PHARMACEUTICAL PATENTS AND PUBLIC HEALTH IN PAKISTAN

Yasir Arfat
Lecturer
School of Law
University of Gujrat
Gujrat - Pakistan.
yasir.arfat@uog.edu.pk

Naveed Hussain
Lecturer
School of Law
University of Gujrat
Gujrat - Pakistan
naveed.hussain@uog.edu.pk

Abstract

Money is important but how much do you need? How much money it costs is not the issue but how much the money costs us is crucial. Whether money is more important than human lives? It seems yes in pharmaceutical industry where they succeed in getting patent against medicines necessary for human's surviving and get exclusive control of their prices. They set their medicine's prices very high out of reach to the poor people who die due to their poverty having not sufficient money to buy them. They work on a trade theory 'higher risk higher return' because medicines are only commodities upon which human life depends. To get patent in medicine is a very successful tool for the accumulation of maximum wealth at the name of innovation and progress. Pakistan being a signatory of TRIPS Agreement has to ensure patent protection, to patent holders when they meet qualifications to get patent which they very easily manage, at the same level as required under TRIPS as international obligations. It adds to woes of poor people because Pakistan's public health sector is also very fragile and it has been identified as one of the country's most corrupt sectors according to surveys by Transparency International. TRIPS Agreement has introduced certain flexibilities for developing countries and compulsory licensing in pharmaceutical patents is one of them but unluckily Pakistan has not granted it even a single time

as it can be seen in India and many other countries not only developing but also the developed like Canada. The countries have been given liberty to interpret the terms of TRIPS Agreement and India has used this liberty very efficiently to make it difficult for getting patent in medicines and also paved ways for the production of maximum generic medicines but unfortunately Pakistan is not even near to that level of efficiency achieved by India.

Keywords: Pharmaceutical, Patent, TRIPS, WTO, Medicine, Compulsory Licensing

Introduction

A successful nation always gives a primary concern to the health of its people. It would be an understatement to call Pakistan's healthcare system poor because it has not gained at least minimum level of satisfaction. Lack of doctors and their nexus with the pharmaceutical industry, expensive hospital's numerous fees, ignored regulation and most importantly high priced medicines make this sector out of reach to the majority of people. Pharmaceutical companies earn huge profit from the sale of essential medicines (Anderson, 2014). The profits result directly from the prohibitive prices of medicines many of which are life saving and a necessity. This report also ascribed that the increase mainly of the two factors one is of shortage of medicines in the market and second is patenting of drugs.

Medicine is, at its center, a moral enterprise grounded in a covenant of trust (Crawshaw et al, 1995). It is the primary responsibility of every government to take necessary steps to improve access to medicines as a basic necessity for sustaining life and quality of life. It would be important to quote Article 38(a) and (d) of the Constitution of Pakistan which says: "The State shall secure the well of the people, irrespective of sex, case, creed and race, provide basic necessities of life such as medical relief for all such citizens as are permanently or temporarily unable to earn their livelihood on account of infirmity, sickness or unemployment." Unfortunately in Pakistan government has failed to fulfill its constitutional duty to provide a better and affordable healthcare to its people due to many reasons. Supreme Court observed that pharma sector is a big mafia of the country and government acts just like a silent witness (Obaid, 2020). The reason is the pharmaceutical cartel consisting of a handful of companies which create unfair business advantages for themselves with the help of Drug Regulatory Authority of Pakistan (DRAP). Pakistan is a poor country which stands in the list of developed countries the prices of medicines must be within the reach of the economic power of the people because it is very painful when someone losing his life because of having no money to purchase medicine. This has been depicted in the tweet of American president Joe Biden on December 4, 2021 in the words

that "there is no worse feeling than not being able to afford the life-saving medication a loved one may need," on the occasion of passing 'The Build Back Better Act' for the purpose of controlling price of insulin to the limit of 35$/month.

