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Compulsory Licensing of Pharmaceuticals Patent in Developing Nations:-Legal Issues and Challenges

Wasif Reza Molla*

Research Scholar, Department of Law, University of Burdwan, West Bengal, India

ABSTRACT

Compulsory licensing of pharmaceuticals remains a contentiousissue specially with developing nations. The Agreement on Trade-Related Aspects of Property Rights (TRIPS Agreement) expresses that all signatories are obliged to grant product patent to pharmaceutical items. Thus, the cost of pharmaceuticals has tended to increase, affecting individuals in developing nations. The adoption of a product patent framework in these nations has impaired people of marginal section who afford to purchase medicine. A recent survey shows since the start of the scourge, more than 70 million individuals have been tainted with the HIV infection and around 35 million individuals have died of HIV. Worldwide, 36.7 million individuals were living with HIV toward the end of 2016. An expected 0.8% of grown-ups adult 15– 49 years worldwide are living with HIV, in spite of the fact that the weight of the pestilence keeps on changing impressively amongst nations.The vast majority of people living with HIV are to be found in low-and middle-income countries, with an estimated 25.5 million living in Sub-Saharan Africa. Among this group 19.4 million are living in East and Southern Africa which saw 44% of new HIV infections globally in 2016.Around 93% of those infected with the AIDS virus can't stand to purchase the anti-retroviral solution which they require. According to The Joint Program of the United Nations on AIDS unequal access to treatment at worthy costs is one of the fundamental reasons behind the low levels of survival in poor countries. In developing countries the poor are casualties of countless diseases such as tuberculosis, malaria, respiratory contaminations, diarrhea for which there is practically no access to drug. The treatment of different ailments, for example, diabetes, asthma, coronary illness and psychological illness is deficient as the drug accessible is beyond the purchasing power of an extensive piece of the populace. Nevertheless, the TRIPs agreement contains a few arrangements which enable nations to dispense with the negative outcomes of granting product patent. In the afore said back drop this paper contend that compulsory licensing is a primary instrument that developing countries may use in particular conditions to ensure the access of patented medicines to poor people. It then turns to the second issue regarding effectiveness of the TRIPS flexibilities, specifically in the Post-Doha environment,it goes on to discuss the challenges developing nations faced in utilizing compulsory licensing and concludes with few recommendations for organizing a convincingcompulsory licensing framework for generalpublichealth purposes in developing nations.

KEYWORDS: Compulsory licensing, Access to medicine, Pharmaceutical Patent , TRIPS flexibilities, Doha Declaration, WTO Waiver Decision

***Corresponding Author**

Wasif Reza Molla

Research Scholar,

Department of Law, University of Burdwan,

West Bengal, India

E Mail ID - wasifreza@yahoo.in

INTRODUCTION

The idea of intellectual property rights isbased on the natural principle that the individual who made intellectual contribution must have an exclusive right to appreciate his rewards for all the hard work. It sounds very consistent, yet the monopoly right given to the inventor isn't just in coordinate struggle with the competition laws yet additionally has insinuation concerning Human Rights law. Patent approach impacts the rate and trend of development for health, playing a positive or negative role depending upon how it is formed and implemented .Patent strategy additionally has basic outcome for access to existing medicines and medicaladvancement[1]thus, there is a need to give safeguard to guarantee that this exclusive right of the patent holder isn't abused. Compulsory licensing is one such shield under which government of the state that granted the patent could enable a third party to utilize the patent without assent of the patent holder on payment of a rationalroyalty or compensation to the patent holder. It is an involuntary contract imposed upon a patent holder by a government entity, the compulsory license grants permission to the government entity or a third party to use the intellectual property rights to further some political or social objective[2].This shield is especially valuable with respects to pharmaceuticals particularly in the occasions of general health emergency when underprivileged states have no other alternative but to keep in mind the end goal to enhance the access to reasonable basic medicines to their poor citizens with constrained purchasing power.But developing nations encounter trouble in utilizing compulsory licensing as a measure to adjust patent protection and access to pharmaceuticals. These challenges persist in spite of important endeavors made by some WorldTrade Organization (WTO) members. As patent protection conceded under the TRIPS Agreement often diminish access to drugs basically in poor WTO members countries so it gives WTO members with specific flexibilities to neutralize the power of patent holders. WTO members have the privilege to allow compulsory licenses to some patentedproducts, furthermore the Declaration on the TRIPS Agreement and Public Health (the DohaDeclaration) reaffirmed this flexibility of WTO members in bypassing patent rights to secure access to drugs by just requiring the payment of "reasonable" compensation. Accordingly, nations now should be able to all the more viably balance patent protections with the requirement for access to medicines by using these flexibilities at whatever point there is a critical requirement for them[3]. Suchflexibility is essential for the adoption of public policies geared to protecting health.Still some low-and middle income WTO members have the accompanying troubles in utilizing compulsory licenses to adjust patent protection with access to medicines in their domain.Such as the pharmaceutical MNCs and rich WTO countries still have a concrete aversion to the utilization of compulsory licensing by poor WTO members. The number and range of territorial and extra territorial legal disputes are likely to

