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Public health and international patent protection: A never ending conflict

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Abstract---After the coming into force of TRIPS Agreement much importance has been given to the concept of public health. Doha Declaration on Public Health provides a legal basis for interpreting the TRIPS Agreement as consistent with public health objectives and for using the flexibility of the agreement for this purpose. However, these efforts could not resolve the apparent conflict between public health and patent protection. The right to health is a basic human right of every person and includes the right to access the essential drugs. However, right to public health cannot be ensured when there is no certainty as to the legal status of the Doha Declaration. Issues, such as, how much weightage will be given to the Declaration when the WTO Panel or the Appellate Body is adjudging a dispute which affects public health, are bound to arise.

Keywords---Public Health, Essential Drugs, Patent Protection, TRIPS Agreement.

Introduction

Article 25 of the UDHR states that “everyone has the right to a standard of living adequate for the health and well being of himself... including food, clothing, housing and medical care” Article 12 of ICESCR also provides for “right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” The Committee on Economic Social and Cultural Rights (CESCR) in its General Comment No. 14 explained Article 12 as an obligation to respect

and fulfil the right to health. It also recognises that access to affordable medicines is one of the components of the right to health and without medicines this right cannot be attained.

When we talk about accessibility then it means both physical as well as economic accessibility. So if medicines are available but not available at affordable prices then also this right to health is not ensured ([Hestermeyer, 2007](#)). The General Comment also states that the right to health facilities includes the right to essential drugs. The WHO also maintains a list of essential drugs on its website. This list is a flexible one and can be adapted to meet different needs. For each member country, the General Comment provides an obligation to develop an appropriate apparatus for the realization of this right. Para 42 of the Comment also provides that healthcare be provided on non discriminatory basis and thus it must take care of vulnerable groups who don't get health services.

The International Covenant on Civil and Political Rights also known as ICCPR also contains provisions as to right to health. It provides that right to health is an inherent right and no one should be deprived of this right arbitrarily. The concept of right to life includes right to access affordable medicines. It has been argued by the scholars that right to life is not limited to stop killing the people but it also includes access to those medicines which can save life ([Ramcharan, 1983](#)). An affordable medicine is the basic condition of life and without them the right to life becomes meaningless. The above discussion suggests that the international covenants recognise the right to affordable medicines as the basic right of the human being therefore the conflict becomes more intense.

Public Health under TRIPS Agreement

The scholars often put forward Article 7 and 8 of the TRIPS Agreement to argue that these articles ensure a proper balance between IPR and public healthcare. Article 7, which provide for the objectives of the TRIPS Agreement, states that "the protection and enforcement of intellectual property right should contribute to the promotion of technological innovation... to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare." Article 8, which talks about the principles of the TRIPS Agreement, provides that the member countries can adopt measures necessary for the promotion of public health.

Article 31(1) of the VCLT provides that a treaty should be interpreted in the light of its objectives and basic purposes. Since Article 7 provides for the objectives of the TRIPS it can of great interpretative value when interpreting other provisions of the Agreement ([Xiong, 2012](#)). Article 7 seeks to reconcile the diverse interests and promotes innovation as well as dissemination of knowledge at the same time. The WTO Panel in the landmark case of Canada Patents pointed out the importance of Article 7 while interpreting Article 30 of the TRIPS Agreement. However, these provisions contain 'should' provisions and thus cannot be used over 'shall' provisions like Article 27. Article 27 provides for an obligation to provide product patenting and this obligation is a must provision considering the language employed.

As far as the Canadian Patent case is concerned, the manufacturing and stockpiling of the patented medicines should have been allowed within the patent protection so that once the validity of a patent expires these generic medicines could be used right after the expiry of the protection. This will enable the consumers to buy the generic medicines on the expiry of the patent protection. If the same is not allowed then this will result in an additional protection which may be between six to twelve months. This is the time required for manufacturing and supplying of the generic medicines.

