Journal of Intellectual Property Rights
Vol 22, September 2017, pp 257-265

Impact of TRIPS on Providing Easy Access to Affordable Medicines in India

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Received: 7 March 2017; revised: 01 November 2017

Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement affected on 1st January 1995 have provided minimum standards for protecting nearly all forms of intellectual property. Product patents were introduced in pharmaceuticals sector in the amended Indian Patent Act (1970) to make it TRIPS compliant. Many eminent IP experts from industry, academia, policy makers, IP practitioners, government officials and regulatory personnel had expressed concern about increase in drug prices, discouragement in R&D, limited manufacturing of drugs and restriction of competition that may impact the access to drugs and new technologies. To curtail the possible adverse impact of patents on access to medicines, flexibilities have been provided in the TRIPS Agreement. These include certain provisions of Indian Patent Act such as compulsory licensing (Section 84), restriction on grant of patent for new use of a known substance as well as for new forms unless they exhibit significant efficacy (Section 3d) and provision of two –tier patent opposition i.e pre-grant and post-grant opposition [(Section 25 (1) and 25 (2)]. Implementation of these provisions has improved access to drugs to some extent in the post-TRIPS era. There are certain regulations concerning interests of the public with which the Government also controls the drug price and the access of drugs to the public. Drug Price Control Order (DPCO) controls price of the drugs in India. The Government has also raised the ambit of DPCO to include all the drugs in the National List of Essential Medicines (NLEM) including the combination drug where one or more drugs fall under NLEM. The procedure for calculating the ceiling price of the drugs has been changed from a cost based approach to a market based approach. Further, an external reference pricing system has been suggested by the National Pharmaceutical Pricing Authority (NPPA) to negotiate the prices of patented medicines so that availability of drugs improves. Keeping several factors into consideration that exerts influence on the drug prices that in turn have a direct effect on the access to medicine to the Indian public, this article mainly discusses the impact of TRIPS on the specific sections of the Indian Patent Act based on flexibilities provided by TRIPS to the developing countries. Contribution of the pharmaceutical industry, the Indian Government, research-based multinational drug companies, medical professionals, drug research policy, drug production, drug pricing on access to medicines is also discussed.

Keywords: TRIPS, WHO, DPCO, patent, generic drug, compulsory license, drug, pharmaceutical company

According to World Health Organization (WHO) estimates, one third of the world's inhabitants including nearly half of the poorest African and Asian countries are still short of essential drugs. The reason could be many, including economic, financial, country specific intellectual property rights (IPR) legislations, progress in drug development and means of providing healthcare deliverables among various countries.[1] One of the major formidable barriers in providing access to drugs for the patient treatment is high pricing especially that of the patented drugs. The elements accountable for the elevated price of drugs include: high capital requirement in drug discovery, drug development, quality maintenance, promotion and marketing, quality of diagnosis, treatment, delivery and administration of medicines, competencies of health care systems, budgetary provision, lack of research and development (R&D), less output through R&D for health care products, undue delay due to regulatory approval requirements and continuous innovation for providing better drugs to the masses. For introducing new drugs in the market, huge funds are required for setting up manufacturing / production facility and its marketing. This could be one of the reasons for low availability of drugs and non-purchasing power of the masses.[2] Drug scarcity also arises due to unforeseen circumstances like occurrence of natural calamity, epidemic conditions, refusal by the pharmaceutical company to produce drugs attributable to market force and due to the drug price control order (DPCO) imposed by the Government where the manufactures were given very low profit margins.[3]

One of the mandates of WHO is that the drug should be accessible and in line with the physical,

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financial and therapeutic needs and be available, affordable to all and within easy physical reach. It simply means that the drug must be easily accessible on the basis of requirements and not on the capacity to pay and priority must be given to health-care aspects. The perspective of WHO on access to medicine is that it's a human right; public health priority is to get essential medicine at affordable price, and essential medicines should not be compared to any other goods or services.[1] Further, Patent legislations should be managed with a sense of balance in incentivizing innovation and public health needs and favoring inclusion of Trade Related Aspects of Intellectual Property Rights (TRIPS) flexibilities in national law, to safeguard public health.