increase in cases of compulsory licensing for new patented medicines. There is however no criteria or models to be considered by an administration giving acompulsory licensing or by a court choosing the legitimateness of such permit. Though some researchers are of opinion that point by point criteria on compulsory licensing would really confine the open door for compulsory licensingare amongthefew problemswhich thelow-and middle income WTO members faces in utilizing compulsory licenses.

TRIPS FLEXIBILITIES AND DOHA DECLARATION

The TRIPS Agreement is the most thorough multinational agreement that administers intellectual property protection.It set out a common global standard for the protection of intellectual property rights, including patents[4]. Perceiving that the regional attributes of patent protection caused huge inefficiencies in global trade, WTO members set up this widespread uniform and conventional intellectual property protection regime (the TRIPS Agreement) with a hope that both developed and developing nations would be in an ideal situation, and would increase the rate and levels of innovative improvement and exchange among WTO members.However, this far reaching protected innovation understanding neglected to give careful consideration to how such widespread intellectual property protectionwould influence individuals living in various nations with diverse social and financial needs.At that time when the TRIPSnegotiations began, over 40countries in the world did not grant patent protection for pharmaceutical products.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.One of the most contentious provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights(TRIPS) in patent regime is the product patent protection for pharmaceutical inventions .The TRIPS Agreement now requires all WTO members, with few exceptions, to adapt this laws to the minimum standards of IPR protection. In order to fulfill the TRIPS obligation, developing nations introduced product patent protection by amending their patent laws.It had a particularly significant impact in developing country like India, a country which had been a major international source of generic medicines. To comply with the TRIPS obligation, India introduced product patent protection from 1st January 2005 by amending the Patent Act of 1970 and in doing so, like other developing nations India in a way re-establish the product patent regime which was prevailing before 1970 in India. Though the main objective of TRIPS is to protect IPRs worldwide and to promote scientific knowledge and advancement throughout the world but now it is not beyond understanding that it is a result of the unholy nexus amongst the developed countries and the MNCs . There was always an

