Pros and Cons of Compulsory Licensing: An Analysis of Arguments

Muhammad Zaheer Abbas

***Abstract*—Patents provide monopoly rights to patent owners to manufacture, sell, and import the product resulting in overpricing of the patented products. Without patents, the inventors and innovators can neither be adequately compensated for their costs of research nor be encouraged or motivated for further research to develop new and improved products. Patent protection is therefore accepted as a necessary evil despite its conflict with the competitions laws and human rights law (in case of pharmaceutical patents). This work analyzes arguments of both opponents and proponents of compulsory licensing which is a legitimate safeguard provided under TRIPS to check misuse of monopoly right and to deal with situations of public health crisis especially in the third world.**

***Index Terms*—Access to drugs, compulsory licensing, pharmaceutical patents, TRIPS flexibilities.**

I. Introduction

Patent[1] protection, despite being contradictory to competition law and human rights law, has been accepted worldwide as a necessary evil in order to foster innovation. However, such situations may arise when this exclusive right to exploit the creation may not stand the test of public interest and may be required to be breached in order to protect human rights. For instance, a patent on a lifesaving drug may be diluted to the detriment of the patent holder in case of an outbreak of an epidemic. "Compulsory licensing is a license issued by a state authority to a government agency, a company or other party to use a patent without the patent holder's consent" [1]. The philosophy underlying compulsory licensing is therefore based on an often repeated saying "Necessity is the mother of invention" [2]. Such situations may arise where diluting a patent becomes inevitable. The flexibility is therefore provided under law to break the patent when need arises. This flexibility is particularly important for third world countries to deal with public health crisis when access to patented drugs becomes unaffordable and patent needs to be diluted to make generic copies of the needed drugs.

II. Rationale of Compulsory Licensing

As regards concern for protection of IPRs, keeping in view the above statement, the countries can be divided into two groups whose behavior is totally different depending on interests of each group. It is a common observation that developing and under developed countries are not so much concerned about protection of IPRs and are not willing to spend on development of a costly administrative mechanism to enforce the protection of intellectual property rights. There are various reasons behind this intentional casual approach towards protection of IPRs.

Firstly, by allowing piracy, developing and underdeveloped countries can ensure availability of needed goods and services to their citizens at affordable prices.

Secondly, the local industries which produce counterfeit goods employee thousands of workers and therefore reduce unemployment.

Thirdly, in order to advance in science and technology, third world countries need maximum access to intellectual property of advanced nations.

Fourthly, more than 80% patents in developing and underdeveloped countries are owned by citizens of technologically advanced countries. Consequently, the governments of third world countries are not willing to spend huge amounts in developing effective administrative mechanism to enforce IPRs of citizens of advanced states [3].

Developed countries, on the contrary, are very much concerned about protection of intellectual property rights because their progress and economic growth, to a great extent, depends on investment in research and development. Their patent system provides incentives to speed up their technological progress, enhance their productivity, and improve their world trade position by strengthening their economy [4] In Italy, for instance, pharmaceutical research and development increased by more than 600 percent in a decade after Italy approved drug patent law in 1978 [5]. A limited exclusive right must be given to the patent owner to enable them to use the invention to recover the cost of their invention and have an incentive for further inventive research. Anything that interferes with the exclusive right of the patentee would certainly discourage investment in the field of research. As the progress of advanced countries is mainly due to extensive inventive research, they are concerned about the protection of IPRs, and they oppose any interference in the exclusive rights of the patentee of the invention.

"Compulsory license is an action of a government forcing an exclusive holder of a right to grant the use of that right to other upon the terms decided by the government"[6].The government, however, pays a royalty to the patent holder in order to compensate them for the use of their patent without their consent [7]. Compulsory license is therefore interference in the exclusive rights of the patentee of the invention. Incentive to innovate and create new works may be diminished as a result of compulsory licensing. There must be an incentive to invent because commercialization of new ideas involves money and effort [8]. The amount of royalties set by the state granting a compulsory license cannot

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Muhammad Zaheer Abbas is a PhD Scholar and Research Associate at the Department of Law, Faculty of Shariah & Law, International Islamic University Islamabad, Pakistan (e-mail: m.zaheer@iiu.edu.pk).

be considered as an incentive for further research; it is no way near the potential financial benefit which the patent owner would have enjoyed on an exclusive basis. Compulsory licensing is therefore opposed by many developed countries. The countries which implement compulsory licensing provisions are criticized by the United States and the foreign multinational firms because the licensee reaps the benefits of other's research without contributing their fair share to the costs incurred on research and development [9].

