

**RESEARCH PAPER****The TRIPS Flexibilities and the Patent Law of Pakistan: A Comparative Study****<sup>1</sup>Saima Butt\* and <sup>2</sup>Noreen Akhter**

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**\*Corresponding Author**      [saima.butt2010@gmail.com](mailto:saima.butt2010@gmail.com)**ABSTRACT**

The WTO agreement on trade related aspects of intellectual property rights (TRIPS Agreement) results in the global implementation of intellectual property (IP). Global implementation of IP and particularly the protection of pharmaceutical patents apprehend that it will affect the public health and affordability of patented medicines. To overcome this issue, the TRIPS Agreement provides a range of flexibilities to ensure public health. This article analysed the provisions of Patent Ordinance 2000 of Pakistan dealing with parallel importation and compulsory licensing. The object of this study is to investigate to what extent the flexibilities provided by the TRIPS agreement has been incorporated into Pakistan's patent legislation. The methodology applied for this research is primarily comparative and bears the qualitative aspect of the issue. This research concludes that the Patent Ordinance of Pakistan fails to incorporate adequate provision of parallel importation and compulsory licensing according to the needs of its people and local industry. Accordingly, this research suggests that there is a dire need to amend the Patent Ordinance of Pakistan to make it more workable and practical.

**Keywords:**      Affordable Medicines, Compulsory License, Parallel Importation, Patent Ordinance 2000 Of Pakistan, Patent, TRIPS Flexibilities**Introduction**

The price of medicine strongly affects its consumption, particularly in countries with limited resources. In Countries with inadequate healthcare systems, the health expenditures are borne by individuals themselves with little or no government support. In Pakistan, health facilities are not fully provided by the government and almost 65% of health expenditures are made out of citizens' pockets. Competition in the market led towards price control but the introduction of patents for pharmaceutical products limited the way of generic competitors. The new patent system gives a 20-year monopoly to the patent holder. This monopoly enables the patent holder to set a high price of his own choice without facing any competition in the market. People from poor jurisdictions have to wait for twenty years to be treated with affordable medicines after the expiry of the patent.

Global implementation of the TRIPS Agreement, particularly the inception of pharmaceutical patents makes the choice very hard for developing countries including Pakistan. Pakistan was bound to confirm all its IP legislation in compliance with the TRIPS Agreement till the first of January 2001. In 2000 Pakistan promulgated Patent Ordinance 2000 of Pakistan to comply with international standards. Pharmaceutical patents result in the high prices of medicines and the same is the case in Pakistan. International reports and indexes revealed that health facilities in Pakistan are the worst in the region and one-third of the population in Pakistan living beyond the line of poverty. Government support in the health sector is inadequate and insufficient and there is a lack of facilities in government hospitals hence people are forced to move the private health care centers. The use of TRIPS flexibilities can make the situation much healthier in Pakistan. TRIPS flexibilities can ensure easy access to affordable

medicines but patent law of Pakistan is not fully equipped with TRIPS flexibilities. Proper usage of these flexibilities is very important it will enable the state authorities to cover the grey area that was created after the implementation of the TRIPS Agreement. Doha Declaration also makes it clear that the purpose of TRIPS flexibilities is to help countries with limited resources to deal with health emergencies. It is also clearly stated that whenever economic interests conflict with the obligation of the state to provide health facilities to its citizens, health concerns will prevail.