Pharmaceutical Patents under TRIPS Agreement

The era of post-World War II brought many substantial changes in the jurisprudence of trade and international organizations by bringing trade from bilateral to multilateral system with an additional aspect of binding laws for its members. WTO was a major shift to the concept of sovereignty of states as it provided dispute settlement mechanism for its members at unprecedented way (Reddy, 2006). As earlier discussed, TRIPS was made compulsory part of WTO, so the members of TRIPS were bound to reorganize their IP laws in the line of TRIPS and make assurance of protection set by this agreement and in case of disobedience they felt the same threat of consequences as it would have been in the trade. Pakistan being its signatory to WTO was also bound to make its domestic laws according to the WTO's requirements and TRIPS also. Pakistan Patents Ordinance is one of the examples of compliance to the TRIPS. Initially there was Patents and Designs Act 1911 but subsequent to TRIPS it was amended and a new Act was formed.

The TRIPS Agreement is widely believed the most controversial agreement amongst all the agreements finalised in Uruguay Round in the end of twentieth century. This Agreement was proved a major departure from the prevailing international IPR system which was based on bilateral treaties (Azam, 2016). It was distinctive on many counts but mainly in three ways: first, it makes mandatory for the WTO members to extend protection on trademarks, copyrights, patents, industrial designs, trade secrets, geographical indication and layout designs for integrated circuits. Secondly it also fixed minimum standards in terms of area of coverage, mechanism of enforcement i.e. civil or penal remedy and more importantly the time span of protection for example the period of patent protection is twenty years from the issuance of patent. The third thing which was the main thing was its compliance through WTO's dispute settlement procedure. Any dispute regarding the IPR will be dealt in the same way as any other trade dispute is dealt.

TRIPS agreement was the brainchild of industrialists from the developed countries i.e. the European Union (EU), US and Japan and such others. The main drive for the formation of this Agreement came from pharmaceutical industry as the CEO of Pfizer was playing main role as a chair of Intellectual Property Rights Committee (IPC). This committee was formed in the negotiation of Uruguay Round with the intention of putting IPRs in the agenda (Madeley, 2000). Initially the primary goal of this committee was to put efforts for the elimination of discrimination which they were feeling against the patenting of

medicines thereafter their went on to get control over clinical and regulatory data of generic equivalents in the process of seeking registration for generic medicines with the intention to stop or delay that process.

The arguments they were advancing for their hidden designs were that strong protection is necessary to stimulate innovation and technologies and similarly for growth in pharmaceutical industry in term of greater domestic and foreign investment in research for new medicines and to cure tropical diseases. Furthermore, this will also boost the economy of developing and least developing countries (LDCs) through technology transfer and foreign investment.

On the other hand, almost more than 50 developing and LDCs very vehemently opposed this inclusion and categorically resisted this approach on the basis that the prices of medicines would go high and out of reach. (Lanjouw, 1998) They also turned down the argument of false hope of economy development by advancing very rational arguments that how it would be increase in research and development (R&D) when they have not technical infrastructure, finance and human resources. Rather the non-patentability of pharmaceutical products existing prior to the TRIPS Agreement provided an opportunity to developing nations to progress and acquire basic technology through reverse engineering before being able to invest in R&D (WHO, 1998).

In the past, patent was not granted against the products even in developed nations i.e. France, Germany and Switzerland etc. In France product patent was started in 1966, in Germany it was started in 1967, in Italy, pharmaceutical were prohibited until 1978 similarly in Spain product patents were also not allowed until after its accession to the European Economic Community with the effect from 1992. The rationale behind prohibition for pharmaceuticals patents was to allow local pharmaceutical companies to copy and produce patented medicines through adopting new procedures. These developed countries continued unauthorised imitation for many years and they gained self-sufficiency in pharmaceutical manufacturing and invested in R&D (Lall, 2003). When they enabled to transform their pharmaceutical industry into innovative and research based industry they began thinking of exclusion and prohibition and ultimately succeeded by creating a strong net of protection globally through linking it to trade by way of TRIPS Agreement (Srinivasan, 2008).

