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Accessibility and Affordability of Drugs under Trips: Ways to Address Public Health Concerns in Developing Nations

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Abstract:

TRIPS agreement permits patenting of drugs, which are generally made with huge investment in research and development. The provisions of TRIPS safeguard the interest of drug makers who invest huge amount of resources in research and development for developing new medicines and drugs. From the perspective of developing nations, where most of the population are poor, there is a huge public health concerns in terms of accessibility and affordability of drugs, because it not only creates dependency on one or few licensed drug manufacturers but also due to monopoly situation, the price of those drugs become very costly. However, there are also different provisions of TRIPS which take care of public health concerns of the member countries by allowing flexibilities in adopting patentability criteria and also allow them to adopt certain measures if there is a serious threatening on public health interest in their nations. This article examines some of the provisions under TRIPS which can provide safeguard to the countries from the adverse affect of patent regime and ensure their smooth accessibility and affordability. It also argues that despite different challenges being faced by the developing nations to address public health problems under patent regime, there are possibilities which the developing nations can exploit to achieve effective balance between both corporate objective and public health concerns.

Key words: TRIPS, Patent, Access and Affordability of Drugs, Public Health, WTO, Compulsory License, Research and Development

Introduction:

Millennium Development Goals (MDG) recognizes the fact that poverty reduction, attaining high level of educational and health status and environment sustainability are crucial for sustainable development. However, in spite of health being one of the important agendas for MDG, the present situation of health indicators in South East Asia and Sub-Saharan Africa is unacceptable and require urgent intervention. Most of the countries in these regions are suffering from double burden of diseases of communicable and non-communicable and important among these are HIV-AIDS, TB, Malaria etc. Globalisation has brought together different nations on one platform and has removed numbers of barriers including trade barriers which not only brought opportunities particularly for developing and underdeveloped nations but also exposed them to number of threats. Intellectual property rights (IPR) is one such example of opportunities and threats and the entire world needs to deliberate upon how this could play role for poverty alleviation, combating disease, positive indicators on maternal and child health and nutrition, access to healthcare services and sustainable development.

IPRs are the ownership rights provided to the individuals or organizations for some invention or creative work. The rights are given in the form of patent, trademark, copyright, industrial design, geographical indication etc. Patent right given to the organization is to provide them market exclusivity for the fixed period of time which allows them to recoup their investments in R&D for product development and also gives them opportunity to generate profits to run the business. If these protections will not be provided then one can easily copy the invention at the fraction of the cost of developing it which is referred as market failure by the economists. Granting patent is one way to address this market failure. From the economics perspective, granting patent

improves efficiency by stimulating and promoting research and development and progress however at the costs associated with monopoly or market exclusivity.

In 1994, the Uruguay Round negotiations instituted an agreement and resulted in the formation of the World Trade Organization (WTO). WTO started its operation from January 1995 and all the members countries were made liable to undertake and abide by its rules and regulations. All the treaties on trade in goods and services entered in different WTO conventions are therefore binding on all its member countries. TRIPS or Trade Related Aspects of Industrial Property Rights is one such kind of agreement which has direct relationship with the pharmaceutical market and industry and definitely on health of the people and the country. It is a multilateral trade agreement which sets a minimum standards in the field of intellectual property and all the members have to comply and make rules and standards either by formulating new policies if they don't have or to modify the policies if they are not in the line of the agreement. The main element of this act is the grant of patent protection to the pharmaceutical products and process inventions.

Previously in the era of General Agreement on Tariffs and Trade (GATT), the issue of intellectual property was not addressed properly and different countries enacted their different laws and regulations to protect the interest of the pharmaceutical innovations and inventions and at the same time provided protections and safeguard to their public health issues. Many countries had not provided such safeguard rules and laws in their country and hence they suffered in terms of weak research and development of the pharmaceutical products and also suffered in terms of weak health indicators. Hence after globalization, it was found that there was non-uniformity of standards in different laws of different nations and realized that to promote high end research and development and also safeguard the public health of different countries, there should

be some minimum standards to set the ground rules. One of such standards is that the member countries have to grant patent for a minimum of 20 years if any pharmaceutical product established the minimum criteria of novelty, inventiveness and usefulness.