### **Literature Review**

It is an ethical obligation on the pharmaceutical companies to ensure affordable access to life-saving medicines (Michael, G. J. 2009). International law also realized this important matter and determined the responsibility of a state towards other states to assist each other in health emergencies under ethics and human rights law (Gostin, L. O. 2007). TRIPS Agreement provides flexibilities for low and middle-income countries with the object to facilitate affordable access to patented medicines (Abbas, Z. M. & Riaz, S. 2013). TRIPS flexibilities are the tools to manage the IP and to improve affordable access to quality medicines. High prices of patent medicines are a universal issue and it directly affects the economy of a country. Potential compulsory license and parallel importation provisions in the national legislation can give a better solution (Elisabeth, H. T. 2018). The private rights of multinational pharmaceutical companies should not be preferred over the public right to access essential medicines. The compulsory license provision and its use compel multinational pharmaceutical to enter into a strategic alliance with domestic firms (Raju, K.D, 2017). Developing countries should incorporate proper workable provisions related to TRIPS flexibilities to provide affordable generic to its citizens (Shanmugaiah, K. 2012). Parallel importation is also an important flexibility. Countries having provisions of parallel importation are allowed to import the product from other countries where the product is placed in the market legitimately. (Brook, 2019). The patent law of Pakistan was amended in 2002 but it failed to take full advantage of TRIPS flexibilities and it added some TRIPS plus provisions (Asim, G. 2002). It is the responsibility of the state to provide adequate and affordable health facilities and it is also the responsibility of state authorities to make proper legislation and policies to coup up with health emergencies (Butt, S. 2022).

### **Material and Methods**

Comparative legal research methodology has been applied for this research. This comparative approach will help to understand the difference between the legal provisions of the patent law of Pakistan and the flexibilities provided under the TRIPS agreement and interpretation by the Doha Declaration. It will also help us to understand and implement the true spirit of the TRIPS agreement and the Doha Declaration. For this research primary and secondary resources are used. Primary resources include the patent law of Pakistan, the TRIPS Agreement and the Doha declaration and secondary resources consist of research papers, scholarly articles and books related to the topic.

### **Flexibilities under the TRIPS Agreement and the Patent Ordinance 2000 of Pakistan**

The TRIPS Agreement provides flexibilities and enable the state authorities to use these flexibilities to handle emergencies in health sectors. Before the use of these flexibilities it is very important to have effective, workable and practical provisions in the national legislation. We will investigate the provisions of compulsory licensing and parallel importation here and find out how affectively the efficiently these provisions are incorporated.

## **Principal of Exhaustion**

The literal meaning of exhaustion is the state of being exhausted and worn out. Under the principle of exhaustion, the patent holder when selling his product in the market then his right over that product is exhausted. The second owner who purchased the product from the patent holder (first owner) has the right to gift, donate or sell the product to anybody he wants. Patent holder after the first sale cannot control the movement or use of the product because this cause restrain in trade and free competition. In common law countries, the doctrine of exhaustion is also considered as the implied license between the buyer and the seller (Carlos, 2002).

## **Principal of Exhaustion under the TRIPS Agreement**

TRIPS agreement under Article 6 also provides the principle of exhaustion. It allows the member states to adopt the principle of exhaustion which in other words known as parallel importation. Article 6 of the TRIPS Agreement narrates as

“For the purpose of dispute settlement this agreement, subject to the provision of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”

Article 28 of the TRIPS Agreement defines the rights of the patent holder. It provides the right to prevent the third party from importation but it has a footnote on this right as “like all other rights conferred under this Agreement regarding the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.” It means that footnote 6 defines that the right of the patent holder to prevent others from importation is subject to article 6 of the TRIPS Agreement which deals with exhaustion. So it is clear that the TRIPS agreement does not prevent the member state from incorporating parallel important provisions (Wei, 2017).

Doha declaration (2001) on the TRIPS Agreement and public health reaffirms the TRIPS and allows the exhaustion in the following wording “The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge,”

## **Principal of Exhaustion under the Patent Ordinance 2000**

Patent Ordinance 2000 of Pakistan defines the right of the patent holder in Article 30. In 2002 first amendment of Patent Ordinance 2000 was introduced and Article 30 was also amended. Article 30(1)(a) describes the right of the patentee against its invention when it is a product and narrates that the patentee has the right “of making, using, offering for sale, selling, or importing for these purposes that product;”. It also provides the same right to the patentee when the process is patented. Rights are provided that the patent holder has all rights related to the patented products but the limitation is also attached with these rights. As Article 30(5) (a) narrates “The rights under the patent shall not extend to (a) Acts in respect of articles which have been put on the market anywhere in the world by the owner of the patent or with his consent or by an authorized person or in any other legitimate manner such as compulsory licenses;”

This new provision introduced the principle of exhaustion which was allowed in the TRIPS Agreement under articles 6 and 28(a). However, the provision of exhaustion as elaborated under the Pakistani patent law has a very restricted and limited scope (Nasir, 2017).