This liberty of imitation of technology was never availed by developing and least developing countries because they were not at the same stage and they straight away went under obligation of WTO. The transitional period was although granted under TRIPS to developing and LDCs for such purpose but it was meaningless for them because they do

not have sufficient technological capabilities to produce generic pharmaceuticals (Sampath, 2007).

Thus, it is very important to discuss how to provide an easy access to those medicines for poorer citizens among developing countries and LDCs against which the patent holders claim huge spending of funding at research and development. This study will focus on this debate with reference to Pakistan being a least developing country, by shedding lights and providing better understanding of the implications of a TRIPS-compliant patent regime on pharmaceutical patents.

TRIPS Flexibilities and the Doha Declaration

The concept of flexibility has been deliberately incorporated in TRIPS Agreement keeping in mind the different economic and social scenarios of each country. Developing countries showed their dissent against pharmaceutical patents because initially medicines were not part of patent system it was very big concern of developing nations that the medicines will be very expensive by doing so. In response to this grievance these flexibilities were included in this agreement. The meaning and purpose of 'flexibility' as described by World Intellectual Property Organisation (WIPO) through its Committee on Development and Intellectual Property (CDIP), as "legal tools that countries can use as they see fit in their national developmental plans and within the framework of the mandatory standards of international obligations". It was further explained "the term flexibilities means that there are different options through which TRIPS obligations can be transposed into national law so that national interests are accommodated and yet TRIPS provisions and principles are complied with". By using this liberty each member state can determine its own approach regarding the relationship between pharmaceutical access and IPRs.

Following flexibilities have been permitted in the TRIPS Agreement:

a. To define the word 'invention' and fix the criteria of patentability while remaining under the broad framework of TRIPS.
b. To issue compulsory licensing upon the emergencies explained by the member state.
c. To set up cogent and reasonable exceptions against patent rights.
d. Number of options relating to the protection of data submitted for regulatory purposes.
e. To set grounds for parallel importation of medicines and exhaustion of rights.
f. To limit the unfair commercial use of protection of undisclosed test data for the purpose of promoting generic medicines.

However, these flexibilities are vague and therefore require putting into operation at the national level while adjusting their national developmental goals, the public interest and the development stage of a specific country. Therefore, the nations had trouble in taking advantage of the flexibilities while dealing with public health emergencies and making sure better access to medicines.

Three main incidents urgently raised the call for tackling these ambiguities and complexities in the TRIPS agreement in the context of public health. First, it was the *Medicines and Related Substances Control Act 1997* introduced by South African government to ensure the medicines for treatment of HIV/AIDS. This law allowed parallel imports and compulsory licensing of such medicines in South Africa and it started legal battle between numerous pharmaceutical companies and South African government. These companies were backed by different trade bodies and American government.

Second incident was the dispute arisen in 2001 between America and Brazil relating to issuance of compulsory licensing against those patents which have not been commercialized since last 3 years in Brazil. America deemed it inconsistent with the TRIPS Agreement and went to WTO against such actions. Final was anthrax threat to public health whereby America and Canada felt strong fear of compulsory licensing of Cipro (an antibiotic used in the treatment of anthrax). They perceived threat of issuing compulsory licensing on the ground of health emergency and started putting pressure upon developing countries to refrain from it while sticking to patent laws. This confliction paved way to clear the ambiguity of grounds for issuing compulsory licensing. There was dire need to define public health emergency and settle the grounds upon which any government can grant compulsory licensing in line to TRIPS Agreement. Developing countries including most of African countries had a huge concern that the TRIPS Agreement should not preclude the ways to deal health emergency by ensuring easy and affordable access to medicines (WHO, 2001). The discussion was arranged by WTO where arguments by both of the parties were heard at length. The contention of developing countries was seeking clarity in using of TRIPS flexibilities and demanded special concession against pharmaceutical patents to deal their national public health emergencies because their economy does not allow to safe their people's lives by purchasing high priced medicines. Whereas on the other hand developed countries like US, Japan, Australia, Canada and Switzerland etc. vehemently opposed these suggestions on the grounds that by doing so it will be huge setback to the innovation and creation and lives will be more at threat when there will be no medicines at all.