The Uruguay Round negotiations mainly talked about the protection of the pharmaceutical products and industries and had very limited discussion on public health issues. In 2001, The Doha Summit on TRIPS and Public Health laid the path to make the patent regime more development friendly and provided various safeguards to the nations to enact measures that are important from the public health perspective of the country. This was happened because countries like Brazil, India and some African nations led the negotiations for the first time to make the regime more development friendly. To safeguard their public health interests, numbers of flexibilities were granted to the countries within the scope of the TRIPS agreement.

Safeguards provided under trips to ensure access and affordability of drugs to the developing and underdeveloped nations

TRIPS gave the legitimate power to the pharmaceutical companies to get rid of all the low cost generic competitors and thus gave them opportunity to create a monopoly market structure and ultimately cash high profits from the market. It also allows the delay entry of generic producers due to data exclusivity protection given under TRIPS policy which reduces price competition. Data exclusivity preclude the registration of generic medicines even if the country has issued a compulsory license because it restricts even the regulator to use the data to establish the safety and efficacy of follow-on drug. The higher prices resulting from the above decrease access to medicines for the lower economic class. The conditions would be even worse

for those countries which have very limited capacity to manufacture drugs and mainly rely on the foreign supplies. Hence to safeguard the public health interest in the developing nations, certain lawful concessions under the TRIPS have been granted which can be used as the tool by these nations to ensure accessibility and availability of drugs and medicines in their nation and to avoid public health crisis. The varieties of options given are:

1. The countries which are currently not a member of WTO can do import and export of the medicines without any procedural obstacles in its own country. Even the countries which being a member of WTO and are in transitional phase can do import and export of the medicines without any procedural obstacles in its own nation and there will be no restrictions imposed on them by WTO.
2. Article 30 of the TRIPS deals with "Bolar Exception" which gives the condition that the generic drug manufacturers can introduce their products soon after the patented drug become off patent. It allows the generic drug manufacturers to do research needed to get regulatory approval before the expiry of the patented drug and for this they can produce and/ or import and use quantities necessary of a patented drug without the permission of the patent holder to conduct tests needed to obtain regulatory approval before the expiry of a patent. Hence there is a safeguard that patented product can be used for research even before the expiry of the product however cannot be used for commercial purpose without the approval of the patent holder. It allows the generic manufacturer to get ready with all kinds of research and approval so that they could enter the market soon after the patented product become off patent.
3. Under "limited exception" of the same article 30, there is

a provision for exporting medicines to the non-producing countries to address their public health concerns. However, the provision also says that it should not unreasonably clash with the normal patent provisions. The advantage of limited exception would be that the importation of medicines will be efficient and expeditious. Even in the exporting country the procedure for getting approval is very easy.

4. Article 31 of the TRIPS, "Compulsory License" is another feature which permits government to extinguish patent exclusivity and permit a licensee to produce the patented product without the consent of the patent holder. The permissible ground for compulsory licence is not exclusively provided under TRIPS and it the country who decides the circumstances under which the compulsory license would be granted to a licensee. The ground for compulsory license includes public health emergencies and public health interest and hence an important safeguard has been provided under the TRIPS for the developing nation. This is done in the situation when the patent holder exploiting the market which makes the product very costly and also availability is not ensured. The issuing government should follow certain norms and procedures so that it should not disrupt the principles of the TRIPS. The licensee also needs to pay the royalty to the patent holder fixed by the government.

Compulsory licence does not restrict the patent holder from supplying their patented product to the market. They can also make supply to the market but need to compete with the compulsory licensee. The patent holder will also get appropriate royalty from the licensee and hence the licensing arrangement will not discourage them to invest in the research and development of drugs which is also important to tackle with new diseases alongside providing access to drugs at affordable price to the patients.

The compulsory licence guarantees assured supply of drugs in the market, enhance the technical knowhow capacity, economic activity and employment and retains wealth and profit within the country itself. Over the period of time, the producers also gain efficiency and economic of scale which reduce the cost and ultimately the price and make the products more affordable for the people.