TRIPS Agreement is the most inclusive multifaceted agreement on intellectual property rights administered by the World Trade Organization (WTO).[4] One of the most provocative TRIPS provisions (Article 65) of WTO Agreement is the obligatory product patent protection for pharmaceutical inventions (WTO OMC fact sheet 2006).[5] Hence, every country needs to formulate its own policy based on the local requirements and conditions that should be in conformity with the international framework. Guidance has been provided by WTO in the national pharmaceutical legislation to sensitize people about the public health implications mentioned in TRIPS Agreement. It covers monitoring globalization effect and various means of achieving access to the medicines by TRIPS. The developing countries through legislative measures that involve IP Laws are taking vigorous steps to safeguard access to medicines.[1]

The World Health Assembly (WHA)[6] in 1975 at Geneva approved a resolution on "essential medicines" that emphasized the problematic areas in access to life-saving drugs around the world as well as to support member countries in purchasing good quality drugs at reasonable cost. (Laing *et al.*, 2003).[7] WHO took the initiative of introducing essential medicines that had been welcomed by India along with other countries. Essential medicines are those which assure and fulfill the healthcare requirements of the majority of public. This idea of NLEM (National List of Essential Medicine) was conceptualized that covered largely cost-effective medicines with assured quality and that can reach to masses.[8, 9]

India is among various developing countries whose purchasing power of essential drugs is very low. Near about 42% population of the country falls below the national poverty line ($1.25 per day). Major issue is to access the health care facilities at reasonable price. The expenditure on drugs is around 70% to 80% of total healthcare spending which is very high as drugs govern the health care system so its price control is essential. The Government also spends money to bring down the cost of healthcare. The pharmaceutical price regulatory authority in India NPPA (National Pharmaceutical Pricing Authority) controls the prices of drugs by implementing DPCO. In spite of DPCO, still significant variation exist among the products having same API (Active Pharmaceutical Ingredient) due to several factors.[10] To conquer the mentioned dilemma and dominating trade practice by patent proprietors / drug manufacturers, TRIPS provides certain flexibilities to the member countries.

Present Situation

Drug accessibility condition is fulfilled only when the drugs mostly needed by the low and middle income countries for Neglected Tropical Diseases (NTD) is met which is the major disease burden of these countries.[11,12] Ample amount of drugs are available in the market. The multinational pharmaceutical companies majorly fulfil the needs of high-income countries for the prevalent disease. This results in lack of drug development incentives for NTD.[13]

The target of the pharmaceutical companies is to attain profit which is incentivized through IPR. The IPR regime offers market exclusivity *via* patent grant for a period of 20 years that in turn encourage inventions and incentivize and promote technological innovation. An overall advantage of this system is its workability that means the patent system works with in a market whereby not the Government but eventually customers "choose" by providing the enticement for production.[14] However, the problematical circumstances in the developing and low income countries is the population that is incapable of providing incentives for production as their ability to pay is minimal, if not absent.

The price of the drugs is significant and their purchase by the Government for public health care sector is restricted due to inadequate funds. The expenditure on the drug sector by the Government in some of the developing and transitional countries is 60% which is substantial compared to just 18% in intergovernmental economic organization countries

called Organization for Economic Co-operation and Development (OECD) countries.[15,16,17] Health care expenditures per capita for high income industrialized countries like United States, France and Australia are as $8,608, 4,952 and $5,939 respectively which is much lower as compared to the developing countries and it is $30 in Guinea, $17 in Ethiopia and $37 in Benin.[18] India spent about $40 per person annually on health care which is much higher than United States (as mentioned previously). Total Gross Domestic Product (GDP) of India was $1.6 trillion compared to US spending alone on health care was $2.6 trillion.[19] In other developing countries higher percentage of GDP is allocated for public healthcare sector (WHO National Health accounts, Global Health Expenditure Database).[20]

On entire healthcare sector, the average growth in expenditure is not only less than the average GDP growth rate, the spending is still lower (as a % of GDP) than the spending of even low-income countries (Fig-1). As per World Bank statistics, India falls among low-middle income countries. Actually, the growth over the total healthcare spending in India has declined from what it was a decade ago (from 4.3 % to 4.05 %).

In India, about 71% of total healthcare expenditure was endured by the families from their pockets.[21] The figure for India was much higher at 86 % for the year 2012 as given by World Bank. The cost of medicine is the major healthcare issue as the majority of the population does not have any health insurance policies and medicine provided by the public sector is often unavailable. People have to pay from their pocket to get access to the healthcare facility. Though the countries are under obligations to provide medicines at affordable cost to those who need them yet it does not happen and leads to propulsion of big groups of the inhabitants of a country into poverty.[22] Most of the Asian countries would be pushed below an income level of US$1.25 or US$2 per day. About