It does not explain anything clearly about the exhaustion whether it allowed national exhaustion or international exhaustion. The term exhaustion, parallel importation

or even the word importation is not used and just in a few words without any explicit terms the right is granted and a lot of room is left for misinterpretation. The language of law demonstrates the intention of legislature so the language should be forceful and cover all the relevant interpretation so that the language should not be misinterpreted. Parallel importation can be used as a very important tool to access affordable medicine so this tool should be utilized to the maximum extent within the legitimate boundaries of the TRIPS Agreement. The patent law of Pakistan should explicitly add new provisions that allow parallel importation clearly for the personal use of an individual and for the government use in the government hospital. These provisions will help patients and government authorities to get access to legitimate and affordable medicines available in other jurisdictions.

### **Use of Patent without Authorization of the Patent holder/ Compulsory License**

The second important flexibility of the TRIPS Agreement is the use the invention without the authorization of the right holder in certain circumstances, such use is recognized as government use and compulsory license. Government use and compulsory licensing are very important flexibilities for developed and developing countries. This key flexibility can be used as an important tool to access affordable generic medicines. Doha Declaration reaffirms that these provisions should be utilized to minimize the suffering of people living with poor health conditions. States are independent and free to determine the grounds for granting compulsory licensing so it is the discretion of states how to incorporate these provisions and make them to facilitate their citizen to a maximum extent (Sisule & Cecilia, 2005) (Deere, 2009).

It is also very important to incorporate compulsory license provisions in such a way that it should be workable when needed. Unfortunately, many developing countries have compulsory licensing provision but the grounds for granting compulsory licensing is too narrow that these provisions are not workable and hence useless (Raju, 2017).

### **Compulsory Licensing under the TRIPS Agreement**

The TRIPS Agreement allows the use of patented inventions without the authorization of the right holder in certain circumstances. The term compulsory license is not used by the TRIPS agreement however it uses the term 'other use without authorization of the right holder' Article 31 explains it as

Where the law of a Member state allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: (a) authorization of such use shall be considered on its individual merits; (b) such use may only be permitted if, before such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable terms and conditions and that such efforts have not been successful within a reasonable time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

The TRIPS Agreement provides a facility to the Member States to manufacture the patented goods for domestic use without the authorization of the right holder, whenever needed in health emergencies. Certain limitations are also attached with such use, however, the grounds for granting compulsory license are not provided by the TRIPS and the States are free to determine the grounds of compulsory licensing according to the needs of its people. The condition of domestic use of the product made by the compulsory license highlights an issue for the countries that do not have manufacturing capacity. Doha Declaration solves the issue and gives a solution to this problem.

## **Doha Declaration on Public Health and interpretation of Article 31 of TRIPS agreement**

In 2001, a ministerial conference Doha Declaration on TRIPS and Public Health was held in Doha and an agreement was concluded between all the members of the World Trade Organization (WTO). The conflicts between the TRIPS Agreement and the health concerns of developing countries are addressed in the Doha Declaration (Anna, 2005). A disagreement was exist between developed and developing countries about the circumstances when the compulsory license will be issued and whether it is available just for 'essential medicines' or otherwise, all these questions are answered in the Doha Declaration.

Doha Declaration makes a very clear interpretation of article 31 of the TRIPS Agreement and makes it very clear that "the TRIPS Agreement doesn't and shouldn't prevent Members from taking measures to protect public health. The Doha Declaration allows the Members to use the flexibility of the TRIPS Agreement to avoid the side effect of the exclusive patent monopoly on the access to medicines. States are free to use "the right to grant the compulsory license and the freedom to determine the grounds upon which such licenses are granted....the right to determine what constitutes a national emergency or other circumstances of extreme emergency".