Critics of compulsory licensing further argue that over 90 percent of the drugs included in the Essential Drugs List published by the World Health Organization (hereinafter WHO) are not protected by United States patents. Moreover, compulsory licenses may raise safety concerns [10]; the consumers of counterfeit products are at risk because the inferior quality unapproved generics may contain many dangerous impurities. Furthermore, there are many diseases which are unique to the third world countries. If patent protection is ensured in these countries, it would provide an incentive to multinationals to invest in the research to investigate these diseases which would otherwise remain incurable; multinational pharmaceutical companies carry out investment on research and development after considering the potential financial gain. Uncertainty about patent protection may halt search for new drugs much needed by third world countries. Absence of business friendly legal climate may discourage patent owning firms to start any new ventures in a country that makes use of compulsory licensing provisions [11].

In addition to this, use of compulsory license may cause trade friction with the countries which produce patented drugs. Actual occurrence of compulsory licensing is not necessary to cause this loss; sometimes even the fear of compulsory licensing has an adverse effect on trade relations between countries [12]. Moreover, the growth of local industry in developing countries is heavily dependent on investment that comes from outside the country [13]. The decision of a government to grant compulsory licenses may lead to the loss of foreign direct investment. In order to protect their products from compulsory licensing, the pharmaceutical companies may find a different venue for their clinical trials. Therefore, a country may lose a potential source of economic growth by issuance of compulsory licenses [14]. Furthermore, as a result of weak intellectual property regime, a country becomes less competitive, and brain drain is an obvious result. It becomes nearly impossible for such countries to retain their human capital; the talented scientists and researchers leave the country in search of better opportunities elsewhere in the world [15].

Another important argument against compulsory licensing of pharmaceuticals is that the pharmaceutical companies normally lower prices, even to the extent of mere cost of production, of their much needed products in the least developed countries on humanitarian considerations [16]. Thus, in the opinion of developed countries, compulsory licensing is neither an effective nor necessary cost controlling measure.

This does not mean that there are no arguments in favor of compulsory licensing. Some are as under:

Firstly, patents, especially on pharmaceuticals, are harmful to developing and underdeveloped countries lacking their own domestic and technical infrastructure; patents may become an impediment in economic growth of such countries and availability of necessities to population of such countries. Threat of non-voluntary licensing may be helpful in negotiating a reasonable price of the needed drug acceptable to both the patent owner and the government [17].

Secondly, opposition of compulsory licensing by advanced countries may raise thoughts of 'neocolonialism' because patent protection disproportionately favors advanced countries as developing countries have much fewer patents to protect.

Thirdly, compulsory licensing of pharmaceutical patents sometimes becomes inevitable to save lives of the populace by ensuring accessibility of drugs at affordable prices; it can be used to break up monopolies and cartels, which are some of the abuses of patent rights [18].

Fourthly, sometimes delay in development of important technology is caused due to deadlocks between the improver and the original patentee. For instance, "holdup problems" occurred in the Wright Brothers [19] and Marconi [20] cases. Similarly, the broad Edison lamp patent [21] slowed down progress in the incandescent lighting field. Compulsory licensing can be used as an effective tool to resolve these deadlocks by pressurizing the original patentee to come to the terms of an agreement with the improver [22]. It can therefore help in generating rapid technical progress [23].

Fifthly, compulsory licensing becomes inevitable to deal with the situations of 'patent suppression'. By incorporating an effective mechanism of compulsory licensing, governments of developing countries may pressurize the patent holders to work the patent to maximum national advantage [24].