As seen above, the countries need to first comply with the obligations and then only it can use the flexibilities under the TRIPS. Articles 7 and 8 cannot be used as grounds for deviating the substantive obligations imposed by TRIPS. Hence, the role which Article 7 and 8 can play in the interpretation of TRIPS provisions is limited and cannot limit the substantive provisions.

TRIPS Flexibilities

The TRIPS Agreement provides a number of flexibilities in order to adjust the national policies of the member countries. These provisions are provided to balance the public and innovators' rights. Provisions such as patentability standards, compulsory licensing, government use, parallel importation, Bolar exception among others constitute TRIPS flexibilities. Accordingly, member countries can make use of these to address the public health concerns. Some countries have made use of these provisions to ensure affordable medicines but some countries are unaware of these provisions. Therefore, technical assistance should be provided by the WTO so that these countries can make full use of such flexibilities.

A. Patentability Standards

Article 27.1 of TRIPS provides that "patents shall be available for any invention provided that they are new, involve an inventive step and are capable of industrial application." Although the member countries were given the power to adopt different patentability criteria and could also deny patents to inventions which fails to satisfy the triple test of novelty, inventive step and industrial application. In order to raise the patentability threshold certain inventions were kept out of patentability viz. Inventions which affects the human, animal and plant life or inventions which are frivolous.

B. Compulsory License

Compulsory licensing is granted after the expiration of three years from the patent grant. This provision is applicable when the medicine requirement is not fulfilled, medicine becomes unaffordable and when the invention is not worked out in the territory of the member country. Further in cases of national emergency or extreme urgency compulsory licensing is resorted to. Article 31 of TRIPS provides certain grounds for the issuance of compulsory licensing. The concept has been discussed in detail in Chapter V of this paper thus I shall refrain from repetition.

C. Government Use

Article 33(h) and 44(2) of TRIPS provide provisions concerning government use. Accordingly, the patented inventions can be used by the government without the consent of the patent holder. Under this provision the government is empowered to authorise the public or even private sector to use the invention in question for non commercial purposes. The objective is to secure public welfare. This provision is also called “Crown use” in the England ([Gopakumar, 2010](#)).

D. Parallel Importation

The TRIPS Agreement, under article 6, provides for the exception of parallel importation based on exhaustion. Many countries allow parallel importation of medicines when patented medicines are sold at higher prices. Resultantly, the prices are reduced as the difference in the prices is huge one. Under the doctrine of exhaustion the patent holder loses its right over the patented medicine once it is sold. This exception allows a person to purchase and import the medicine in the country where the prices are comparatively higher. But it is to be noted that the extent of this exception is dependent on the type of exhaustion a country is following.

There are three types of exhaustions under IP regime viz. International, regional and national. International exhaustion means that the patent holder ceases to have control over the sales of medicine anywhere in the world. In regional and national exhaustion the control is lost within the region or the nation. The TRIPS provides that the members are free to establish its own regime for exhaustion.

E. Limited Exceptions under TRIPS

Article 30 of the TRIPS Agreement states that limited exception can be given granted to the member countries provided it fulfils three conditions. The Article states these exceptions cannot unreasonably conflict with the normal exploitation of the patent granted. Secondly, it should not unreasonably prejudice the legitimate interests of the patentee. Thirdly, these two conditions should be applied by taking care of the legitimate interests of the third parties as well. This provision is widely worded one and thus often confuses as to what constitute a reasonable exception.

The scope of Article 30 is uncertain and has been subjected to different interpretations. The question which arises is how limited is the exception can be? The Canadian Pharmaceuticals patent case is an example of how WTO Panel strictly interpreted the provisions of Article 30 and gave primacy to the rights of the patent holder over the rights of the third parties ([Haag, 2002](#)). The facts of the case are such that the Canadian law provided for stockpiling of the medicines without the authority of the patentee which the WTO Panel held not to be covered by the limited exception concept under Article 30 of TRIPS.

The scope of Article 30 seems restricted, and maybe it was enshrined in the TRIPS just to act as a guiding principle for the member countries. The member countries can provide limited exceptions keeping in view the conditions contained therein. But this Article cannot be used for the purposes of allowing compulsory licensing

or parallel importation because these measures cannot be classified as limited exception. Hence, we move on to discuss compulsory licensing at the international level with regard to the changes that have been made by the Doha Declaration.

