Journal of Intellectual Property Rights
Vol 22, January 2017, pp 23-31

Compulsory v *Voluntary Licensing*: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries

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Received 27 March 2016; accepted 11 November 2016

Compulsory licensing (CL) (the TRIPS language is that other use without the authorisation of the right holder, A.3) is provided under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) regime under the World Trade Organization (WTO). Across the world, the CL on IPRs is granted on similar grounds like unreasonably exorbitant prices of a medicine; patent being not worked in the country; where substantial public interest is affected by the way in which IPR holder is exercising his rights etc. The Doha Declaration on Public Health provides special privileges for countries without manufacturing facilities.

Presently, more and more multinational pharma companies are turned into strategic alliances with domestic companies for manufacturing patented drugs in order to avoid CL. For example, the Swiss drug maker Hoffman La Roche has entered into an agreement with Emacure Pharmaceuticals for locally manufacturing three patented cancer drugs in India. Strides Arcolab has entered into collaboration with US Pharma Gilead Sciences for manufacturing HIV/Drugs. The first CL case in India has compelled multinational pharmaceutical companies to change their strategy of strategic collaborations and technology transfers with domestic companies. It is argued that a threat of CL encourages parties for entering into voluntary licensing and it is economical and an alternative option (not exclusive) for developing countries in providing essential medicines to poor people.

Keywords: TRIPS, compulsory licensing, voluntary licensing, developing countries

The philosophy of granting patent is to provide incentive to innovation and monopoly for a limited period of time.[1] The patenting supporter argues that the patent system is indispensable as it encourages research and creativity, and enhances a country's technological and economic development.[2] However, patent rights should not be a license to exploit and misused by the benefit of the multinational companies that are detrimental to the interest of public health protection. The social good and public rights cannot be overridden by private rights under the intellectual property protection umbrella of the TRIPS agreement. The human right to health guarantees a system of health protection for all under many international law conventions.[3] "Compulsory licensing (CL)" is a non-voluntary licensing from the Government without the consent of the patentee in order to protect public interest which acts as a cushion to balance the interest between patentee's rights and rights of public at large. Thus the "CL therefore serves to strike balance between two disparate objectives- rewarding patentees for their invention and making the patented products, particularly pharmaceutical products, available to large population in developing and under developed countries at a cheaper and affordable price".[4] The CL may constitute an important tool to promote competition and increase the affordability of drugs, while ensuring that the patent owner obtains compensation for the use of the invention.[5] However, the pharmaceutical industry all over the world has opposed to CL and they argue that it will kill innovation and discourage R&D.[6]

India issued its first compulsory licensing order in favour of a domestic pharma company NATCO against the pharmaceutical giant Bayer, which has generated a lot of attention all over the world and compulsory licensing, has been viewed as a remedy to curb abuse of exclusivity protected by IPRs. One of the conditions for granting CL is that, before filing of an application, the applicant must take efforts to get a voluntary license from the patent owner in mutual terms and such effort must have been failed. The first CL grant itself is met with stiff opposition from the multinational pharma companies and end up in a series of litigations and apex court later upheld the validity of the CL. These litigations take lot of time, cost and tension between the patent owner and the prospective licensees.

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On the other hand, voluntary licensing between the patent holder and another manufacturer in developing countries may reduce the cost as well as offer opportunities to the patent owner as well as the licensee. The kind of opportunity depends upon the terms of license and the capacity of the licensee to build a relationship in a longer term within the purview of the intellectual property regimes.

This paper argues that a threat of issuing CL encourages the parties to negotiate a voluntary licensing and agreements which enable reduction of opportunity cost and availability of patented drugs in developing countries. But it is not my intention to argue that voluntary licensing can be replaced by CL in all circumstances. It analyses the CL provisions in the TRIPS agreement followed by CL provisions in the Indian patent law and first CL case in India in order to expose the arguments of multinational companies and will examine how India was successful in granting the CL. Third part of the paper will examine the voluntary licensing system and agreements which can demonstrate how it can provide an alternate mechanism for a harmonious relationship between the patent owner and the domestic industries and thus a viable and TRIPS legitimate mechanism to enhance access to medicines in developing countries.