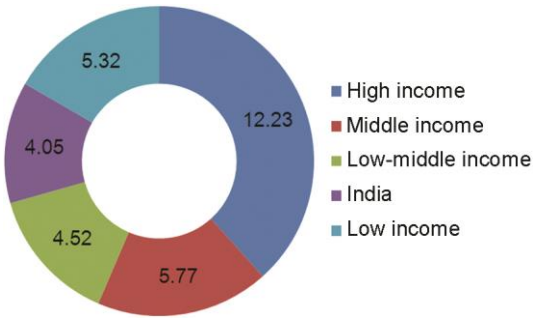

Fig. 1 — Health care expenditure as % of GDP[19]

77% of the population in Tanzania and Nigeria live below US $2 a day and have to purchase the medicines. These basic facts and figures point out the critical circumstances prevalent for affordability of medicines for India's health care system. Introduction of product patent regime in pharmaceutical sector in fact has deviated the rules of the game. Generic firms are lawfully stopped from developing the generic form of patented drugs. The generic version of patented medicine can be introduced in the market through compulsory licensing provision or for the Government use approvals, otherwise the pharmaceutical firms can only manufacture the off-patent drugs, which lead to renunciation of affording new innovated drugs due to price issues by the patients.

TRIPS Flexibilities: Putting into Practice

TRIPS implementation has become an essential requirement for the countries to become WTO members and for those countries who seek benefits in trading and marketing prospects from WTO. The country is obligated to stringently fulfill IPR provisions of TRIPS. One of the mandates of TRIPS is to provide product and process patent protection in all fields of technology and manufacturing, including pharmaceuticals. It abolishes the chances for the pharmaceutical companies of the developing countries to manufacture and sell drugs at lower prices through reverse-engineering.[23] It also regulated the minimum period of protection for patented invention to 20 years.

Implementation of TRIPS

TRIPS is administered through WIPO and it is the minimum purpose Agreement.[24] This Agreement was introduced to promote multilateral trade practices among fellow nations under the General Agreement on Tariffs and Trade (GATT) and the member countries are free to introduce protective measures required in their domestic law.

Intellectual properties covered under TRIPS Agreement constitute industrial property (patents, trademarks, industrial designs, geographical indications, and trade secrets); and copyright and neighboring rights (literary and artistic works). It is obligatory for the WTO member countries to adopt universal minimum standards in their national laws.

TRIPS mandates enforcement of IP rights that result in development of innovative and useful products, generation of funds for product manufacturing and marketing which in turn would

influence the trade and economic development of fellow nations. Further the objective of TRIPS is to bring global harmonization in the field of IPR, to promote free market access, technology transfer, cross border investment and to bring out the status of most favored nations among the fellow countries.[3]

Role of TRIPS to promote public healthcare was fully discussed for the first time in the Inter-Ministerial Conference in Doha in 2001.[25] The rights and obligations for the WTO member countries were confirmed in Para 4 of Doha Declaration. It mentioned that implementation of TRIPS is to be in a way that supports health of the masses by providing access to the vital drugs. Further, it suggests provisions for the export of patented drugs to those countries which lack manufacturing capabilities.[26]

To strengthen the functioning of WTO, Doha Round had taken care of some of new issues in addition to the previously existing and agreed terms and conditions. These are safeguarding affordability of drugs required by the developing and least developed countries at reasonable price especially of patented ones. TRIPS mandate is not to monopolize the invention and create anticompetitive practice but is to promote innovation by preserving the rights of the patent holder for a limited period as well as a means of evolving an unbiased system of protecting the innovator's interests and harmonizing the same with the public. The effort made in Doha declaration on TRIPS and public health emphasized that flexibilities provided under TRIPS will support member countries to resolve the national health issues.[3] Further, it encourages the member countries to enforce their rights by implementing TRIPS flexibilities like compulsory licensing provision, for Government use, parallel imports and through national intrusions including drug price control. Special provisions have also been provided under compulsory license for the member countries lacking technological and manufacturing capability to produce the drugs without sacrificing the rights of the patent holder, in return inventor/applicant receive appropriate reimbursement from the licensee. So, it can be inferred that to safeguard and benefit the public interest at par, member countries need to incorporate TRIPS provisions to their national laws. Simultaneously, TRIPS prevents member countries from altering their laws where the agreement is not in line with the national interests.[1]

To comply and fulfill with the TRIPS obligations, the Indian Government has made conscious efforts in this regard and amended the Indian Patent Act. This not only brings the incorporation of TRIPS provisions in the national law but the amendments made had raised the proficiency of patent management.