Sixthly, compulsory licensing might be necessary in situations where its refusal may prevent utilization of another important invention which can be significant for technological advancement or economic growth.

Seventhly, the proponents of compulsory licensing argue that compulsory licensing does not discourage research and development because the costs incurred on research are recovered from sales of the patented products in the advanced states of the world having stringent patent protection [25].

Eighthly, it is argued that compulsory licensing plays a vital role in developing and fostering a local generic pharmaceutical industry.

Lastly, apart from economic arguments, use of compulsory licensing to protect the public interest can be defended on social justice grounds; strict adherence to patent protection can hardly be recommended at the cost of human lives.

Despite criticism and drawbacks of compulsory licensing, the right of sovereign states to grant a compulsory license has been effectively recognized at international level. Since patent is a privilege granted to the patent holder by the state, government of the state can therefore limit that privilege in certain situations? This is the basic rationale for compulsory licensing. The concept came to the limelight after outbreak of pandemics like HIV/AIDS as the issue of access to necessary drugs emerged as an important global issue. The dilemma of patent rights versus patient rights deserves a detailed analysis.

III. Health Care and Access to Medicines as a Human Right

Provision of public health care has been a major concern not only for the third world countries but also for developed countries [26]. Not only international treaties and conventions but also Constitutions and municipal laws of many states acknowledge the importance of a healthy life. A number of international instruments recognize the right to health as a human right.

In 1948, the United Nations Universal Declaration of Human Rights (hereinafter UDHR) asserted that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care" [27] In 1966, Article 12 of the International Covenant on Economic, Social and Cultural Rights (hereinafter ICESCR) reaffirmed the right to health as a human right [28]. The right to health care has been further elaborated in the Convention on the Rights of Child, [29] the Convention on Elimination of all forms of Discrimination against Women (hereinafter CEDAW), [30] and the International Convention on the Elimination of All Forms of Racial Discrimination (hereinafter ICERD) [31].

Similarly, at national level, right to health as a human right has been recognized in the national constitutions of at least 135 states [32]. For instance, constitution of Thailand, [33] South Africa, [34] and Brazil [35] contains provisions guaranteeing a right to health care [36]. Access to essential medicines, though expressly recognized by only five countries as a prerequisite to the right to health [37], is given much importance under international law as an obligation of states to protect the fundamental human right to health [38].

IV. The Relationship between Trips and the Human Right to Health

TRIPS Agreement –one of the most comprehensive treaties on intellectual property rights- introduced a strict legal regime for the protection of IPRs. IPRs protection is particularly more important in the pharmaceutical industry in order to enable pharmaceutical industry to recoup its investment and development cost and to provide incentive for further innovation and research. To develop new successful molecules is a costly process which involves a lot of spending on research and development [39]. Patents are therefore considered lifeblood of the pharmaceutical industry [40].

TRIPS Agreement provided protection to patents in all fields of technology, including pharmaceuticals for a period of twenty-years [41]. Moreover, though WTO Agreements are meant to foster free trade, patent protection under TRIPS has trade restrictive implications; it not only increases the price of imported patented pharmaceuticals but also reduces the level of their trade flows [42].

Prior to TRIPS, pharmaceuticals were excluded from patent protection in domestic laws of about fifty countries. Even many of the present world's developed countries excluded pharmaceutical products from patent protection prior to TRIPS, For instance, "Germany until 1968, Switzerland until 1977, Italy until 1978, Norway, Portugal and Spain until 1992, Finland until 1995" [43]. TRIPS forced all countries to provide patent protection to pharmaceuticals [44]. However, keeping in view the problems of developing and under developed countries; they were provided extended period for compliance with the new obligations.

Nevertheless, States in the developing world are faced with a dilemma with pharmaceutical patent protection on one hand and access to drugs on the other hand. Higher price of drugs due to monopoly provided to the patent holders is a common concern of developing countries considering stronger IPRs protection [45]. When TRIPS Agreement was concluded, the problems faced by the third world countries, especially due to an outbreak of epidemics and pandemics, were not foreseen and public health concern was not given due importance.