Thereafter this discussion concluded positively and on 14 November 2001, the WTO Doha Ministerial Conference finalised a declaration while confirming that "TRIPS Agreement

does not and should not prevent members from taking measures to protect public health. According, the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and in particular, to promoted access to medicines for all".

Strategies by India toward Access to Medicines

This part illustrates how an individual country may promote access to medicine while still complying with TRIPS. Most of the developing countries have failed to exercise such discretion due to many reasons but there are some who have made it possible like India. The patent law of India is an important example for other developing countries to ensure access to medicine without violating international obligations. TRIPS Agreement is a wide agreement which is called a skeletal like a constitution of any country defines only main routes. Member states of TRIPS have freedom and flexibility to define important terms and other requirements to promote easy and affordable access to medicines while exploring ways what flexibilities will be or should be under TRIPS.

India's current patent law encompasses three main approaches toward promoting access to medicines while still complying TRIPS requirements and allowing patents. To get patent there must be novelty, inventive step and commercial use of the article which was invented. TRIPS require these three elements for every patent granted but it does not elaborate them and fix their boundaries. India has restricted the scope of what is patent, secondly they created maximum exceptions against patent rights and thirdly courts have major role in interpreting the above mentioned three essential requirements for granting patents toward promoting access to medicines and production of generic medicines. By these efforts India is the world's major producer of generic medicines (Cynthia, 2011).

Harder Criteria for Granting Pharmaceutical Patents in India

As earlier mentioned there are three main requirements: (a) it must be new (b) there must be inventive step (c) and it must have commercial application. However, TRIPS does not define these terms so the member states have liberty to define them so long as these definitions should not violate the major obligations of TRIPS. How each of these terms is defined can have very significant role to the access of medicines.

India has provided two main exceptions against pharmaceutical patents grants by limiting scope of invention through inclusion of section 3(d) of Indian Patent Act 1970. This section has restricted drug companies from taking new and new patents by using some shortcuts in the form of minor changes in their already patented drugs. These companies

claimed new ways of using and variations of their existing blockbuster medicines with the intention of getting maximum benefits because patents are expired after twenty years so they enable themselves in getting afresh time period of patent and succeed in refraining production of public enrichment in the form of production of generic medicines. Insertion of section 3(d) is big embargo for such companies in India. This section categorically prevents such so called invention by declaring them unpatentable: (a) new use of known substances (b) new forms of known substances unless there is significantly different efficacy.

The word 'efficacy' has special importance to determine whether variation claimed in new use or new forms is worthwhile or not. Although the word efficacy has not been defined the courts have to measure it according to the facts of each case. In a case *'Novertis AG v. Union of India (2007)*, when a patent was refused by Indian Patent Office on the ground that the Novartis new variation of anti-cancer drug was inadequately efficacious was challenged in the High Court of Madras. The court maintained the decision although the company claimed that the new medicine had 30% more bioavailability meaning thereby that it will more easily absorbed into bloodstream. It was also challenged that this provision is against the TRIPS Agreement and the Constitution of India but court dismissed all these claimed. It was a huge discourages to the tactics of these pharma companies because they prolonged their patents upon such methods. For example, if a skin cream which was initially patented for the use of acne was subsequently claimed useful for the treatment of wrinkles as a new use and hence new patent is sought. They changed the name like Xyzal into a new variant of already patented tablet Zyrtec and in this way they succeed in making their patent evergreen.

It is very important to know that section 3(d) complies with TRIPS or not? Although US has showed its concern regarding this section that it will bring down the pharmaceutical patents may be hamper to innovation but did not declared violation to TRIPS. Furthermore, it has also been not challenged in WTO dispute settlement process by any country since it became effective in 2005. Apart from, there is also need to understand whether insertion of such section will be an embargo to the future inventions and the growth of technology. Although, some patent enthusiasts suggest that TRIPS has explained the things which are not patentable but it is widely accepted amongst scholars that nations are free to define what is patent unless their definition contradicts and discriminate the growth of technology. Moreover it is also worth to mention that some categories of things may be called invention but every invention is not to be the subject of patent.