Doha Declaration in paragraph 6 recognized a very important issue which is related to the Member states that do not have manufacturing capacity. Countries with no manufacturing capacity or with little manufacturing capacity cannot take benefit from the compulsory licensing provisions. The Council for TRIPS was advised to find some solution to solve this problem and submit a report in 2002 to the General Council. It was not an easy task to find the solution, however after a very hard negotiation, the developed and developing countries came to an option acceptable to all. On 30<sup>th</sup> August 2003 the problem was resolved and the WTO announced that the restriction on the export of patented medicines was abolished and countries with no manufacturing capacity could import the patented medicine from another country (Deere, 2009).

### **Pakistan Patent Ordinance 2000 and Compulsory Licensing provisions**

Patent Ordinance 2000 also provides the compulsory license provisions under sections 58 and 59. In 2002 the Patent Ordinance was amended and two new provisions were added 58(iii) and 58(iv). The compulsory licensing regime under the Patent Ordinance 2000 was very weak and poorly worded and even after the amendment in 2002, it failed to equip with the strong, effective and workable compulsory licensing grounds (Asim, 2014). Here we will discuss and analyse the provisions of compulsory license in Patent Ordinance 2000 and suggest how these provisions can be made more effective and workable within the boundaries of TRIPS. Article 58 describes it as

Exploitation by a Government agency or third Person: - (1) Subject to subsection (2), where

- I. the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
- II. the federal government has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the federal government is satisfied that the exploitation of the invention in accordance with this sub-section would remedy such practices; or
- III. the patent holder refuses to grant a license to a third party on reasonable commercial terms and conditions; or

- IV. where the patent has not been exploited in a manner that contributes to the promotion of technological innovation and to the transfer and dissemination of technology,

The Federal Government may, even without the consent of the owner of the patent, decide that a Government agency or a third person designated by the Federal Government may exploit a patented invention.

Under the Patent Ordinance, of 2000 Pakistan four grounds are provided when the Federal Government has the right to grant the compulsory license and authorize the government agency or the third person to manufacture the patented product without the permission of the right holder. The use of patented invention is subject to adequate remuneration which would be paid to the patent owner.

The grounds for granting compulsory license are very narrow and limited. The first ground for granting a compulsory license is public interest. The word public interest is not defined and explained. Public interest needs to be explained properly what it includes and what it means. The term public interest is so wide that it might be misused against the public if not explained properly. There is a need to clarify and incorporate clearly that the patent invention should not impede public health and it must be used as an instrument to protect and ensure public health. In a country like Pakistan where one-third of the population are living beyond the line of poverty and 66.5% of health expenditures are made from the citizens' pockets, the high prices are the main issue to access medicines. It must be included in the compulsory licensing ground that multinational pharmaceutical companies should provide medicine at affordable prices for the public of Pakistan to avoid the consequences of the compulsory license.

The second ground of granting a compulsory license is when the patent holder practices the patent in an 'anti-competitive' way. Anti-competitive practice is not elaborated, what practices by the patent holder will be considered as anti-competitive. Procedure is not provided for how the federal government will act and control anticompetitive practices. The third ground for granting a compulsory license under the Patent Ordinance 2000 is that if the licensee fails to get a license from the patent holder on reasonable terms and conditions then the Federal government may issue a compulsory license. 'Reasonable commercial terms and conditions' need to be explained because one thing that is reasonable from one side might be unreasonable from another side and there is apprehension that this term might be misused while interpreting. It must be strongly worded that the object of giving patent right is to encourage inventions and to support the local industry to be equipped with new technologies. It should be added that the inventions should work in Pakistan on commercial terms and conditions so that the local industry learn, flourish and competitive environment grow. License by the patent holder to different licensees help to generate competition which will resultantly become the true source of technology transfer and dissemination of knowledge. It must be incorporated that the patent holder should not depend on the imported products only as imported products are unable to create fair competition. Local production units by the multinational pharmaceutical companies and the voluntary license to more local firms will help to create competition and lower the price which is direly needed for the poor patients of Pakistan.

The fourth ground of granting a compulsory license is if the patent holder fails to 'exploit in a manner which contributes to the promotion of technological innovation'. No particular time is prescribed for the patent holder during which he should exploit the invention. Duration should be fixed after which it will be considered that the invention is not exploited within reasonable time. No rules and regulations are provided about the practical application of section 58 this is the reason that the compulsory license provisions are a waste of time and inactive. There is a dire need to review the compulsory licensing

provisions and explain the administrative procedure to make it more helpful and convenient.