Compulsory Licensing under the TRIPS Agreement

Presently there are 164 WTO members[7] who have to provide patent protection for any invention (LDCs are temporarily exempted), whether a product (such as a medicine) or a process (such as a method of producing the chemical ingredients for a medicine), while allowing certain exceptions. Article 7 of TRIPS states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to transfer dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". This provision not only talks about protecting innovation, but that innovation must be used in such a manner to balance the economic and social welfare of the society with the innovator's rights.[8]

Article 8(1) of the TRIPS provides freedom to countries in taking appropriate measures to protect public health in vital sectors in accordance with each countries socio-economic and technological development. Article 8(2) provides that "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." Hence, abuse of the monopoly power cannot be tolerated by the society especially when it affects public interest and in the case of fighting life threatening diseases like cancer and HIV. Compulsory licensing (CL) provision is incorporated in the TRIPS agreement as an antidote to monopoly power granted to the patent holder. If the voluntary licenses are refused by the patentee, there is no other choice than to issue a CL complying with the grounds clearly mentioned in the present TRIPS, which is a practice followed much before the General Agreements on Tariffs and Trade (GATT), 1947.[9]

Article 28 of the TRIPS provides for conferring exclusive rights to patent holders and this ensures that without the patent holders' permission others cannot make, use, offer for sale or import a patented process or product.[10] The term 'compulsory licensing' is not mentioned in the TRIPS agreement. However, Article 31 of the TRIPS Agreement 'on other use without the authorization of the right holder' contains a detailed set of conditions for the granting of compulsory license. The TRIPS Agreement refers to five possible specific grounds for the granting of CLs. These include refusal to deal, emergency and extreme urgency, anti-competitive practices, non-commercial use, and dependent patents. Issuing of one or more compulsory licenses drastically reduces the prices of medicines by competition in the market between proprietary medicine and generic one. Many countries have explicit CL provisions in their domestic laws when the patent holder refuse to grant voluntary licenses on reasonable commercial terms and to address national emergency or extra ordinary state of affairs occurs.[11] However, most of the developing countries never issued a CL to take advantage of the exceptions provided in the TRIPS agreement. This is mainly due to the fear of trade falls and retaliations with the developed countries.

Compulsory Licensing in India

The TRIPS Agreement provides minimum standards for the protection of intellectual property rights (IPRs) within the jurisdiction of all WTO members. The aim of the TRIPS agreement is not harmonization of domestic intellectual property laws,

but fixing minimum standards.[12] The TRIPS does not create a "uniform law", but preserves a certain degree of freedom to legislate at the national level to its members. The way in which the agreement is implemented have important implications for developing countries like India, mainly considering the conditions and their access to technology and their economic and social development. Some of the countries like South Africa amended its patent law (South African Patent Act 1978) in 1997 itself to supply more affordable medicines so as to protect the health of the people under the TRIPS regime.[13] But the Government faced stiff opposition from pharmaceutical companies against implementing the CL provisions.[14] Even in the Indian Patents and Designs Act, 1911 provides for CLs to be issued by the Controller in certain circumstances.[15] Wide powers are granted to the Controller in the Patent Act, 1970 as well.[16] In the post TRIPS regime, India amended its patent law three times in 1999, 2002 and finally in 2005 to facilitate product patent protection.[17] Compulsory licensing has been viewed as the only tool in its bag of a government to fight against monopoly pricing sanctioned by the TRIPS.[18]

Section 83 of the Patent Act, 1970 provides that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. They are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. Moreover the protection and enforcement of patent rights contribute to the promotion of technological innovation, transfer and dissemination of technology.[19] Patents are also granted to make benefit of the patented invention made available at reasonably affordable price to the public.[20]

Section 84 of the Indian Patent Act, 1970 (amended in 1999, 2002 and 2005) provides for compulsory licensing. Compulsory licensing can be granted in the following circumstances:

1 After three years of grant of patent any interested person may apply to the controller of patents for a CL.
2 The reasonable requirement of the public with regard to the patented invention has not been met.
3 That the patented invention is not available to the public at a reasonably affordable price.
4 That the patented invention is not worked in Indian Territory.