The amended Indian Patent Act introduced:

Exclusive Marketing Rights (EMR) in 1999; prolonged the term of patent protection to 20 years, incorporated in 2002 and introduction of the product patent regime in 2005.

The introduction of product patent regime was a major policy decision as before India became signatory to TRIPS Agreement in 1995, no product patent was granted in the field of pharmaceuticals.[27] Thus, to curtail the possible adverse impact of patents on access to medicines, numerous provisions were provided in the TRIPS Agreement and India adapted to the TRIPS provisions considering public health.

Patentability Standards

Article 27.1 of TRIPS Agreement says that patents shall be available for any invention "provided that they are new, involve an inventive step and are capable of industrial application". WTO member countries were free to define patentability criteria and limit the inventions which do not satisfy novelty, inventive step and industrial application clause. Further, to raise the threshold of patentability, certain types of inventions are excluded from patenting *viz.* frivolous inventions, inventions which are in conflict with the public order or morality, inventions that are detrimental to human, animal and plant life or that affect the national security and patenting of incremental inventions called patent ever greening, (Amended Indian Patent Act, 2005).[28] However, patent right is allowed for incremental developments in the United States. Some experts are of the view that such proliferation is of particular significance and is necessary for the growth and development of the pharmaceutical industry (U.S-India Business Council. 2009).[29] In India, Section 3d of Patent Act excludes incremental inventions and thus has impact on the patentability by preventing ever greening and hence protecting the genuine innovators and genuine inventions that are significantly different from the prior art and get patent protection. Section 3(d) excludes patenting of new forms, discovery of new property and new use of substance already in existence. Further, esters, ethers, polymorphs, salts, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives which already exist in public domain

considered to be the same substance. To evade patent proliferation, this approach is desirable from the public health stance of the developing country. Pharmaceutical company's intent is to obstruct or delay competition *via* filing several patent applications on the variants of existing substance creating so called "patent thickets" or "patent clusters".[30] While patentability criteria set forth by the Indian Patent Office offers regulations or guidelines as laid down under Section 3(d), as amended in 2005, having detailed criteria for the patenting of pharmaceutical substances. Therefore, when the claimed subject matter consists of salt, polymorphs, esters, isomers, active metabolites, pure form, dosages or new form of known medicines, the patent applications are liable to be rejected on the basis of lack of inventive step under Section 3(d).

In the year 1998, Novartis claimed for β-polymorphic form of imatinib mesylate salt in the Indian patent application for its anticancer formulation used in the treatment of Chronic Myeloid Leukemia (CML).[31] The provisions of product patents was not available till 2005 and Novartis application was a 'mailbox' application. Meantime, Novartis applied for EMR and obtained it in the year 2003 for 5 years. The anticancer drug sold under the brand name Glivec costs around INR 1,20,000 (US$ 2666) per patient per month, that limited its affordability, while the generic version manufactured by Ranbaxy and Cipla costs around INR 8000 to 10,000 (177 to US$ 266) per patient per month. Glivec application was rejected under Section 3(d) of the Indian Patent Act on the basis that it was mere modification of the existing substance and the claimed subject matter did not prove significant enhancement of therapeutic efficacy clinically.[27]

Recently Boehringer Ingelheim's patent for respiratory drug Spiriva (crystalline tiotropium bromide monohydrate) bearing Patent Application No.558/DELNP/2003[32] has been revoked under Section 3(d) in a post grant opposition filed by Cipla. The Indian patent of the drug sold by the German MNC has been revoked for being obvious and held as incapable of exhibiting significant enhancement in therapeutic efficacy (Section 3(d)).

For Government Use

Article 44(2) and 31(h) of TRIPS Agreement and Section 47, 100 and 101 of The Indian Patent Act provide provisions to the Government to use any patented invention without the consent of the patent holder. Government can authorize the public or private sector to use the patented invention for noncommercial purposes, for public welfare like importation of generic medicine as well as its production for use in the public hospital. This includes the use of patented drug, medicine, process, apparatus or article that can be imported or manufactured on the behalf of the government merely for its own use. It ultimately provides autonomous protection against patent infringement when the patents are commercially worked for Government use. This provision can also be enabled for "fast-track "compulsory license. This provision has been a part of national patent laws of many countries In United Kingdom and United States. This 'Government use' provision is called "Crown use" where the services to the Govenment are further broadened by the law.[33]