The central issue is whether the insertion of section 3d in the Indian Patent Act 1970 is a bona fide exception which primarily deals with a glaring issue that specifically exists in the

area of pharmaceuticals patents called 'evergreening'. Debatably, this section deals with the situation exclusively to the pharmaceutical industry as evergreening is the only problem in the relating to drugs. Conversely, drugs companies claim this practice legitimate while characterising it fair business practice administering it life cycle management. Therefore, they would not consider it bonafide exception. It is clear from the context of pharmaceutical companies behavior that the section 3(d) has been inserted to curb this unjustified business tactic and therefore it can be argued that the section 3d is not discriminatory due to it bonafide nature. It is also worth to mention that Doha Public Declaration is very crucial to consider here because it is very relevant interpretive document which has been made for particularly pharmaceutical patents and it demands special treatment. Furthermore, article 8 of TRIPS Agreement emphasizes public health as an important social value with respect to patent rights.

Apart from above all, to determine an invention in true sense a criteria has been developed that there must be an inventive step. This is considered most important in term of determining real invention and to make sure that only deserving inventions are registered for patents. Recently it has been observed in various studies that this criterion has not been observed stringently (Stephan, 2003). This might be a problem in any field of technology but most importantly this has to be addressed preferably in pharmaceutical patents because a large section of patients are died due to lack of access to medicines which gone out of reach being patented medicines. India has provided tougher definition of inventive step in term of making sure that there is actually technical advancement or economic significance or both available and it is not obvious to any technical person expert in such field. The purpose of this effort is to make patent more difficult.

Application Procedure for Patents and India's standpoint

There is no concept of global patent so every country will grant it after the satisfaction and fulfillment of all the requirements demanded by its own patents laws. The person who has invented something new must file an application to the national patent office of the particular country where the rights are desired. Countries have little bit different procedure and have variations apart from the TRIPS core requirements. The purpose of patent office is to examine whether the invention meets all the requirements of patentability. For this purpose, patent office conduct an exhaustive enquiry through searching public similar information known as prior art. To grant patent is very complex process and involve many requirements i.e. searching prior art, invitation of opposition and publication of processing etc which are lengthy in nature.

Opposition of patent application is one of the most important parts of all the procedure wherein a due time is given to the third party to oppose granting of patents. In most of the countries only few people are allowed to oppose who have to first prove their right to *locus standi* but in India there is no such restriction and any person is allowed to oppose it. Any individual or an organisation working for generic medicines and promoting access to medicines will be allowed to oppose patents. Likewise, pre-grant opposition filed by cancer patients and health groups against *Novartis* had been recorded in India in September 2006 for the interest of cancer as well HIV patients. Opposition can be allowed on any ground of qualification for getting patent; novelty, inventive step and commercial use and in India section 3(d)'s requirements. In India requirement of section 3(d) is very hard and therefore it is very difficult to meet the qualification of inventive step. The majority of pre-grant oppositions have been successful thus far, with the rate of successful opposition being nearly 80 percent, comparable to the percentage of patents found invalid when challenged by generic companies in the United States.

Notably, filed oppositions may result in abandonment of patent applications (Feroz, 2008). Although these statistics are not predictive of future cases in India, let alone other countries that may adopt such procedures, they indicate that pre-grant oppositions may be a useful tool to promote access to medicine.