Indian CL Case

The development of a new drug is time -consuming and expensive process and the process to develop superior versions of existing drugs further ads on to the overall R & D expenditure.[21] This case exposes the argument of the multinational pharma companies that they spend huge amounts[22] for developing a drug and they have to take it back from the market in order to sustain and further innovation.

Bayer is the patentee in this case invented the drug called Sorafenib Tosylate (Carboxy Substituted Diphenyl Ureas – Nexavar is the brand name) useful for the treatment of liver and kidney cancer. The patentee filed patent application in India in 2001 and granted it in 2008.[23] The drug in question 'Nexavar' was launched in 2005 for the treatment of kidney cancer and later got approval for liver cancer as well in 2007. The patentee got regulatory approval for importing and marketing the product in India in 2008. The CL applicant was NATCO Pharma Ltd., a generic producer in India. The drug is not a lifesaving one rather life extending to the tune of four to five years. The drug was charged Rs. 2,80,428/- per month and Rs.33, 65,136/- per year. The application was filed by NATCO in 2011 under Section 84(1) of the Patent Act, 1970 and Rule 96 of the Patent Rules 2003. The applicant proposed to sell the drug for an amount of Rs.8, 800/- which is non-comparable with the proprietary Nexavar.

The Controller held that affordability question has to be evaluated carefully and it depends not only on the purchase power of the people and the amount charged by Bayer was "unaffordable" to the public in India. The patent is working in other countries since 2006 but not in India. Bayer given a justification that the quantities required in India do not economically justify a setting up of manufacturing facility in India. The Controller rejected most of the arguments of Bayer and granted the CL. The royalty paid under Section 90 was fixed as 6 per cent of the net sales by the licensee which was increased to 7 per cent by the Intellectual Property Appellate Board (IPAB) in an appeal by Bayer. It is interesting to note that this is one of the highest royalties paid in any CL case around the world. In the US the royalties range from 3 per cent to 6 per cent, Malaysia set a royalty of 4 per cent on HIV/AIDS drugs, Mozambique 2 per cent, Zambia 2.5 per cent, Ecuador 4 per cent and Indonesia 0.5 percent (WHO Guidelines For Non-Voluntary use of a Patent on Medical Technologies, TCM Series 18, 2005).

The first CL grant in India is considered as a historical one as it is an important decision for all developing countries and its TRIPS compatibility. Bayer lost in all legal points argued and ultimately find no justification for overpricing and not manufacturing the drug in India. Bayer preferred an appeal against the order of the Controller to the Intellectual Property Appellate Board (IPAB).