TRIPS Flexibilities and Public Health

Since its inception, the TRIPS Agreement has been the object of much heated discussion concerning its effect on public health in developing countries. Several members were of the opinion that the agreement initially paid too little attention to the problems of poorer developing countries with limited capacity to produce medicines themselves.

In 2001, the WTO Ministerial Conference adopted a separate Declaration on the TRIPS Agreement and Public Health. This declaration is called Doha Declaration which explicitly states that “the TRIPS Agreement should be interpreted as supportive of the members’ right to protect public health and, in particular, to promote access to medicines for all.” The Declaration thus sets the scene for differentiating intellectual property policies to protect public health. It explicitly recognizes “the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

All members, including developing country members, are entitled to use the flexibility provided by the TRIPS Agreement to achieve national policy objectives for public health, such as providing affordable medicines for HIV/AIDS. The declaration is more than an expression of political ambition. It provides a legal basis for interpreting the TRIPS Agreement as consistent with public health objectives and for using the flexibility of the agreement for this purpose.

One area where member countries have some flexibility is in the scope of the patent protection granted at the national level. According to the TRIPS Agreement, members must make patent protection available for “products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” This means that all members are obliged to make patent protection available for new pharmaceutical inventions.

However, there is no obligation to make patent protection available for new ways of using existing patented inventions. It is also up to the national authorities to assess what constitutes an “inventive step”; therefore the threshold for deciding whether a new medicine is eligible for patent protection is flexible. The scope of the exclusive rights conferred on the patentee is also flexible. For example, a country is at liberty to allow research to be carried out on the basis of the invention without compensation to the right holder, thus providing others with the opportunity to further develop the patented drug.

The TRIPS Agreement does not oblige member countries to introduce penal sanctions for patent rights violations either. A country may leave it to the patentees to enforce their rights through civil remedies. A large multinational pharmaceutical company would probably be more reluctant to pursue its claim

on patent protection if it had to go through a civil law suit rather than have the state prosecutor do the job.

In many cases, developing countries have difficulty mastering the legal and technical expertise necessary to take advantage of the flexibility provided by the TRIPS Agreement. Moreover, the sheer complexity of setting up a patent protection scheme could prevent a country with inadequate resources from effectively using the flexibilities built into the TRIPS Agreement. Technical assistance is thus needed to ensure that policy-makers are aware of the options available to them when they are amending patent legislation.

The TRIPS Agreement recognizes that the need to use an invention without the endorsement of the patent holder may arise, and thus, under special circumstances, national authorities are allowed the right to compulsory licensing. Compulsory licensing schemes can be used to keep prices from increasing in developing countries as they implement the patent protection required by the TRIPS Agreement.

Developing countries may, however, find it difficult to apply compulsory licensing for several reasons. Firstly, compulsory licensing requires an effective administrative system for processing applications. Many developing countries may not have the administrative capacity necessary to establish an independent and effective system for compulsory licensing, hence the need for technical assistance mentioned above. Secondly, even when a license to produce a pharmaceutical product is granted, many of the poorer developing countries have limited facilities-or none at all-for the production of medicines. These are often countries that have serious public health problems or a high prevalence of diseases such as HIV/AIDS. They are in need of large volumes of imported medicines but at the same time have limited purchasing power.

Almost two years after the Doha Declaration, the WTO on 30 August 2003 finally adopted a system of compulsory licensing which addressed this problem of compulsory licensing in countries with insufficient domestic production capacity. The decision included a waiver of Article 31(f) of the TRIPS Agreement, and in so doing opened up for exportation to poor countries generic medicines produced on the basis of compulsory licensing.

So far, limited countries have implemented the decision, but other countries are likely to follow suit in the near future. There is still some disagreement among members as to how the TRIPS Agreement should be amended to reflect the decision. Amending the TRIPS Agreement should be a purely technical exercise that would in no way alter the content of the 30 August 2003 decision. Deviation from the carefully drafted agreement could mean a reopening of the debate.