Towards the end of 1990s, with the outbreak of HIV/AIDS pandemic, especially in Africa, the relationship between access to medicines and TRIPS Agreement was discussed at World Health Organization (WHO) and World Intellectual Property Organization (WIPO) in order to address the problems faced by the developing world [46]. Public health concern as a political priority emerged for the first time at international level [47].

In 2001, the United Nations Sub-Commission on Human Rights [48] recognized that "there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other" [49] The World Intellectual Property Organization (WIPO) also says that "conflicts may exist" between the two [50] Doha Declaration 2001 and WTO General Council's Waiver Decision of 2003 were the result of the efforts of the representatives of third world countries who raised their voices at 2001 WTO ministerial conference.

Thus, changes were made in the TRIPS obligations to provide more flexibility to the poorer countries and to increase the safeguards that countries could use remaining within TRIPS obligations to improve public health care. However, whether the changes were substantial or cosmetic and to what extent the third world countries have been able to use the flexibilities are a debatable issue and this debate is beyond scope of this work. The human rights impact depends on how the developing countries practically use the safeguards provided under TRIPS Agreement.

V. Conclusion

Although patent encourages monopoly and overpricing, it is a necessary evil because without patent protection firms have no incentive to develop new products. Thus, patent protection is necessary to ensure innovation; the patent is therefore an imperfect but effective instrument to promote the development of new products. The pharmaceutical patent protection, however, works well only in high income countries with citizens having purchasing power to buy expensive patented pharmaceuticals. It does not work well in developing and least developed countries because of different factors, affordable access to medicines being the most important of them.

Compulsory licensing is therefore yet another necessary evil. It is a violation of the rights of the patent holder. But this violation sometimes becomes necessary in order to avoid misuse of monopoly right and to protect human right to health. Compulsory licensing is one of the most

comprehensively debated concept at international level. Representatives of the developing countries and non-governmental organizations express concern that stringent patent law will inhibit access to essential drugs [51]. On the contrary, there are those who argue that not protecting IPRs will inhibit access to health care because the monopoly provided to pharmaceutical companies through patent protection enables them to recover costs of research and development and to finance further research and development projects [52].Not protecting IPRs adversely affects the access to essential medicines because of the reluctance of pharmaceutical firms to introduce products in the countries lacking patent protection [53]. To sum up, a compulsory license falls mid-way; neither full patent protection is granted, nor is it denied altogether.

Appendixes, if needed, appear before the acknowledgment.

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Muhammad Zaheer Abbas was born in Pakistan on January 15, 1986. In 2010, he completed his LL.B (Hons) with distinction from International Islamic University, Islamabad. In 2012, he completed LL.M International Law with distinction from the same university and got enrolled in PhD Law in the same university after scoring highest marks in GAT Subject that was conducted for screening of PhD candidates.

In January 2011, he joined Department of Law in the International Islamic University Islamabad as a regular faculty member. Presently he is working as RESEARCH ASSOCIATE at Faculty of Shariah& Law, International Islamic University, Islamabad. He is Editorial Assistant of 'Islamabad Law Review', a research journal of Faculty of Shariah& Law.

Author worked as Executive Assistant with Prof. Brady Steele Coleman, HEC Professor of Law from America, during Spring Semester 2011.The Author has written and reviewed many articles for Islamabad Law Review as Editorial member of the Journal. His recent research includes:

"Practical Implications in the Enforcement of Theoretically Existing Tenancy Laws in Islamabad", the Capital of Pakistan, IUB-Research Journal of Social Sciences and Humanities, 2013.

"TRIPS Flexibilities: Implementation Gaps between Theory and Practice", Nordic Journal of Commercial Laws, 2013

"Evolution of Compulsory Licensing: An Analysis of Key Developments before and after TRIPS", Pakistan Perspectives, 2013

Mr. Abbas is Coordinator of Transparency International- Pakistan in his university. He is also focal person from his university for Intellectual Property Organization (IPO) Pakistan.