Compulsory License

Compulsory license (CL) is granted after three years from the date of patent grant to an invention, subject to certain conditions, when the reasonable requirement of the public for such drug is not fulfilled, drug being non-affordable and the invention not commercially worked in the Indian territory.[34] Further, TRIPS allows the use of CL not only when the access to medicine is hindered due to high price but it is also allowed in cases like 'national emergencies', 'circumstances of extreme urgency' and for 'public non-commercial use' as mentioned in the Article 31 of TRIPS Agreement. Further, there is no requirement to negotiate with the patentee before the grant of CL in such cases.[35] Therefore, it is under the purview of the Government to issue non voluntary or forced licenses on any patented invention and allow third party to use it without the consent of patent owner.[36] By utilizing such licenses, the pharmaceutical firms produce the generic versions of patented medicines or import the generic drugs from the foreign pharmaceutical multinationals. There are certain conditions given under Article 31 (TRIPS Agreement) for the issuance of CL. Case-by case consideration for compulsory license applications including applicant's capacity to work the invention and undertake risks, prior negotiations with the patent holder for voluntary license which came out to be unsuccessful (Article 31(b) of TRIPS), and adequate payment of royalties and remuneration (Article 31(h)) as decided by the court or government to the patentee (WHO/TCM/2005).[37] Mostly, in case of pharmaceutical inventions it can be seen that the

inventions which are vital and of high value, the patentee in unwilling to give voluntary license due to financial considerations in order to get more profit out of it. But by the grant of non-voluntary licenses, the patented invention can be accessible and affordable to the poorest in the developing countries at a more competitive price.

In 2012, first compulsory license was granted to Natco Pharma for generic production of Nexavar drug used in treating liver and kidney cancer. The drug was originally invented by Bayer and costs US$ 5500 compared to US$ 141 cost of the generic variant.[38,39] Bayer challenged the compulsory license of Nexavar in the Indian court but lost the case.[39] CL was issued on the basis that the drug availability could not satisfy the requirements of the public, it was not affordable and not locally manufactured / worked in India.

Parallel Importation

Article 6 of the TRIPS Agreement provides parallel import exception based on "exhaustion of rights".[33] Countries like India, Argentina, Malaysia and South Africa have parallel import provision in their domestic laws that allow parallel import of patented goods from one country to another country without the consent of patent owner when patented products are sold at higher price in the concerned country.[1] This in turn reduces the prices as there is huge difference in price of similar drugs across different countries. This policy provision combat the ill effects of robust IP enforcement as well as it eliminates the unfair means using IP rights by IPR holders.

The "Bolar" Exception

Article 30 of TRIPS allows members to provide for limited exceptions to the patent rights conferred by a patent, provided that

> *"such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".*[26]

The exceptions under this may include, for instance, limited manufacture of the patented drug to conduct specific tests and get regulatory approvals, request of marketing approvals before the expiration of the patent without authorization of the patent holder (known as the "Bolar exception''). This would enable quick commercialization of the generic version immediately after expiry of the patent. This exception is incorporated in patent legislations of several countries such as United States, Canada, Australia, Israel, Thailand, Singapore, India etc. In Indian PatentAct Section 107 (A) outlines the provision of "Bolar exception''.

Medicines Patent Pools

Medicines Patent Pools (MPP) is a new approach to collectively manage the IP created for medicine in a single pool for the developing countries with a global health goal in mind and overcome the patent barriers imposed by patent protection. Patenting activity provides motivational support to the pharmaceutical companies to innovate; but nearly 90% of patented pharmaceutical products are not marketed and remain on shelves and finally lapse.[3] The reason could be nonexistence of target markets, monopolizing invention by big Multi National Corporations (MNCs) and design around the breakthrough innovations. Thus, huge number of patented inventions remain commercially unexploited without getting any attention. The outcome is that many valuable and potentially beneficial innovations remain unused that might have benefitted the patients. With the formation of medicinal patent pools, IP is jointly managed and this increases the access to preferred therapeutic products and technologies.