Considering the key role some middle-income countries play in supplying the developing country market with cheap generic medicines, it could be argued that these countries have a responsibility to ensure that their national legal framework and implementation do not entail a decrease in the accessibility of essential medicines for poorer countries.

Compulsory licensing schemes will obviously never be as effective in controlling the prices of medicines as unrestricted competition from generic copies. It appears, however, that compulsory licensing is an effective bargaining tool in negotiations with patent holders on the prices of essential medicines in developing countries. Several large pharmaceutical companies have had a change of heart regarding voluntary licensing. This may be due, at least in part, to the credible threat of compulsory licensing combined with political pressure. The number of voluntary licensing schemes has increased significantly over the last few years, delivering effective affordable medicines for HIV/AIDS to an increasing number of people each year.

According to studies carried out by *Medecins Sans Frontieres*, generic competition is the most effective way of lowering drug prices. The prices of antiretroviral medicines for HIV/AIDS have been falling steadily since 2000, particularly as a result of competition from generic products from India. However, the price fall has not been sufficient in degree or scope to ensure general access to affordable medicines.

New medicines are normally highly sophisticated. It is often argued that they cannot be easily or cheaply copied without the help of the inventor or patent right holder-thus, the quality of copy medicines may be inferior, and they may not have the intended effect or may cause serious side effects. The validity of this argument for the production of generic medicines has been questioned by both experts and public sector officials.

The capacity to safeguard quality is, however, a bottleneck in most developing countries. According to the WHO, less than one in three developing countries have fully functioning drug regulatory authorities. 10 to 20 percent of sampled drugs fail quality control tests in many developing countries. The failure to follow good manufacturing practices too often results in toxic, sometimes lethal, products. To compensate for this problem, the World Health Organization has established capacity for testing the quality of generic medicines for the treatment of HIV/AIDS, malaria, and tuberculosis.

TRIPS Agreement and the Issue of Product Patenting

The TRIPS Agreement provides that patents should be available for both process and product. But, giving product patents to medicines can lead to violation of the basic human right to health as the resultant medicine's composition will be monopolised. It is argued by the scholars that product patenting can be used as a tool for the protection of human right ([Ranjan, 2008](#)). If only process patenting is allowed for the medicines then the generic medicines can help balance the diverse interests.

The Indian model of non-patenting the medicinal products (before 2005) can be used as an example of an effective legal tool to ensure affordable medicines. The Indian Patents Act, 1970 did not recognise patents on products till 2005. This led to the growth of lot of generic pharmaceuticals companies in India which became the source of cheap medicines in India and other jurisdictions (Sampath, 2006).

On the other hand, product patenting allows a temporary monopoly over the medicines for 20 years. This monopoly, due to lack of competition, bars the production of generic medicines for the period of 20 years. Non grant of product patents is surely an effective tool for making generic medicines available in the market but it is not the only tool for making affordable medicines available to the public. Moreover, accessibility of medicines will also depend on other factors as well. The delivery mechanism is one of the factors which affect the accessibility. If we see specific cases of medicines then the conflicts becomes clear in the case of HIV AIDS where the UNAIDS stated that patent protection is one such factor which is responsible for high prices of HIV medicines.

The supporters of the product patenting argue that a false conflict has been portrayed by the human rights activists. There seems to be no conflict as the intellectual property protection regime seeks to encourage the research and development of essential drugs. The monopoly provided by patent acts as an incentive for manufacturing new medicines. Therefore the IP regime promotes the human rights.

But the other side of the argument is that, allowing product patents will not be sufficient in encouraging research and development. It is also argued that not much investment goes into developing drugs that affect the poor countries. The poor countries are not seen as luxury market and therefore the companies tend to focus on manufacturing drugs that concerns the developed countries. It is therefore desirable that the governments should spend on the research and development of such medicines.