A recent example of compulsory license in India granted to Hyderabad based Natco Pharma Ltd. to make and sell a generic version of cancer drug of German based drugmaker, Bayer, which is first of its kind in India. The drug was patented by Bayar in the year 2008 which were being used for treating kidney and liver cancer. Its monthly costs were approximately INR 3 Lakhs which raised a huge question on accessibility and affordability of drug by even the average income class people in India. After Natco was allowed by Indian Patent office to make the generic version of this drug, its cost is drastically come down to INR 9,000. In the past, similar approach was undertaken by countries like Malaysia, Indonesia and Thailand. Countries like China and Philippines are also thinking of taking similar stand to safeguard their public health interest.

5. Another option is "voluntary licence" under which the patent holder voluntarily grants the licence to any local producer to produce and sell the patented products. They either grant it without any compulsion or under the threat of compulsory licence. The advantage of voluntary licence is that it is quickly negotiated with the patent holder without any administrative and time consuming procedures. The access to data and transfer of technology automatically happen. It not only ensures accessibility and affordability of medicines within the country but also enhance countries capacity to export production.
6. Under Article 6 of the TRIPS, there is a provision of

"parallel Importation" which allows import of patented drugs by the least developed countries or non-producing countries through compulsory license or government order from the outside country when the same product is legally produced in the later country. The importing country needs to adopt the international exhaustion rule for smooth import of drugs from the exporting countries. Hence if the same patented product is being cheaply and legally sold in another country, then one is allowed to import it from that country without the consent of the patent holder. This also includes product produced under the compulsory license or government use order in that country.

The advantage of this provision is that the importing country will get the drug at a very competitive price, of assured quality and can meet the demand very quickly. There is no restriction of importing the drugs by the importing country if it is used for the domestic consumption and not for the commercial purpose. This will also help to achieve efficiency by the exporting country's manufacturer because they can produce in scale.

7. Under the same Article 6 of the TRIPS, Least developed or non-producing countries are also free to import unlimited quantities of unpatented, older medicines and more limited quantities of newer and newest medicines through "compulsory licenses" or "government use orders".

One of the important features of importing drugs from other countries is that it not only addresses momentous public health anxieties like TB, Malaria, HIV/AIDS etc. but also wide range of public health concerns can be addressed through this. It covers all the products of pharmaceuticals including diagnostic tests, vaccines and active ingredients. It covers all the least developed countries and also covers all the countries that do not have the capacity of produce these drugs. The non-producing capacity is also loosely defined by WTO which leaves it on the

country only to decide their own production capability and the constraints.

8. Articles 7 and 8 of this agreement deal with the issues related to transfer of technologies particularly in context of developing nations, provide measures to protect public health, prevent misapplications of IP rights, price rise and price control of drugs. They suggest that in the free pharmaceutical market, the government needs to create an enabling environment and also appropriate regulatory mechanisms so that every player should prosper in the market and at the same time price and availability of the drugs should not go beyond the control.

All the above measures are required to be use in good faith and only in the circumstances necessary to safeguard the interest of public health. The above measures will be taken by the country only in the cases to address emergencies or matters of extreme urgency or to remedy of anti-competitive practices and not for the commercial purpose. Before implementing the above measures, the prospective licensee or government should negotiate with the patent holder of the particular product on all commercially reasonable terms and conditions.

It is also important that the country should clearly define the scope of patentability and it could keep the definition narrow to avoid excess applications for patent. The country should not allow patent to the incrementally modified medicines. Allowing incrementally modified medicines patent could increase the price of those medicines; avoid competition which will affect availability and affordability of the medicines within the geographical boundary of the nation and even outside the country where the country has the potential to supply.

It is also recommended for the developing nations that they should go for the utility patent which is a lower form of property rights to promote traditional medicines, traditional

knowledge, new plants etc. To promote investments in the pharmaceutical industry, there are different ways like giving tax subsidies, tax credits or tax deductions for promoting research and development and also declare special geographical zones so that more and more such industries would be set up within a close periphery which will be helpful to develop synergy between them.

However, the above measures do not undermine the role of research and development in the pharmaceutical sector as the volume of diseases to be tackled are huge which, if not addressed quickly, will threaten the public health interest of any nation.