As with all other Indian patent laws, the pre-grant opposition proceeding must be evaluated for TRIPS compatibility. There is no specific TRIPS provision regarding oppositions, only a general requirement regarding procedures for issuing patents. In particular, TRIPS requires patent examinations be done "within a reasonable time" to avoid "unwarranted curtailment" of protection. In other words, TRIPS imposes the requirement of "reasonableness" for issuing patents to ensure the patent term is not unduly limited. The connection to the patent term exists because TRIPS requires the patent term to be calculated from the date of filing, such that if the patent examination time were unduly long, the actual term of a patent might be abbreviated. Importantly, the focus of this TRIPS provision is on the overall process for issuing *all* patents and not individual ones. Accordingly, even if individual patents took longer to issue, as long as the process overall was reasonable there should be no problem. However, even if opposed patent applications take longer to issue, it could still arguably be reasonable, as the word itself reflects a notably ambiguous and flexible standard. In addition, even in wealthy countries with substantial resources devoted to patent examination, the length of time applications take to issue seems to vary. Accordingly, for a country with more limited resources (such as India), a reasonable time could potentially be longer than in wealthier countries.

No Presumption of Validity for Issued Patents

Indian law also ensures that patentability requirements are satisfied by providing no presumption of validity to issued patents even after the opposition period has passed. This rule has been explained as logical in that the patent office search is not considered exhaustive. In addition, it is recognized that questions of novelty and inventiveness need to be assessed from the view of experts, including those who would normally oppose a patent. However, given that many patents are not opposed, patent validity is considered to be appropriately assessed in litigation proceedings without the hindrance of any evidentiary presumption. This is a marked difference from other jurisdictions that provide an evidentiary presumption of validity, making it more difficult to invalidate a patent after it is granted. For example, some countries consider issued patents to have a presumption of validity; although this can be challenged, the challenger must establish the patent is not valid based on a heightened evidentiary standard. The presumption of validity has been explained as appropriate because as the patent office is an expert agency, it should be entitled to deference.

The Rights and Remedies of Patent Holder and How India Deals with It

Under TRIPS, each patent owner has the usual right to exclude unauthorized others from certain activities regarding the patented invention for a particular term. Patent rights are to be provided without discrimination as to the field of technology. In other words, inventions in all fields should be provided the same rights. Beyond the nondiscrimination requirement, standard patent rights include exclusionary rights that last for a certain period of time. Those standard rights are subject to the exceptions provided in TRIPS for special circumstances like issuing of compulsory licensing in case of medical emergency etc.

Patent rights and remedies under Indian law, including limitations as to both rights and remedies, may promote access to medicine under TRIPS. India's law is consistent with the minimum patent rights required under TRIPS. Then, it is worth to understand how it promotes access to medicines while ensuring rights of the patentees which they have been assured under the TRIPS.

TRIPS imposes two basic requirements for patent rights. First, the patent owner normally has the right to exclude all others from making, using, selling, or importing the patented invention during the term of the patent. Second, these rights are to exist during the term of the patent which must end no earlier than twenty years from the date the patent application was filed.

India also provides a patent term consistent with TRIPS one that ends twenty years from the filing of the application. However, in contrast to some other jurisdictions, India does

not provide more than required under TRIPS. For example, India does not extend the patent term in cases where either the patent examination process or the regulatory approval process for a patented drug is lengthy. Accordingly, a drug patented in both India and the United States which does provide for patent term extensions is likely to have differing patent terms. Moreover, the patent term for patents issuing from mailbox applications may be particularly short; as the term is twenty years from filing and mailbox applications may have been pending for up to five years before even being examined, patents issued from these applications are likely to have shorter terms than other patents. However, this is permissible under TRIPS, which only requires the patent term to end twenty years from the filing of the patent application. India also provides a wide range of limitations on patent rights and remedies. It begins with specific exceptions to the usual patent right to exclude: regulatory review, compulsory licensing, and international exhaustion. After these specific exceptions, Indian law also provides the ultimate "exception" to patent rights their complete revocation.

Indian law has a provision that fosters regulatory review of generic applications during the patent term to ensure generics medicines can quickly enter the market upon patent expiry. Some type of exception is common in many national laws, but there are differences among them. India exempts from infringement any making, using, selling, or importing of a patented invention that is related to development of information required under any national law regulating the manufacture, sale, or import of any product. It has been almost settled that it would not be treated infringement what is mandatory to seek regulatory approval for generic medicines. A WTO panel (under dispute settlement procedure) examined whether these two provisions of Canadian law, which have been enacted for the purpose of speedy entry of generic medicines against those medicines whose patents have been expired, permissible exceptions under article 30 of the TRIPS. It was held in their decision that "permitting a generic company to make limited quantities of a patented drug during the patent term for the purpose of seeking regulatory approval to sell the drug after patent expiry was a permissible exception to the patent owner's usual right to exclude others from making the patented invention".