The conflict between patents and human rights can be seen in the case of South Africa where in 1977 South Africa faced a serious epidemic and passed legislation for compulsory licensing. As a result, some big pharmaceutical companies filed a lawsuit against this action but after the UN Secretary's intervention the firms withdrew their lawsuit (Swarns, 2001). These incidents clearly indicate that there is a tussle between patent rights and the human rights.

Doha Declaration: Is it really a Solution?

The effects of TRIPS Agreement on public health became evident over the course of time and this led to the adoption of a declaration on public health at Doha. It was the 4th ministerial conference of the WTO which resulted into passing of this declaration. It was affirmed in Para 4 of the said Declaration that the TRIPS Agreement does not prevent the member countries to take measures which protect public health. The TRIPS Agreement flexibilities can be used to provide compulsory licensing in case of need. Even the Paris Convention, under Article 5, talks about compulsory licensing. It was also clarified that the countries are free to determine their own healthcare needs.

However, it is difficult to say whether measures such as non-granting of product patents can be done under the TRIPS flexibility? Also, there is no certainty as to the legal status of the Doha Declaration. How much weightage will be given to the Declaration when the WTO Panel or the Appellate Body is adjudging a dispute which affects public health? These issues are also not clear. Some argue that the

Doha Declaration is a mere *ad hoc* solution and there is lot of uncertainty as to its use (Gold & Lam, 2003).

Article 31(f) of the TRIPS Agreement states that any compulsory license issued must be restricted to the domestic use. This has given rise to another issue which is that of manufacturing capacity of the member states. As highlighted by the Declaration itself, compulsory licensing does not seem to be a solution when the member countries lack the manufacturing capability. As a result, goods manufactured under compulsory licensing cannot be exported to other countries. These issues were highlighted and the result was in the form of a protocol, adopted in December 2005, which amended the TRIPS Agreement. Under this protocol the countries can issue compulsory licensing and export the medicines to other countries. Therefore, the countries having manufacturing capacity can export medicines to countries which do not have the required capability. This provision which waives the requirement of Article 31(f) can be used by least developed and developing countries by giving a notification to the TRIPS council. Rwanda became the first country to notify the council to use this provision for importing medicines.

A notable provision which is made under this arrangement is that the least developed countries are presumed to have insufficient manufacturing capability whereas the developing countries need to prove the same. This gives rise to another issue as to the factors which will determine the manufacturing capability of a country. The Appendix provides a little (rather no) support for determining the manufacturing capability of any country. This lack of clarity as to compulsory licensing acts as an impediment in the issuance of compulsory licenses.

Other impediment which affects the delivery of essential medicines is the requirement of special packaging of those medicines meant for exports. This requirement affects the cost of the medicines and resultantly the medicines become costly and the whole purpose of providing affordable medicines gets defeated. The protocol contains a proper procedure to be followed when granting compulsory licensing. There has to some efforts for voluntary licensing and if it fails then compulsory licensing can be done. This is a time consuming and burdensome procedure for any country looking for some emergency medicines.

Conclusion

In view of the apparent shortcomings highlighted above, the solution put forward by the Doha Declaration and the protocol seems to be hard choice for those countries requiring essential drugs. These countries if they fall under developing countries category will find it more difficult to get the certification as to the manufacturing capacity. The LDCs often require small amount of medicines and considering the additional costs occurred by the special packaging these companies find it a non-profit venture. In this way the medicines becomes unavailable to a large segment of the poor people.

The Authors are of the view that, there should be efforts made by WTO to recognise those countries which do not have manufacturing capability. A list of these countries can be made and published on the website of the WTO. Moreover,

the requirement of special packaging should also be relaxed in order to cut the cost. A specialised cell can be established for the purpose of supervision over such transaction. In this way the conflict can be settled down.

The Doha Declaration has failed to properly address the issue of public health. Serious diseases like Corona Virus and HIV do not wait for the procedural formalities to get completed. Many a time the time consuming process results in the medicines being not available at right time. The LDCs are the most vulnerable to many diseases and they find it really difficult and costly to get these medicines even under the compulsory licensing. The time required for the production coupled with the formalities takes a lot of time for the medicines to reach the affected places.

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