1 The first argument of Bayer was that NATCO has not attempted seriously to obtain a voluntary license from Bayer on reasonable terms and conditions according to Section 84 (6) (iv). But the letter written by NATCO to Bayer and its reply from Bayer clearly shows that there is a request and denial from the parties which is sufficient to fulfil the conditions of Section 84 (6) (iv).
2 On the substantial issues the IPAB ruled that Section 84 contains three conditions which need to be satisfied for the grant of CL, under which even one of the ground is sufficient for issuing the CL.
3 IPAB reiterated that the objective of patent protection is to balancing individual monopoly rights and the public's access to the benefit of the invention. Patents are an interventionist instrument, ultimately for the sake of community welfare. Article 8(1) of the TRIPS agreement allows the members to take steps for protection of public health and nutrition, and promotion of public interest vitally important to their socio-economic and technological development. If the invention is not met, the requirement of public interest cannot be satisfied. The public interest and affordability of the drug cannot be separated as two criteria.
4 The Cipla's presence in the market was not considered by the IPAB in calculating the public interest due to the infringement case filed by the appellant against Cipla in the Delhi High Court.
5 The patented drug must be made available to the public at reasonably affordable price and the contribution of an alleged infringer's market share cannot be considered.
6 The selling of the drug at Rs.2,80,000/- can by no stretch of imagination satisfy the requirement of the public.
7 A termination application was filed before the Controller by the Appellant on the ground that NATCO is supplying drugs in Pakistan and Chinese markets is of no relevance in this proceeding before the IPAB and the Controller will decide the issue on merits.
8 Hence, the IPAB dismissed the stay petition filed by Bayer against NATCO on the reason that it will jeopardise the interest of the public and will prevent the patients from leading a dignified life.
9 The IPAB did not agree with the Controller that working in India under Section 84 (1) (c) would be only complied when the patented drug is manufactured in India. The IPAB was of the view that importing of the drug can also satisfy these criteria if the manufacturing is not possible in India. Hence, manufacturing is not necessary to comply with S.84 (1) (c) of the Indian Patent Act.

The Bombay High Court has reaffirmed the findings of the IPAB and later the Supreme Court of India refused to interfere in the findings of the Bombay High Court and IPAB. This is the single successful compulsory licensing in India but it was issued in 2012 and it is not clear that whether NATCO has started producing the much awaited drug after last round of legal fight in the Supreme Court of India in 2014.

Voluntary Licensing

Issuing compulsory licensing always end with political rhetoric and threat of trade retaliation and investment red flags.[24] The grant of first compulsory license in India met with lot of resistance and litigation in various forums and took seven years to get the final verdict from the Supreme Court of India. Some activists argue that multinational companies should provide unconditional voluntary license (VL) to countries those who cannot afford the cost of patented medicines. The voluntary licenses can be granted to international organizations like WHO for nominal royalty payments which can be later paid by the respective governments who use the drug in question. The massive production can be given to generic producers and imported into needful countries.

The advantages of granting such license can be summarized as follows:

1 The negotiations can be done directly without any litigation or time consuming process.
2 This could reduce the time for issuing CL and consequent litigation.
3 This will enable transfer of technology and economic development in developing countries.
4 It is not threatening the rights of the pharma companies rather the companies get a good name for helping the developing and least developed countries.

Voluntary licenses should be promoted as it is in favourable of developing countries as it is only for local market. Parallel importation should be restricted to the extent of Doha Declaration on Public Health[25] and re-exportation to the developed countries should be banned. The TRIPS allowed compulsory licensing, but all over the world it is few in number and as a policy tool many countries are under tremendous trade pressure from its developed country partners for abandoning CL at every opportunity. Moreover, in the absence of a significant presence of domestic pharmaceutical industry in many developing and least developed countries, implementation of the CL is difficult. Even the CL is issued, human and capital investments are made more barriers than legal berries to implement the decision.

The VL has got momentum after the South African competition cases which led to VL issued by Glaxo SmithKnile and Boehringer Ingleheim pharma companies to the generic companies of South Africa.[26] Most of the countries are looking for India with largest generic pharmaceutical industry and how it is going to implement the product patent regime in the country under the TRIPS agreement. Novartis' patent application for the cancer drug Gleevec being rejected by the Indian patent office in 2006 and a legal challenge was futile before the Supreme Court of India which confirmed the Patent Office decision 2013.[27] The first CL also issued by India and it is confirmed by the Supreme Court of India as well. India utilized maximum flexibilities available within the TRIPS framework.