apprehension in the minds of the MNCs that the time is not very far when Indian pharmaceutical companies would be dominating over the international market. Thus to stop the growth of Indian generic product in international market the developed countries being dictated by the MNCs initiated agreement in the form of TRIPS to work their technologies in monopoly over the developing and underdeveloped countries. India was neither willing nor in a position to sign the TRIPS agreement. Nevertheless under the continuous pressure of various international monetary organizations especially World Bank, India was compelled to become a member of TRIPS. However to decrease the negative impacts of patent protection (for both pharmaceutical items and their manufacturing forms) on access to drugs in poor WTO member nations some flexibilities has been incorporated in TRIPS (otherwise called the "TRIPS public health safeguards")Theseflexibilitiesareparallel importation,exceptions to exclusive rights (also known as "Bolar exception) and compulsory licensing. Among these flexibilities, compulsory licensing has been the most important option for poor WTO members Article 31 of TRIPS recognized the right of member to invoke compulsory licensing. Rather than listing or characterizing circumstances in which compulsory licensemight be granted, it just sets out specific conditions for the issuance of non-voluntary license. Leaving the issue to the signatory states to choose each instance of granting a compulsory license on case-by-case basis becauseit would be against the pith and soul of Article 31 of TRIPS Agreement if a person turns out to be lawfully qualified to get compulsory license automatically upon fulfillment of some specific conditions.There is a condition that proposed user must have made attempted for reasonable business endeavors to consult with the owner of the patent for consent to utilize the patent for a reasonable period of time.In any case, this state of earlier arrangement with the patent holder may be mete out in the instances of national crisis, situations of extreme urgency, or for public non-commercial use. The TRIPS Agreement makes an arrangement that the owner of the patent must be given a satisfactory royalty as a matter of right. Compensation is settled on the case-by-case basis depending upon the economic value of the approval. In order to decide if any decision of granting a compulsory license was legitimately substantial and to give a chance to the patent owner to counteract abuse of his right, TRIPS Agreement obliges the signatory states to a judicial review or other autonomous review.But the high price of the patented branded medicines has increased concern on national and international level. This apprehension contributed to the outcome at Doha in November 2001. In response to the issue of patents on pharmaceutical drugs, the conference released the "Declaration on the TRIPS agreement and public health" on November 14, 2001 and later on August 30th,2003. The declaration did not offer any substantial revisions to TRIPS rather, it recognized flexibilities that already exist in the agreement, such as Article 31, which establishes the procedures by which a compulsory license may be granted .According to Article 31(f), a compulsory

license must be “predominantly for the supply of the domestic market of the member authorizing such use.” The Doha declaration stressed that TRIPS “should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.” Moreover, “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”

EXPERIENCES OF COMPULSORY LICENSES GRANTED BY SOME DEVELOPING COUNTRIES

For the previous few years in its yearly Special 301 Reports, the US has consistently reprimanded nations that don't have compulsory licensing benchmarks that Big Pharma companies ratifies , the nations that intimidated to issue compulsory licensing, or that have really had the boldness to issue a compulsory licensing. It happened many times as in cases of Brazil U.S. initiated a WTO dispute against Brazil over a longstanding issue between the two countries regarding Article 68 of Brazil’s patent law, which requires all patent owners to manufacture their patented products in Brazil or else be subject to the compulsory licensing of their patents. In addition to these U.S. represented a serious concern with deficient IPR protection in Thailand, in late 2006 and early 2007, there were further indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products. There was vociferous threat against India after it issued only one compulsory licenses on an overrated growth medication, the United States continues to monitor India’s application of its compulsory licensing law. The United States requests clarity from the Government of India regarding the compulsory license decision-making process, as it affects U.S. stakeholders. The United Sates continues to monitor developments concerning compulsory licensing of pharmaceutical and agricultural chemical products in Ecuador. The United States remains concerned by Indonesian government statements indicating that Indonesia failed to abide by Indonesian legal procedures in issuing a compulsory license decree in 2012 and Indonesian patent law does not require individual merits review in connection with the grant of compulsory licenses.

In spite of its numerous allegations, subtle provocations, and reserved alcove moves against compulsory licensing, the USTR's bark has been a whole lot louder than its chomp. That hasn't halted a few nations, for example, India, Brazil, and Thailand from briefly calling it quits, however all developing nations ought to understand that they can't adequately address monopolies on drugs if they are unwilling to act independently and together to utilize their sovereign forces and universally settled upon rights to issue compulsory and government utilization licenses when it is to their greatest advantage to do such. Likewise in spite of U.S. threat, some striking nations have as of late

issued compulsory licensing or have started ventures to do as such. Most promisingly, Malaysia issued a compulsory licensing for Gilead hepatitis C prescriptions, sofosbuvir, in September, 2017, additionally, Colombia has tidied itself off from dreadful threat against its tranquility procedure and a speculator state-question settlement guarantee when it issued an open intrigue revelation on Novartis' tumor pharmaceutical, imatinibmesylate, that would have legitimized the issuance of a compulsory licensing. Rather than forever throwing in the towel, Colombia has as of late started a similar sort of open intrigue statement to have the capacity to issue compulsory licensing if necessary to increase moderate access to HCV medicines.