Two or more patent holders enter into an agreement to pool their patents of less commercial interest and the patents in the pool are further licensed on already existing terms and conditions for utilization by the sponsor. Nominal start-up and functioning costs is required to function the patent pools within the framework of existing patent laws, this eases the R&D venture risks for stakeholders.[40] Therefore, if the patent pools are managed efficiently, it can ultimately lead to the proficient drug development process obtained via centralizing licensing methods [41] thereby reducing the license transaction costs, risk distribution among the patent pool members and improved exchange of information.[42]

Problems And Key Approaches towards Improved Access to Drugs

Exclusivity provided through patents are accountable for high prices of drugs but generic or off-patent drugs are available at lower price and even affording them at reduced prices would not be in the physical reach of the poor patients or even by the healthcare campaigns organized by the countries. The

price of off patent drugs drop dramatically but to afford them still remains a difficult issue. As it was discussed earlier, the price of generic anti-cancer drugs like Glivec and Nexavar is at about one tenth of patented drug prices, still they would be out of reach to the poor patients including patients of middle income groups. In fact, even if the generic version of life saving modern biotechnological drugs needed for treating chronic diseases are available, it would still cost more than Rs. 10,000 a month. In countries, where per capita income is less than US$ 1 a day, drugs even at the price of generic drug are unaffordable.[3]

In order to make sure the accessibility of drugs to the needy, the developing countries should be proficient enough to use such provisions as mentioned in TRIPS Agreement. Further, these countries should be able to manufacture the drugs, maintain their quality standards, providing data related to safety and efficacy and market the drug via efficient storage and distribution channels. Parallel imports that correspond to local working of patented invention as mentioned in TRIPS Agreement exclude the mandatory requirement of local manufacturing of drugs.

Drug price control systems are functional in many countries but the actual and realistic production cost is too high which makes the drugs unaffordable. Differential pricing approach of patented drugs has been adopted by many countries to lower down the stress of poor patients.[43] Further, utilization and sharing of resources by subsidizing drug cost at national level to the needy patients could be a better way to ensure access in addition to effective health insurance scheme. R&D efforts to be made to discover and develop new cost effective and efficacious drugs having faster regulatory approvals that lower the overall cost and make the drugs cheaper. R&D on NTDs is also a necessity of the low and middle income countries since big MNCs are not likely to capitalize funds in that area in view of the small market size and huge amount invested on its R&D. Healthcare needs that are not resolved by competitive industrial R&D, the public-private partnership (PPP) can offer innovative and effective comeback to the healthcare requirements associated with low profitable earnings. These partnerships can help to make available the inexpensive and effectual health care products to the developing world.[44]

Government Programs for Providing Inexpensive Healthcare

Realizing the social and economic status of people concerning their healthcare aspect, the Government of India prioritizes the healthcare in its manifestos and acclaims its transformation *via* healthcare mission called "National Health Assurance Mission (NHAM)".[45,46] The out of pocket expenses on healthcare of people in India is very high as many people do not possess any health insurance schemes. Universal Health Coverage (UHC) was envisaged to cover the access to superior, effective and inexpensive health care services without imparting financial burden and under this all medical, surgical, diagnostics facilities are available to all citizens entitled to a comprehensive health package, without paying at the point of use (Planning Commission of India, 2011)[47], but this has not yet been achieved. There is lack of accountable public health sector and little (1.3% of GDP) is spent under public spending for public health.[18] Further, Uniform Code of Pharmaceutical Marketing Practices (UCPMP) – a voluntary code controls the immoral and undesirable prescriptions of medicine to ensure access to health for everyone. The aim of UCPMP is that the doctors should prescribe the branded generic medicine. It's an effort to restrict the disreputable practices and cooperation between pharmaceutical MNCs and doctors.[48]

An initiative like National Health Service Corporation provides financial support to the primary healthcare services. The state based initiative came out to be successful in Tamil Nadu by Tamil Nadu Medical Services Corporation Limited, which is involved in the accessing, storing and supply of drugs as well as surgical items to primary health centres and government hospitals, through state.[49] In Maharashtra, the Indian Medical Association (IMA) is also planning to promote and provide inexpensive and effective medicines available through a scheme called Nirmalaya.[50] In Madhya Pradesh and Bihar states mobile medical facility is also available so that the medicine should reach to the people living in remote areas.

Conclusion

Access of medicines to public at reasonable price is a serious concern in developing countries. The provisions laid down in the TRIPS Agreement and its impact on drug prices is a matter of concern. Several

recommendations including strict patentability standards, compulsory licenses, parallel imports provisions etc. have been proposed during TRIPS implementation that ensure access to affordable drugs. All these provisions may results in lowering price of drugs and hence result in better affordability to the needy. Inclusions of healthcare scheme that take care of hospital expenses, professional charges and costs of drugs have minimal impact on the overall health of the public. More emphatic work should be done in a direction to lower the effect of patents on drug price. This effort should be complemented by nationwide programmes including healthcare insurance schemes implemented by governmental and non-governmental organizations to benefit overall health of the poor patients. While considering the total healthcare costs, the high price of drugs constitutes only one component. The other initially mentioned factors, if managed properly then more affordable drugs would become easily accessible and help to solve the existing public health care issues. In addition to the incorporation of TRIPS flexibilities in the country's legal system, a sound robust policy is required that not only addresses the concerns of high priced drugs but also other measures to protect public healthcare.