Article 59 also provides the ground to grant compulsory license by the controller on the request of any person on the reason of non-working of patent, again the term non-working is not explained. Article 59 enables any person to ask for a compulsory license if the patented invention is not working. Under this section, a lot of room is available for the lawmakers. They can explain the term "non-working" and add more grounds to this section to make it workable and effective. Article 58 authorizes the Federal Government to issue a compulsory license and provides four grounds to grant a compulsory license however Article 59 authorizes the controller to issue a compulsory license on the request of any person if the patented invention is not working but provides only one ground to grant a compulsory license.

Most developing countries have provisions to grant compulsory licenses just for domestic markets and not for import or export purposes. The decision of 30 August is not operative in the countries that did not amend their laws and implement the Decision through the proper legislation. Doha Declaration and implementation Decision are the result of a strong battle between the developed and developing countries hence there is a need to implement these flexibilities into the national legal system otherwise all the efforts will become useless. (Carlos, 2005).

Compulsory licensing provisions of Pakistan's patent law did not take benefit from the Doha Declaration and the Decision of 30 August. The decision allows the member countries they may incorporate provisions in their national legislation to issue a compulsory license and import drugs from other countries if they do not have manufacturing capacity. Pakistan must incorporate the Decision into its national patent legislation so that in case of any national emergency compulsory license can be issued for those medicine for which our pharmaceutical industry do not have manufacturing capacity.

It is the basic responsibility of the state to provide affordable health facilities to its citizen and making proper legislation and policies to ensure public health is also a state responsibility (Butt, 2022). It is not sufficient just to have provisions in the national legislation unless these provisions have persuasive and forceful grounds. So it is the need of the hour that Pakistan should incorporate conclusive provisions in its national legislation to avoid doubts and dubitation. Few grounds for granting a compulsory license will limit its use and it will become difficult to avail compulsory license.

## **Conclusion**

The TRIPS Agreement is the most controversial component of the WTO and with the implementation of the TRIPS, it seems that the health will be compromised over the trade. It was quite evident during the AIDS crisis when millions of people were dying in Africa because they couldn't afford the high cost of the patented drugs. AIDS crises highlight the controversy between patent and health. Indeed, other factors are also involved in access to medicines i.e. health facilities, infrastructure, administrative control and professional support but it is also true that the price of a drug is also very important to determine how many will die due to the non-availability of medicines in the upcoming years. Flexibilities provided under the TRIPS Agreement compensate for the worst effects of the TRIPS and the proper and wise use of these flexibilities can make the situation much better for the developing countries including Pakistan. Pakistan incorporates flexibilities in its national legislation but the grounds for availing the flexibilities are very narrow and restricted. Restricted ground will limit its use and at times make these flexibilities useless. There is a dire need to incorporate more ground and in this regard, Pakistan may take help from the regional countries that how they are using and implementing flexibilities in their national

legislation. India and Brazil are using these flexibilities very rightly and trying to utilize the patent system for the benefit of their people and local industry.

Decision 30 August allows the countries to issue a compulsory license for importation of drugs. The Patent law of Pakistan does not incorporate this flexibility and compulsory licensing provisions become useless for those medicines that cannot be manufactured by the local pharmaceutical industry. It is very important to include the Decision in the patent law of Pakistan as the local pharmaceutical industry cannot manufacture cancer medicines. It means Pakistan cannot issue compulsory licenses for cancer and other medicines for which it does not have manufacturing capacity. There is a dire need to include the Decision in the patent law of Pakistan to make compulsory license provisions effective and workable. All developing countries must incorporate the Decision into their national legislation to make compulsory license provisions workable for those medicines for which these countries do not have manufacturing capacity. In this way, developing countries would be able to perform their core duty towards their citizens to ensure public health. Developed countries should also incorporate the Decision into their national legislation to help the countries with no manufacturing capacity. In this way, a true atmosphere of competition and dissemination of technology will be created that will lead to affordable access to patented medicines for all from all around the world.



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