The VL can be also be issued in different ways such as "in-licensing", a common modelling adopted by the pharmaceutical companies which licenses a compound before or at clinical stage to generic companies which take it to the market as a product. Ranbaxy has entered into such agreements with the Debiopharm Group and Eurodrug Group.[28] Recently Gilead slashed pricing for 'Sovaldi' (its anti-Hepatitis C drug) in India as well as its proposals to tie up with seven Indian generic companies[29] for the manufacture and export of the drug and consequent reduction in prices of the drug. This VL scheme includes 91 countries participating and any country can manufacture and export into other participating countries.[30] A preliminary survey of voluntary licenses all over the world reveals that only a handful of inventions are undergone VL (Table 1).[31]

The data shows that majority of the VLs are issued for fighting a single pandemic, the HIV. Very recently

Table – 1 Number of VL issued for respective drugs

Company	No. of VLs issued	Category of treatment
GSK	8	ARV
BI	7	ARV
BMS	3	ARV
MSD	2	ARV
Roche	4	ARV/Avian Flue
Gilead	19	Hepatitis B&C -ARV
Roche	3	Cancer

Source: Basic Oxfarm Study 2007 and recent data added.

the Swiss drug maker Hoffman La Roche has entered into an agreement with Emacure Pharmaceuticals in India for locally manufacturing three patented cancer drugs. Strides Arcolab an Indian company has entered into collaboration with US pharma Gilead Sciences for manufacturing HIV/Drugs. NATCO Pharma has collaborated with Gilead Sciences for supplying generic version of Hepatitis C drug patented by Gilead on Sovaldi (sofosbuvir).[32] Gilead Science's policy on Patient Access declares that "recognition of IP is central to ensuring ongoing innovation in biomedical research ….at the same time … establishing voluntary licensing and technology transfer partnerships with generic drug manufacturers as a proven and effective approach to expanding use of patented medicines in low-income countries."[33] VL is not entered for free, but for a reasonable amount of royalty paid to the patent holder not depending upon the relative bargaining power of parties. There is no such standardized fixed royalty in the industry and the TRIPS agreement did not give proper guidelines neither for CL nor VL royalties to be paid to the patent holder other than the 2005 WHO Guidelines.

Price competitions within the generic manufacturers of VL are mostly depending upon the licensing terms and the patent holder may not allow its licensees for a huge price competition in the market. But Indian companies are offering generic versions of drugs which do not undergone VL at a cheaper price than the drugs of VL. Gilead's reduced prices are available to 100 countries under the Access Programme not for middle income countries (but only 91 countries availed it). It is interesting to note that Gilead's patent application for drug sofosbuvir had rejected by the Patent Controller in 2015.[34] This compelled Gilead to go for a VL with seven Indian generic companies to produce the same drug for the treatment of Hepatitis C.[35]

The future of parallel importation is also seems dim as it is practically and economically non-viable because of the higher prices in the developed markets and transporting cost to developing countries make it higher prices in developing country markets. Moreover, parallel importation is profitable only when there is unparalleled difference in prices in different world markets.[36]

Normally, the person or company applying for a license must have first attempted, unsuccessful, to obtain a voluntary license from the right holder on reasonable commercial terms under Article 31b of the TRIPS and corresponding provisions under domestic laws. If the attempt is failed then only any applicant can approach authorities for issuance of a CL. The only exception provided under this provision is for "national emergencies", "other circumstances of extreme urgency" or "public non-commercial use" (or "government use") or anti-competitive practices, there is no need to try for a voluntary license in these cases. Voluntary licensing in developing countries can offer opportunities for significant cost cutting in the drug manufacturing sector.[37] The Delhi High Court in *Bristol-Myers Squibb Company and another* v *J.D. Joshi and another*,[38] it was observed that BDR Pharma had not made out a prima face case for grant of a license as the applicant/ BDR Pharma did not make efforts to obtain a license from the patentee on reasonable terms and conditions and relegated the applicant/ BDR Pharma to approach the plaintiffs for voluntary license. Attempting to get a voluntary license before applying for a compulsory license is mandatory under the Indian law.[39] The due process mentioned under Section 84 has to be complied mandatorily before applying for a compulsory license. The controller must be satisfied prima facie to proceed on the CL only when the pre-requisites under Section 84 are met [Section 87(1)].