WTO panel previously found Canada's regulatory review provision to be a permissible "limited exception." However, a brief consideration of whether India's provision differs from Canada's is necessary to evaluate TRIPS compliance. Canada's law was similar except that it did not create an exemption for imports. The Indian laws have been framed according to the same interpretation hence in a little bit broader sense. It is in consistent if you make laws with the intention to expedite the regulatory procedure for speedy entrance of generic drugs and therefore a strong need exists in Pakistan as well. After all, the panel

noted that "whether an exception was limited was not a function of how many of the patent owner's usual rights were impacted".

Furthermore, India provides a substantial exception to the usual rights of a patent owner through its detailed and expansive infrastructure for issuing compulsory licenses. India provides extensive grounds for issuing a compulsory license that include traditional ones, such as failure of the patent owner to "work" the patent locally (meaning the patent owner is not making the patented product in India and only importing the patented invention). India also provides some unusual bases for issuing compulsory license that are particularly pertinent to the issue of access to medicine. In particular, India specifically permits a compulsory license to issue if the patent owner is not providing the patented medicine at a reasonably affordable price.

Exemption from Contributory Infringement to Consumer

India's law does in fact provide patent owners with the right to generally exclude others from the range of activities as set forth under TRIPS. However, what is notable is that India does not provide more than TRIPS requires in contrast to some other jurisdictions. For example, in some countries, patent liability may exist for someone who contributes to the infringement of another which is commonly known as contributory infringement. In other words, if a patent exists on a method of using a compound to cure hair loss, the person who uses and thus violates the method would actually be the consumer. However, in the case of contributory infringement, the person who makes the compound used by the consumer could be considered liable. This would thus enable the patent owner to sue the maker of the compound, who is likely a company with more resources than an individual consumer; moreover, it would be more effective to stop a company from supplying consumers who infringe, rather than suing each individual consumer. Of course, from a public relations perspective, it is also preferable to sue a corporate entity rather than a consumer.

Issuing of Compulsory Licensing Against Pharmaceutical Patents

Pakistan is a member of WTO since its beginning in 1995 and the Patent Ordinance allows patent against the invention of any medicine as it has been instructed in the TRIPS Agreement. This Agreement has also introduced certain flexibilities where any member state can act differently when special circumstances prevail. State can withdraw patent against certain medicine and order generic production to meet the special emergencies and it is compulsory licensing. WTO defined compulsory licensing in the words that "Compulsory licensing is when a government allows someone else to produce the patented

product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property (WTO, 2018)." Compulsory license can be issued on national emergency, or other circumstances for extreme urgencies or when voluntary license could not be issue on reasonable commercial terms (TRIPS, 1995). There are number of countries even some developed countries i.e. Canada, America and Germany who initially opposed the provision of compulsory licensing have issued compulsory licensing to meet their medical emergencies (Kiani, 2012). Prior to TRIPS, some countries such as India and Canada had provisions that automatically granted compulsory licenses on inventions relating to pharmaceuticals or food, with a set royalty rate. It was also proposed by developing countries in the negotiation process that patent licensing should be automatically against food and pharmaceutical products.