Importance of propriety drug development and its safeguard provided under trips

The patent regime in the drug and pharmaceutical market has brought a new dimension of its development. It has several advantages like it ensures quality of drugs in terms of safety and efficacy because, the drug development process goes through several phases of research and also a stringent process to getting approval for its marketing. Company also invest huge investment on the post market follow-up on patient's experiences of the branded drugs which is important from the public health perspective as it ensures long term safety and efficacy. Patent facilitates market, because it works as an asset to sell or license and provide standard to police the conduct of the contracting party which reduces the transaction costs and make technology based transaction more feasible. It ensures technological advancement on continuous basis and induces others to discover new applications. The drug manufacturers always try to find out the scope for improvement as patent recognizes the importance of improvements and innovations and provide incentives for these.

Patent provides monopoly and market exclusivity power

to the drug company for its patented product which gives them opportunity to earn high returns. The high returns work as an incentive for all the stakeholders in the value chain and this ensures the availability of the product in the market as everyone in the value chain are motivated to produce, keeping stock and sale of the product in the market to earn profit. Even if in the short run the companies incur loss, because of the potential of getting high returns in the future they don't exit the market as they have ability to absorb short term loss and hence ensures the product availability. The high returns of pharmaceutical companies also contribute to the economy in the form of taxes and employment.

To overcome of the challenge of providing drugs to the developing nations at affordable price and ensure their accessibility, the manufacturer can think of differential or tiered pricing which means selling the same drug at high price in the developed nations' market and at lower price in the developing and under developed nations' market. This will give them opportunity to earn profit which could be recouped for investing in further R&D and at the same time they can also take care of public health interest of the developing nations. There is also a possibility that the drug company will reduce the price of the patented drug because of the given opportunity of monopoly market, they can easily recover the costs and achieve economy of scale and also because of the threat of issuance of compulsory license provided under the patent law by the government to safeguard its public health interests.

Challenges being faced by the third world under trips regime

One of the challenges being poised by the developed nations or multinational pharmaceutical companies to developing nations is enactment and implementation of 'Data Exclusivity' under their present patent law. It means that, when the company has

applied for patent registration to the approving authority and got patent, then under data exclusivity clause, the company will get additional safeguard that its data will not be disclosed to anyone under any circumstances. Hence this is an additional right given to pharmaceutical company for the product that has been patented over and above the exclusive marketing right for the period of 20 years. The data exclusivity right is proposed to be provided after the drug is registered by the approving authority before the product come to the market. In US and EU, it is being provided for five and ten years respectively. Its major impact is that, even if the government has issued compulsory license against any patented product to safeguard its public health interest, it will not have any effect because no licensee company will get access to data of the patented product from the approving authority because of the extra safeguard being provided under data exclusivity. Because of this, the licensee company will not be able to produce and market the cheap version of the patented medicine and the patented company will enjoy its monopoly power in the market. This will negatively impact public health interest of any country because it will affect accessibility and affordability of the medicine.

It is being considered that data exclusivity is less stringent as compared to patent right because this clause doesn't prevent other companies from generating their own registration data. However, generating research data is time consuming and resource intensive process which may work as market barrier for a generic drug company to get into it. It also makes the government responsible for protecting the data of the drug company, which it cannot disclose even in the public health emergency.

Also, if any countries adopt data exclusivity under its patent law, then it may create complication in the calculation of time period under *data exclusivity legislation* and *marketing exclusivity legislation*. Under data exclusivity legislation, a generic applicant will get the data of the original drug only

after the expiry of the period from the date the original drug was registered unlike under market exclusivity where it can get the data before the expiration of market exclusivity period. For example, let say the period of data exclusivity is of five years. Then, this means that the patent holder effectively has a market exclusivity of five years plus the time it would take the regulatory authorities in that country to approve the generic application. This is unlike under market exclusivity legislation where a generic applicant would be allowed to get the data of the original drug prior to the expiration of five years which will avoid delay its entry into the market and it will ready with the product, gets approval of the product and can soon bring it in the market just after the expiry of five years. This will avoid time lag to get the data from the authority, get ready with the product and getting its approval with the authority. Hence data exclusivity is much more damaging than the market exclusivity and bad from the public health perspective.