These two late activities on compulsory licensing are gaining wails of challenge from Big Pharma and thundering in the U.S. government, which dependably jumps to the protection of its pharmaceutical paymasters. Malaysia and Colombia, and whatever other nation that steps up with regards to issue compulsory licensing, should rest guaranteed that such licenses are totally legitimate under the WTO TRIPS Agreement. Additionally, there are numerous points of reference for mandatory, government utilizes, and legal licenses in the U.S., Germany, Italy and numerous other nations. Likewise, developing nations ought to progressively act in an organized manner to safeguard their entitlement to embrace and send reasonable and simple to-utilize necessary, government utilize, and legal licenses. Their utilization can wind up routine as opposed to exemption where patent holder keep on denying access through voluntary licenses or moderate costing of their invention.

REASONS FOR UTILIZING COMPULSORY LICENSING MORE ACTIVELY AND COMPREHENSIVELY IN POOR COUNTRIES

Compulsory licensing has conjointly been recognized as a helpful approach toincrease access to patented medicines by many scholars and activists. If a Governmentof developingcountry issues a compulsory license for the production of a patented drug, then generic drugmakersarelegally allowed to manufacture and sell the patenteddrug. Being excluded from patent protection, the drug are oftenproduced at comparativelylow price by generic drug manufacturers and so be obtainable at low price to thosewho want it within thecountry. Thoughcompulsory licensing is neither a sole nor acomplete solution to the problem of access to patented medicines in developing countries. However, it should be used actively and, if necessary, combined with alternativeproposals, to increase access to patented medicines in these countries at leasttillother proposals become totally operational. The consequences of compulsory licensing arequickand effective, compared to alternative proposals that take an extended time to be totally effectivedue to their various challenges.Compulsory licensing is an efficient policy option inreducing cost of patented medicines in developing countries, as long as thesegovernments have the robust political will to implement them. Firstly, theeffect of compulsory

licensing is prompt as a result of, as reconfirmed within theDoha Declaration there are no more legal barriers that prevent developing countries fromgranting compulsory licenses to increase access to patented medicines. Despiteseveral lawsuits filed by international pharmaceutical firms, the legality ofcompulsory licensing has been confirmed by the TRIPS Agreement and also the Paragraph 6 system, the Doha Declaration.Compulsory licensing willreduce drugprices (which usuallyare set high through patent monopoly in developingcountries) effectively by merely depriving patent owners of their monopoly power,and by making free competition within the market[5].

The effects of compulsory licensing are overall positive, thoughit mayhave some negative effects also. The foremost positive impact of compulsory licensing is to reduce the cost of patented medicines considerably by permitting the manufacture or import of generic medicines. This alone saves the lives of poor patients who were unable to get these costly medicines. For instance, in Malaya, the value of an HIV/AIDS medicationmade with 3 substances (which was USD$363 per month per patient in 2001) was reduced to USD$115 whencompulsory licenses were granted by the Malaysian government for twoof those substances in 2003.In India interestingly when the Bayer Corporation case was pending before the Intellectual Property Appellate Board Cipla, an Indian pharmaceutical company, has immediately slashed the price of its cancer drugs, including sorafenibtosylate, which it now offers at Rs6,840 (approximately US$128) per month. The Swiss company Roche has also slashed prices of some of itslife-saving drugs. Being aforementioned, the main drawback of compulsory licensing is to discourage investment in R&D for brand spanking new medicines, the development of whichis crucial to the protection of the lives andhealth of people at large. However, it'suncertain that compulsory licensing can significantly reducethe quantity of R&D investment within the pharmaceutical sector because investment policies aredifficult and aremoredoubtless to be influenced by factors more weighty than compulsory licensing in poor countriesas an example, if a substantial product demand is anticipated to exist in major markets like the EU, the US and Japan, pharmaceutical manufactures can invest their capital to develop these medicines, despitewhether or not some poor countries might grant compulsory licenses for them[6].