Voluntary Agreements

Voluntary agreements can be the second category of solutions to provide drugs at cheapest rates in developing countries. These terms and conditions on the price, quantity and supply arrangements are to be determined through negotiations. Accelerating Access Initiative (AAI) is a voluntary price reduction project of the UNAIDS established in the year 2000 with six multinational pharma companies[40] and transferred it to the WHO in the year 2001. The main AAI goal is to provide developing countries with access to ARV medicines at reduced prices. The agreement reduced the ARV treatment prices from US$ 12 000/year to US$ 1 200/year. The entry of the Indian generic companies in the area further reduced the prices.[41] Nineteen countries have participated in the programme and had individual agreements with pharma companies in 2002.

The countries those who negotiated for a voluntary price reduction had offered incentives for these companies like import duty reduction as did it by China. Negotiations conducted in the backdrop of CL may reap more benefits or the negotiations can also break down. Voluntary pricing scheme is working very well in other countries like Britain[42] but price regulation is necessary in countries like India for life saving medicines.[43]

Medicines and Patent Pools

Patent pools have been recognized by the international health community as an important tool to promote innovation and access to health for poor people in the world. Patent pools are collective management structures for patents and other forms of intellectual property to facilitate the availability of new technologies. It can be defined as an agreement between two or more patent owners to license one or more of their patents to one another or to third parties.[44] The principle is to make IP more readily available to entities other than the patent holder through licenses that authorizes them to use the technology.[45] A patent pool "may also be defined as the aggregation of IP rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a JV, set up specifically to administer the patent pool".[46] In 2008, the international medicine financing agency, UNITAID took initiation to make a patent pool to fight against the pandemics like HIV/AIDS.[47] WIPO is also collaborating with UNITAID to provide HIV treatment to more than 33.3 million patients all over the World.[48]

In 2011, Medicines Patent Pool (MPP) announces its first VL agreement with Gilead Sciences (UNITAID is developed the concept of MPP). The agreement allows for the production of the HIV medicines *Tenofovir, Emtricitabine, Cobicistat,* and *Elvitegravir* as well as a combination of these products in a single pill known as the "Quad".[49] This is the first time that a patent holder allowed a group of generic manufactures to produce the patented goods. The royalties fixed were 3 to 5 percent of the generic sales. The licenses allowed distribution of generic

Table 2 – Products Licensed to MPP

ARV	Date of Adult License	Pediatric License
Abacavir	July 2014	February 2013
Atazanavir	December 2013	December 2013
Cobicistat	July 2011	July 2011
Darunavir	September 2010	September 2010
Doutegravir	April 2014	April 2014
Elvitegravir	July 2011	July 2011
Emtricitabine	July 2011	July 2011
lopinavir		December 2014
Raltegravir		February 2015
Ritonavir		December 2014
Tenofovir disoproxil formulate	July 2014	July 2014
Tenofovir Alafenamide	July 2014	July 2014
TDF/FTC/EFV	June 2015	June 2015

Source: http://www.medicinespatentpool.org/licensing/target-medicines/, accessed on 24 October 2016.

drugs in more than 100 countries. This single initiative has decreased ARV prices more than 80 percent. MPP has sublicensed the deal with ten[50] generic manufacturers India in 2015. The list of medicines licensed so far to MPP is given in Table No.2.