Consolidation in the pharmaceutical industries in the developing nations through merger and acquisition and its impact in the pharmaceutical market and ultimately on access and affordability of medicines:

Recent mergers and acquisitions of developing nations' major pharmaceutical companies by the big multinationals companies (MNCs) are the serious matter of concerns. For example, some of the major Indian companies like Ranbaxy, Dabur, Shantha Biotech, Orchid Chemicals and Piramal Health Care have been acquired by the MNCs from US, France, Japan, Singapore etc. Some of the other companies of the developing nations have been acquired by the large MNCs like Sanofi Aventis took over Medley in Brazil and Zantiva in the Czech Republic, GlaxoSmithKline took over BMS in Egypt and Pakistan. There are the concerns that these takeovers of companies from developing nations by the big MNCs will orient them away from

these nations and will cause serious threats of availability of drugs in the developing nations. Also alliances of developing nations' pharmaceutical companies with the foreign companies like GSK with Dr Reddys; Pfizer with three companies - Aurobindo, Strides Arcolab and Claris Life Sciences; Abbot with Cadilla Health Care and Astra Zeneca with Torrent will somehow detach these companies from the developing nations market. If this trend will continue then there will also be the possibility that an oligopolistic market may develop under which few companies will dictate the prices of the medicines which are important from the public health perspective and make them costly in the hands of patients.

Such kind of environment will also weaken the developing nation's government's ability to issue compulsory license as the large generic medicines manufacturers having capability to produce and market generic drugs are being taken over by the big multinational companies. These generic manufacturers will not be willing to apply for the compulsory license and if the government will notify a public emergency and recognizes the need to issue compulsory license then there will be no capable companies to manufacture drugs. Possibility is also there that these big MNCs will utilize the marketing channel of these acquired firms to push their costly drugs into the developing nations' market. These things will have serious threat on the developing nations' pharmaceutical industries and may pose serious threat on availability and accessibility of the medicines and drugs in these nations.

Conclusion

We know that the pharmaceutical industry should be supported with high end R&D and government needs to create an enabling environment to promote R&D in the pharmaceutical sector. It is important for the government to see the interest of producers who invest substantial amount of money in research

and development to bring any drug in the market and provide some form of incentives to promote them. There is also a need to promote R&D for those drugs which are preventive in nature and also for high burdened diseases from the developing and underdeveloped nations' perspective which are generally neglected. However, at the same time, it needs to strike the balance so that their monopoly should not paralyze the drug market and make them unaffordable and inaccessible. Governments should play a larger regulatory role and see that the public health interests are not being compromised.

Big industrial houses should fulfill their commitments in real sense so that public health interest could be safeguarded along with their market interests. They should closely work with the government and integrate the developmental objectives within their framework and reconcile their commercial objectives with the public health objectives. The countries should frame their IP rules in such a way that there should be enough flexibility to accommodate both the interests. Developed nations and WTO should ensure that the global IP systems evolve in such a way so that it can also safeguard the interests of the developing countries, promote technological innovations and appropriate technology transfer at competitive price which will contribute to their development.

Public sector investment in research and development, at least in developing and under developed nations, will be more equitable both from the economics perspective and from the perspective of access and availability of medicines. Public sector investment in research and development will not be lopsided to the high profiled diseases e.g. life style related diseases but also invest R&D on tropical diseases or preventive drugs which are often neglected by the private sector R&D. Public sector investment in research will also give opportunity to various small and medium enterprises to get license to produce medicines and drugs which are more affordable to the patients and promote competition in the market.

The country should also create enabling environment and build required infrastructures etc. for generic producers to promote healthy competition in the generic market soon after off-patenting of the patented drugs and these generic products get market entry. The government needs to design its competition law in such a way to promote healthy competition in the pharmaceutical market and also at the same time design and implement a robust consumer protection law to provide safeguard and protections to the consumer of the pharmaceutical market. Also instead of allowing foreign investments in the market through automatic route (allowing mergers and acquisitions) the government should evaluate all such proposals and after its clearance from its foreign investment boards should allow such investments. The government should also strengthen its national drug pricing board so that it can control the drug prices in their market. At the same time to achieve the balance between the growth and safeguarding public health interest, there could be a public private partnership in which the government should take the lead role in the research and development through public finance which will also take care of neglected disease R&D and licensing out IP to different private players which will promote competition among them and ensure accessibility and affordability of drugs to the end users. Developing nations should also need to defend their positions in different WTO ministerial conferences with unity so that they should not come under the trap of developed strategies which may cause serious problems in their own nations.

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