Section 59 of The Patent Ordinance 2000 of Pakistan has provided a way for compulsory licensing in case of failure to work and further to ensure that the patents do not impede the protection of public health and nutrition and the patent rights are not abused by the patentee. Compulsory licensing plays a vital role in achieving a major objective in term of provision of pharmaceutical products to a large population in developing and under developed countries at cheaper and affordable prices. On March 9, 2012 India's first compulsory license was granted by the Indian Patent Office to Natco Pharma Ltd. for producing generic version of Bayer Corporation's patented medicine Nexavar, used in the treatment of Liver and Kidney cancer. Bayer was selling this drug at very exorbitant rate with one month's worth of dosage costing around Rs. 2.8 Lakh whereas Natco pharma, after the issuing of compulsory licensing, offered to sell it around for Rs. 9000/month (Nayanikaa, 2019). The generic production of medicines costs very low than to its brand version, as evident from above mentioned example, hence India is the largest international provider of generic medicines and further India supplies over 50% of the global demand for various vaccines (Ammar, 2021). The countries have been given liberty to interpret the terms of TRIPS Agreement and India has used this liberty very efficiently to make it difficult for getting patent in medicines and also paved ways for the production of maximum generic medicines but unfortunately Pakistan is not even near to that level of efficiency achieved by India.

Conclusion

It is a common prayer in our society, people offer to other not to go to hospital. It is offered for not only one's good health but also for ones money because in Pakistan hospitals are not less than a nightmare for a common people with respect to scaring of money. There are many reasons in this deteriorated and one of the most corrupt sectors in Pakistan which

make the people's lives more vulnerable and miserable because health is the most sensitive issue of every human where he does not want to compromise. Average income people always feel fear shortage of money and they even compromise their foods but it becomes impossible when they go to hospitals. Purchasing of medicines constitutes a much larger percentage of budgets for individuals in poor countries than in wealthy ones. Ironically, individuals from wealthier countries often pay lower prices for their drugs because their governments both impose price controls on drugs, and often have insurance that further subsidizes their out of pocket expenses. Neither of these things is typically true for individuals in poor countries. Accordingly, their out of pocket expenses for medications often far exceeds those in wealthier countries. Inadequate number and poor conditions of government hospitals provides huge space for private hospitals owned by investors whose top priority is their maximum earning at any cost. Doctor's relations with the pharma industries are also unchecked in Pakistan and many doctors work for the interest of pharmaceutical industry, which gives them many incentives, rather for their patients. A senior doctor whose name was not disclosed on his request told in news in the following words: "Several of my friends, consultant cardiologists and gastroenterologists are in the Northern areas alone or with their families; all on the expense of different pharmaceutical companies. I have commitments here in Karachi so a pharmaceutical company has arranged for week-long recreational trip for my spouse and kids at a family resort on newly-constructed Motorway. After seeing my patients in the night, I join my family at the picnic resort" (Bhatti, 2019). Due to such and many other reasons health sector is one of the most corrupt sectors in Pakistan. Supreme Court of Pakistan had also observed pharmaceutical mafia is huge mafia in Pakistan (Khan, 2020).

Apart from all the above national issues, the issuance of patents against new invented drugs is main concern relating to cheap and frequent availability of medicines in Pakistan. International obligations under the TRIPS are the same to any member country including Pakistan but we find a lot of difference in the responding and treatment by different states toward in the efforts of accessing medicines. How it is possible when it is supposed that the national laws of all the members nations are to be framed in the line of TRIPS Agreement because these states are bound to set their intellectual property laws ('IP laws') according to the requirements set out in the TRIPS Agreement. Basically TRIPS Agreement is very general document, dealing generally with the IP laws of many areas i.e. copyrights, trademarks, geographical indications and patents etc, which was formed after a lot of negotiations among the countries having different point of views and agendas. Therefore, it was concluded in very generic sense because the different terms in the Agreement have not been defined anywhere. For example there is requirement of patent that it must be new and having inventive step but what amounts to new and inventive step is not defined in the Agreement. It provides an opportunity for member states to set their

laws which create balance between innovation and to easy access to medicines. When TRIPS was under negotiation process it was huge concern of the developing nations that to provide patent in pharmaceutical products the prices of medicines will go to the out of reach of people. But this concern was not entertained because behind the TRIPS there was huge move of pharma industry so there is need first to understand how TRIPS was formed and then we will observe that when we have TRIPS how we can still promote access to medicines and India is very successful example for us and Pakistan where high prices of medicines is very glaring issue needs to follow the suit.

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