Pharmaceutical firms do, after all, earn most of their profits fromdeveloped markets, not from developing markets. Therefore, on a surface level, it issafe to assume that the majorityhuge pharmaceutical firmshaven't reduced their R&Dinvestment despite manycompulsory licenses granted for their pharmaceutical patents. Altogether, the impact of compulsory licensing is toincrease access to patented medicines in developing countries are rathermore positive than negative.While granting and implementing patent rights has been reinforced indeveloping countries in line with the patent protection necessities of the TRIPS Agreement, a lot of developing countries becamecurious aboutcompulsorylicensing as a measureto extend access to patented medicines, particularlywhen

generic versions areavailable at abundant lower costs in other countries. There are alsomany reasons for this growing interest of governments of developing countries in compulsory licensing than other proposals. First of all,the result of mandatory licensing on the value of patented medicines is quick andeffective, providing cheaper generic Medicines.The government of a developing country willbe able to reducethe price of a patentedmedicationconsiderably by granting a compulsory license as a result of such a license canenable themanufacture or import of generic medicines in that country. Asmarket competition isone of the foremost powerful measures which willreduce drug costs. Secondly, a real andimmediate risk of compulsory licensing will encourage patent ownersto reducetheir drug costs or to work drug donation programs voluntarily for the patients ofdeveloping countries as a result ofthat they mayneed to avoid the compulsory licensingoftheir medicines.Lastly, compulsory licensing are oftena decent policy for thegovernments of developing countries thatneedto safeguard their infant industriesuntil those industries become old because compulsory licensing could allow follow of innovations and local producing of generic medicines.

For the reasons talked about over, the requirement for compulsory licensing has developed, and an expanding number of developing nations have turned out to be keen on compulsory licensing. Since the Doha Declaration, mandatory licenses have been conceded in a few nations, including, however not constrained to, Malaysia, Indonesia, Thailand and Brazil has granted compulsory licensing. In 2003, the Malaysian Ministry of Domestic Trade and Shopper Affairs conceded a mandatory permit (on the grounds of "government use") to import nonexclusive solutions for the treatment of HIV/AIDS (didanosine, zidovudine and lamivudine+zidovidine, mark name: Combivir®) from India.In 2004, Indonesia conceded compulsory licenses for the residential generation of two nonexclusive HIV/AIDS drugs (lamivudine and nevirapine), setting the remuneration for patent owner at 0.5% of the net offering value.These licenses stayed powerful until the finish of the pertinent patent term. In the vicinity of 2006 and 2007, the Thai government allowed several compulsory licenses to increase access to medicines for the treatment of HIV/AIDS and heart diseases. In 2007, the Brazilian government issued a compulsory license to import an antiretroviral medicine (efavirenz) after it failed to reduce the price of this medicine through its negotiation with the patent owner, Merck & Co[7].

CHALLENGES TO ACTIVELY AND COMPREHENSIVELY USE OF COMPULSORY LICENSING IN POOR COUNTRIES

Nation allowing compulsory licenses may confront significant difficulties. The most regular ordeal that is affirmed against a dynamic and broad utilization of compulsory licenses is that it will decrease R&D venture for new drug since it denies patent owners of their exclusive rights to produce