References

1 WHO, Intellectual Property Rights and Access to Medicines: A South-East Asia perspective on global issues, (2008), http://www.searo.who.int/entity/intellectual_property/trh.pdf.

2 Nair M D, Impact of emerging IPR regime on India pharmaceutical industry, *National Intellectual Property Organization Souvenir*, 2004, p. 29.

3 Nair M D, TRIPS and access to affordable drugs, *Journal of Intellectual Property Rights*, 17 (7) (2012) 305-314.

4 Donoso E A, Global Solution for the Protection of Inventions, 2014, http://*pd*f-directory.org/ebook.php?id=a51nAwAAQBAJ.

5 WTO OMC FACT SHEET, TRIPS and pharmaceutical patents, 2006, https://www.wto.org/ENGLISH/ tratop_e trips_e/tripsfactsheet_pharma_2006_e.pdf.

6 World Health Assembly, Resolution WHA28.66, Geneva, World Health Organization, 1975.

7 Laing R, Waning B, Gray A, Ford N & Hoen E, 25 years of the WHO essential medicines lists: Progress and challenges, *R - The Lancet*, 361 (5) (2003) 1723-1729.

8 Sinha K, Govt. to bring essential medicines under price control, *Times of India*, 28 September 2012, http://articles.timesofindia.indiatimes.com/2012-09-28/india/34147534_1_price-controlnlem-essential-medicines.

9 NLEM, 2011, http://pharmaceuticals.gov.in/pdf/NLEM.pdf.

10 Kumar R S P, Balamuralidhara V, Kumar P T M & Dave A J, Need for drug price control in India, *Adv J Pharm Life Sci Res*, 1 (1) (2013) 22-30.

11 What are Neglected Diseases?, *News Medical*, 2011, http://www.newsmedical.net/health/what-are-neglected-diseases.aspx (accessed on 27 October 2016).

12 Neglected Tropical Diseases, *World Health Organization (WHO)*, 2013, http://www.who.int/neglected_diseases/en/ (accessed on 27 October 2016).

13 Bors C, Christie A, Gervais D & Clayton E W, Improving access to medicines in low-income countries: A review of mechanisms, *The Journal of World Intellectual Property*, 18 (1-2) (2015) 1-28.

14 Vacca R, Intellectual Property and Public Health - A White Paper, *Akron Research Paper No. 13-11*, School of Law, University of Akron, 2013.

15 Cameron A, Ewen M, Ross-Degnan D, Ball D & Laing R, Medicine prices availability and affordability in 36 developing middle-income countries: A secondary analysis, *The Lancet*, 373 (2009) 240–49.

16 Drug Spending in OECD Countries Up by Nearly a Third Since 1998, According to New OECD Data, *Organization for Economic Co-operation and Development*, 2005, http://www.oecd.org/general/drugspendinginoecdcountriesupbynearlyathirdsince1998accordingtonewoecddata.htm.

17 The World Medicines Situation, *WHO*, 2004, http://apps.who.int/ medicinedocs/pdf/s6160e/s6160e.pdf, (accessed on 27 October 2016).

18 Health Expenditure Per Capita, World Bank, 2014, http://data.worldbank.org/indicator/SH.XPD.PCAP.

19 Business News, 26 February 2016, http://www.firstpost.com/business/budget-2016-healthcare-cannot-wait-mr-jaitley-healthy-india-can-hasten-wealthy-india-2644650.html.

20 WHO National Health accounts, Global Health Expenditure Database, http://www.who.int/health-accounts/ghed/en/.

21 Annual Report, MHFW, December 2011, http://www.mohfw.nic.in/showfile.php?lid=121.

22 Niens L M, Cameron A, Van D P E, Brouwer W B F & Laing R, Quantifying the impoverishing effects of purchasing medicines: A cross-country comparison of the affordability of medicines in the developing world, *PLoS Medicine*, 7 (8) (2010), e1000333. doi: 10.1371/journal.pmed.1000333.

23 Greene W, The emergence of india's pharmaceutical industry and implications for the U.S. generic drug market, *Office of Economics Working Paper U.S. International Trade Commission*, 2007, https://www.usitc.gov/publications/332/EC200705A.pdf.