It can be observed that the category of medicines undergone VL are mostly ARV medicines. This is important in the background of total 37 million HIV patients worldwide are suffering from this disease.[51]

Means and Ways of Enhancement of Access to Medicines in Developing Countries through Voluntary Licensing

- VL can speed up access to patented medicines than CL and an issue of a CL can expedite a VL negotiation
- Despite the threat of litigation, many Indian companies had produced generic version of drugs mainly used for HIV/AIDS before getting a VL. This may lead to unnecessary litigations.
- Pre-grant and post-grant oppositions are used effectively by the Indian companies against multinationals for making late granting of the patent or an appeal from the Controller, rather than CL arrangements to pressurise the patent holders.
- Even the CL granted, the entry of patented medicines to the market may be late by many months and the generics won't be able to market the same medicine during this period of extended litigation.
- Issuance of VL and technology transfer is the best commercially viable mode of making generics in countries without or less technology available in the pharmaceuticals sector with most of the developing countries like Sub-Saharan countries.
- VLs are non-exclusive and can have greater competition in the market, and consequent further reduction of price in the market.
- Pre-grant VLs may be to divert the attention of generic companies not to file any pre-grant opposition and subsequent market exploitation on the ground of patent grant.
- VLs are rarely offered as "voluntarily" rather, mostly as a result of litigation and civil society pressure or on the wake of the outbreak of pandemics.
- The issue of VL without transfer of technology may again delay the entry of such drugs in the market.
- The so called technology transfer done by the companies like Gilead does not add much more than the patent specification disclosure far less than producing the actual drug which will act as a delay and entry barrier of the drug in the developing country markets.
- Many licensors are able to put geographical restriction characterising counties as middle income and lower middle income according to their own definitions rather than adopting the World Bank classification for countries.
- VLs may also divide the market and only permitted to supply to government and public health programmes. This will act as a disincentive barrier for the generics to enter the market.
- The VLs can also limit the Active Pharmaceutical Ingredient (API) by putting conditions on supply of API from few suppliers prescribed by the patent holder. This may be for the active control on supply of APIs and prices of generic medicines produced. For example Gilead excluded China from sourcing APIs which will further reduce the prices.
- VLs may ask for grant back of any intellectual property developed or improvement of the product. This may act as a disincentive for the generic manufactures to further innovate on the product.

- Only exclusive licenses will give commercial incentives for the generic manufactures in a long run. But it does not promote competition in the market.
- The royalty payment standards for the VLs are neither provided in the TRIPS nor by the international agencies like the WHO which gives amble room for the patent holder to negotiate with the generic producers. If the royalties increase, it readily pass on to the ultimate patients as price rise.
- VLs may deter the governments from issuing CL, but ultimately the patent holder get number of advantages through a VL. Because the conditions in a CL is imposed by the patent offices and in the VL it is the originator company itself.
- The granting of VL did not mean that all such licensees are going to produce the generic version and reaching the market. The licensor can create a number of technical and legal barriers in order to late production and entry of the product to the market.
- According to the technical and other competence of the licensee, they may find it difficult to produce the product and market it in a competitive price in the market.
- The generic companies in India believes that if the originator company does not hold the patent yet, then there is no need to negotiate for a VL.
- Regional restrictions are not a concern of generic industries in countries like India or South Africa. Basically, even the CL is also issued for the consumption of the local market only, other than under the Doha Declaration provisions.
- But the VL still carries some of the provisions of contractual restrictions such as territory limitations, grant back and non-challenge provisions which has to be negotiated as removed.

Conclusion

It has been observed that the pharmaceutical patents under the TRIPS Agreement have increased the drug prices exorbitantly, especially in developing countries. This made the patent regime itself most unpopular especially in developing countries. Right to health is the heart of the idea of CL provisions. Voluntary licenses and patent pools are promising and a new approach to delivering affordable medicines to developing and least developed countries under the TRIPS regimes of intellectual property protection. These concepts may be converted into practical realities in treating poor patients throughout the world rather than only protecting the intellectual property rights and the interest of multinational pharmaceutical companies. There must be a balancing act between the social welfare and the protection of innovation and intellectual property rights. The system of voluntary license in any form will make the medicines more affordable and faster delivery in developing country markets. The WTO members should promote voluntary agreement system at international level like MPP and through their domestic legal system with more incentives for VL. It is not an easy task for the developing countries on the background that CL is always issued when VL is denied.

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