encourage generic drug industry. The amended section 107 A(a) states that any act of making, constructing, using, selling or importing a patented invention solely for uses related to the development and submission of information does not amount to infringement of a patent. This exemption is specially used by generic manufacturers to prepare generic version in advance of the patent on expiry.

The sections related to compulsory discussing under Section 92A of the Indian Act deals with compulsory licensing of pharmaceuticals for export purposes. This facilitates the Indian Industry to continue supplying cheaper generic versions of patented drugs to Less Developed Countries. Article 30 and Article 31 of the WTO agreement on Trade Related Intellectual Property Rights prescribe the procedure for obtaining Compulsory Licensing that facilitates the existence of generic drug industry. However, previously such procedure was not so cumbersome but TRIPs agreement makes it a complex process. With the process patent regime prevailing in India till 1995, India became a champion with wide ranging exports to other countries in low-cost medicines[21].

The Indian generic pharmaceutical industry has earned global accolades with reliable and cheap generic versions of exorbitantly priced medicines made by multinational pharmaceutical companies. However, the United States Trade Representative objected to its counterfeit pharmaceuticals shipped in the name of generic versions. The US government in its annual report sought to negotiate with Indian Officials on issues of strengthening patent laws[22]. In fact, during the year 2013, Ranbaxy (one of the pharma giants in India that makes a long list of generic medicines from antiretroviral drugs to treat HIV/AIDS to commonly used antibiotics) pleaded guilty of seven felonies relating to drug manufacturing fraud. There are shortcomings in drug regulation. In fact, the Rajya Sabha Standing Committee on Health and Family Welfare lambasted the functioning of the Central Drugs Standard Control Organization (CDSCO) and apprehended the “collusive nexus between drug manufacturers, some functionaries of CDSCO and some medical experts[23].”

Thus, the WTO agreement on Trade Related Intellectual Property Rights (TRIPs) influenced the functioning of Indian Patent Laws (1970) with amendments carried out in 1999, 2002 and 2005. These amendments also facilitated the issuance of compulsory licenses and based on these licenses only generic pharma units are functional. Further, Indian generic medicines should comply with the provisions of data protection to make the drugs more standard. Hence, Drug standard control mechanisms are to be strengthened.

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