and sale of pharmaceuticals made with their patented inventions. However, this impact is little since, as has already been settled that investment decision of pharmaceutical companies are for the most part influenced by developednations market, where the vast majority of their profits are earned. Another contention against the wide utilization of compulsory licenses is that such licenses may negatively affect social welfare since it permits inefficientproducers to enter the market. While it is hypothetically conceivable that compulsory licenses will acquaint inefficient manufactures with the market, but practically speaking compulsory licenses will probably increment and helpto makefair distributionofsocial welfare. It does this by making rivalry in the market, and giving little and moderate sized pharmaceutical companies great business openings. Giving these business openings likewise is probably going to expand social welfare in the long run on the grounds that the general public can have recourse of new drugs. Finally, a wide utilization of compulsory licenses can be criticized in light of the fact that it would unjustly disperse of the financial weight of R&D for new pharmaceuticals by making patients in developed nations to a great extent or exclusively in charge of bearing the financial weight of R&D for newmedicine , while giving patients in developing nations the enjoyment of "free rides."This is a moral inquiry that should be looked into from a social equity point of view. Practically speaking, one awesome test to a wide utilization of compulsory licenses by developing nations would be the danger of trade retaliation by developed nations[8]. The danger of trade retaliation striking back is frequently of extraordinary worry to numerous developingnations into their thought of whether or nottograntcompulsory licenses to increase access to medications. Without a doubt, the extent of thesetrade retaliationmay not be constrained to the particular items or enterprises that are specifically influenced by the compulsory licenses conceded by developingnations. Developing nations can beespecially helpless against this kind of risk, particularly when their domestic ventures are young or depend extraordinarily on international trade.The danger of trade retaliationsis very genuine, and developing nations are some of the time made alert that by issuing compulsory licenses they walk a fine political line. For instance, after the Thai government conceded compulsory licenses to expand access to a few patented medicinesin 2007, the United States Trade Representative lifted Thailand to the priority watchlist in its yearly Special Report, particularly referring to the Thai government's compulsory authorizing as proof of debilitating patent rights. The European Union Trade Commissioner additionally sent a letter to the Thai government and cautioned that Thailand ought not make additionally move to compel pharmaceutical organizations to diminish the cost of their pharmaceuticals. The USTR has placed India on its “priority watch” list for two years in a row, saying the country’s patent laws unfairly favor local drug makers .Another basic Challengeis the absence of concurrence amongst developed and developing nations on whether necessary permitting ought to be utilized widely or just once in a

while in developing nation settings. The TRIPS Agreement and the Doha Declaration have not constrained the extent of disease for which an obligatory permit could be issued,even sodeveloped nations are as yet endeavoring to restrict the utilization and extent of compulsory licenses and to strengthen patent protection for medicinesin Developing nations through purported " TRIPS-plus" arrangements which might be incorporated into bilateral or regional trade agreements. Theone critical challenges to a wide utilization of compulsory licenses in developing nations is that these nations have close to nothing (and regularly clashing) data on how their compulsory licenses may impact or be affected economic and technical development. For instance, a few people contend that a nation conceding compulsory licenseswill encounter diminishes in decreases in export, foreign investment and innovative activities, while others contend that a nation's compulsorylicensing is irrelevant to economic and technical development in that nation. This inadequate and conflicting data on compulsory licensing effectively prompts perplexity when developing nations need to settle on choices about whether to give compulsory licensesto expand access to a specific pharmaceutical that is under patent protection.

CONCLUSION

From the above discussion it can be concluded that compulsory licensing ought to be considered as a basic component in patent laws and other intellectual property administrations. Developing nations should neglect any endeavors by developed nations to restrain under reciprocal or under bilateral or other agreements the extent of and grounds for compulsory licensing. The grounds and conditions for compulsory licensing ought to be deliberately controlled by national laws. The degree to which such licenses would be accessible and compelling should rely upon the arrangements of national enactment and on its adequate administration by national experts. Developing nations should have the greatest conceivable opportunity under global guidelines to plan their compulsory licensing frameworks, as per their own advantages and needs, incorporating into such regions as the assurance of protection of health and the environment. Courts in developing countries can play an important role in improving access to medicines in their countries if they incorporate a right to health perspective when adjudicating patent cases involving pharmaceutical products. By the patent weapon of interpretation judiciary must come forward as and when required with liberal interpretation so that social justice actually prevail .Further, the provisions like compulsory licence and government use must be granted as much as possible without fear of criticism from the developed nations or threat to with draw FDI by MNCs. Hence, amendments to

the existing provisions on scope of patentability and compulsory licence are required for the effective implementation of the TRIPS flexibilities.

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