24 TRIPS Agreement, https://www.wto.org/english/docs e/legal_e/27-trips.pdf.

25 Implications of the Doha Declaration on the TRIPS Agreement and Public Health WHO, 2002, http://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf.

26 Ellen F M & Hoen T TRIPS, Pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond, 2003, http://www.who.int/intellectualproperty/topics/ ip/tHoen.pdf.

27 Arora S & Chaturvedi R, "Section 3 (d): Implications and key concerns for pharmaceutical sector, *Journal of Intellectual Property Rights*, 21 (2016) 16-26.

28 Amended Indian Patent Act, 2005, http://www.ipindia.nic.in/.

29 The Value of Incremental Pharmaceutical Innovation, U.S-India Business Council, 2009, http://www.indiaenvironmentportal.org.in/files/USIBCIncrementalInnovationReport Final.pdf (accessed on 20 November 2016).

30 Rodriguez V, Patent pools: Intellectual property rights and competition, *Open AIDS Journal*, 4 (2010) 62–66.

31 Nair G G, Fernandes A & Nair K, Landmark pharma patent jurisprudence in India, *Journal of Intellectual Property*, 14 (2014) 79-88.

32 558/DELNP/2003, Crystalline Tiotropium Bromide Monohydrate and Process Thereof, http://ipindiaservices.gov.in/decision/00558-DELNP-2003-9637/558-delnp-2003%2025(2)%20decision.pdf (accessed on 25 September 2016).

33 Gopakumar K M, Product patents and access to medicines in India: A critical review of the implementation of TRIPS patent regime, *The Law and Development Review*, 3 (2) (2010) Art. 11.

34 Nair G G & Fernandes A, Patent policies and provisions relating to pharmaceuticals in India, *Journal of Intellectual Property Rights*, 19 (1) (2014) 7-17.

35 Ramani S V & Urias E, Access to critical medicines: When are compulsory licenses effective in price negotiations? *Social Science & Medicine*, 135 (6) (2015) 75–83.

36 Kaur A & Chaturvedi R, Compulsory licensing of drugs and pharmaceuticals: Issues and dilemma, *Journal of Intellectual Property Rights*, 20 (9) (2015) 279-287.

37 WHO/TCM/2005, Remuneration guidelines for non-voluntary use of a patent on medical technologies, http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf.

38 Kochhar R, Indian pharmaceutical industry: Policies, achievements and challenges, *Current Science*, 106 (10) (2014) 1345.

39 Hirschler B, Bayer fails to block generic cancer drug in India‟s top court, *Reuters*, 2014, http://in.reuters.com/article/2014/12/12/us-bayer-indiaruling-idINKBN0JQ1XA20141212.

40 Hoffman S J & So K, Assessing 15 proposals for promoting innovation and access to medicines globally for the global access to medicines, *Reform Study Team Ann Glob Health*, 80 (6) (Nov-Dec 2014) 432-43.

41 Bermudez J & 't Hoen E, The UNITAID patent pool initiative: Bringing patents together for the common good, *Open AIDS J*, 4 (2010) 37–40.

42 Clark J, Patent pools: A solution to the problem of access in biotechnology patents? 2000, www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf, (accessed on 27 October 2016).

43 Danzon P M & Towse A, Differential pricing for pharmaceuticals: Reconciling access, R&D and patents, *International Journal of Health Care Finance and Economics*, 3 (2003)183–205.

44 Wheeler C & Berkley S, Initial lessons from public–private partnerships in drug and vaccine development Bulletin of the World Health Organization, 79 (8) (2001) 728.

45 Golechha M, Healthcare agenda for the Indian government, *Indian J Med Res*, 141 (10) (2015) 151-153.

46 Golechha M, The National Health Assurance Mission for India, 384 (9949) (11) (2016) 1185–1186.

47 High level expert group report on universal health coverage for India, Planning Commission of India, 2011, http://planningcommission.nic.in/reports/genrep/rep_uhc0812.pdf, (accessed on 6 November 2016).

48 Basant R & Srinivasan S, Intellectual Property Protection in India and Implications for Health Innovation: Emerging Perspectives, *No. WP2015-04-01*,Indian Institute of Management Ahmedabad, Research and Publication Department, 2015.

49 Lalitha N, Tamil Nadu Government intervention and prices of medicines, *Economic and Political Weekly*, 2008, 66–71.

50 Nautiyal S, IMA to promote affordable and efficacious branded generics through Nirmalaya, (2015), http://www.pharmabiz.com/NewsDetails.aspx?aid=86804&sid=1, (accessed on 20 November 2016).