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Compulsory Licensing For Public Health And USA's Special 301 Pressure: An Indian Experience

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The TRIPS Agreement concluded with a win-win situation where both the developed and developing countries could incorporate their supportive provisions. But the inclusion of a broad compulsory licensing provision, which is a supportive provision for the developing countries, was against the wishes of United States which was always against any form of restrictions on the rights of the patentee. In order to achieve its aims which it had failed in the TRIPS Agreement, USA began to use its new strategy to prevent countries from using this TRIPS flexibility, by the threat of trade retaliations through Special 301 Report. India being one of the victims of US strategy had many a times faced this intimidation from USA. The researcher has thoroughly analysed the Indian position in the Special 301 Report till 2018. Also, the researcher scrutinized the effect such an act on India and how the Indian Government responded to such situation. The researcher could found that such unwelcomed behaviour on the part of the luring market in the world had affected the public health and access to patented life saving drugs in India. Any such activity is in violation of principles embodied in the TRIPS Agreement and similar international commitments and also against the basic human right to health. The researcher suggests for a strong protest against such activities either by putting the matter before WTO-DSB or by forming a regional collaboration with other similarly affected countries and take retaliatory action against US.

Keywords: Compulsory license, TRIPS Agreement, Special 301, Trade Sanction, United States Trade Representative, WTO, U.S.-India Business Council, Pharmaceutical Research and Manufacturers of America, Indian Intellectual Property Appellate Board, Department of Industrial Policy and Promotion, Doha Declaration, Priority Foreign Countries, Priority Watch List, US Generalized System of Preferences

The conflict between patents and public health is not a novel one. A patent gives the patentee a 20 year exclusive right over his patented product/process, but creates for the common man, the problems of availability, accessibility and affordability of lifesaving drugs. This exclusive right allows the patentee to decide the price of the drug, which will normally be unaffordable to the low and middle income countries.

The patent legislations over the globe which are tuned in light of TRIPS Agreement (Trade Related Aspects of Intellectual Property Rights)[1] are equipped with the provision of compulsory license. Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner.[2] In other words, it is an authorization given by a national authority to a person, without or against the consent of the title-holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights.[3] Countries can grant compulsory license in a variety of situations including instances of abuse of the exclusive right by the patentee such as unaffordable price, non-availability etc., emergency use or public non-commercial use by the Government.

This TRIPS flexibility was further strengthened by the Doha Declaration on the TRIPS Agreement and Public Health, [4] whereby utmost freedom has been given to countries to issue compulsory license for the protection of public health. Both these international documents together provide ample freedom to the member nations to use this flexibility to tackle the problems of availability, accessibility and affordability of patented medicines. Thus, compulsory licensing functions as a balancer of two conflicting interests *viz.*, patent and public health. This is especially true for developing countries like India.

The experience around the globe shows that developing countries are being pressurised by USA, the hub of pharmaceutical industry, to restrict/prohibit the use of compulsory licensing by these countries. The United States which is always against any forms of restriction including compulsory licensing on the rights of the patentee prevents the developing

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countries from using this TRIPS flexibility, by the threat of trade retaliations through their Special 301 Report. This is in violation of principles embodied in the TRIPS Agreement and similar international commitments and also against the basic human right to health.

Trade Retaliations for Compulsory License: The Special 301

The establishment of The TRIPS Agreement in April 15, 1994 was a significant step as far as intellectual property regime is concerned. It concluded with a win-win situation where both the developed and developing countries could incorporate their supportive provisions. This is especially true in the case of provision relating to compulsory license. This flexibility in the TRIPS Agreement had succeeded to overcome the persistent resistance from USA, to form an important public interest protector for the developing countries. But the USA began to use its new strategy to achieve its aims which it had failed in the TRIPS Agreement. Thus through the intimidation of trade retaliations/sanctions USA prevented other countries from using compulsory license. This is achieved through the Special 301 threat whereby USA exerts pressure on a foreign country which has a wide compulsory license provision or which had issued a compulsory license to change its policy on compulsory license to create a USA inventor friendly environment with an intimidation of trade sanctions.

The Special 301 is a mean that the United States employs to ensure protection to its intellectual property in a foreign country. It is the result of an annual review of the state of IP protection and enforcement in U.S. trading partners around the world, which the Office of the United States Trade Representative (USTR) conducts pursuant to Section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988, the Uruguay Round Agreements Act, and the Trade Facilitation and Trade Enforcement Act of 2015 (19 U.S.C. §2242).[5] The US Trade Representative's (USTR's) Special 301 Report - a Congressionally-mandated annual report that has been issued every year beginning in 1989 identifies trade barriers to US companies and products in foreign shores due the host country's intellectual property laws, including trademarks, patents, copyright, trade secrets, etc.[6]

Under the Special 301 Report countries are listed as 'Priority Foreign Countries' (PFC), 'Priority Watch List' (PWL) and 'Watch List' (WL) countries depending on the gravity of IPR violation. The aim of the 301 process was to push and prod the developing countries into accepting intellectual property rules that would allow their economies to be integrated into a global knowledge economy being led by US entrepreneurs. For this purpose it was more important for countries to give the feeling that their behaviour on intellectual property was the subject of constant surveillance. Thus the special 301 report threatens and rewards countries via inclusion on or delisting from its annual 'Watch List', 'Priority Watch List' and Priority Foreign Country list and has the power to implement unilateral trade sanctions when U.S. demands are not met. It is therefore a weapon of intimidation for USA against foreign countries to be in pace with the US IP standards thereby protecting the US inventors rights in foreign countries. Trade sanctions were the most effective way to get quick action from a country on intellectual property.[7]

The major change that made to the Special 301 process by the TRIPS is that the agreement had specifically prohibited unilateral sanctions and launched a dispute resolution process by the establishment of a Dispute Settlement Body (DSB) to deal with disputes between WTO members thereby putting an end to the Section 301 retaliations by the USA. Thus Article 23.2(a) of WTO agreement on Understanding on Rules and Procedures Governing the Settlement of Disputes[8] reads:

"Members shall not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding, and shall make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding;"

As it is clear from the provision, the prohibition is not only limited to any unilateral sanctions but also on any 'determination to the effect that that a violation has occurred'. Therefore even inclusion of a country in the special 301 watch list, putting such country under the fear of sanction itself is violative of WTO

Agreement on Understanding on Rules and Procedures Governing the Settlement of Disputes.

Unfortunately, USA surmounted this prohibition by amending its Trade Act to the effect that the section 301 will not get affected by the WTO Agreement. Thus the amended Act provided that:

"A foreign country may be determined to deny adequate and effective protection of intellectual property rights, notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights referred to in Section 3511(d)(15) of this title".[6]

The effect of such an amendment is that the Special 301 review continues with its full vigour which is a clear violation of the WTO Agreement. The only change that made to this process is that whereas in the pre-1994 period the US appeared to be relying on a credible threat of sanctions as its main tool to promote compliance with its wishes, after the WTO the main tool of persuasion was "to give countries the feeling that their behaviour on intellectual property was the subject of constant surveillance.[9] For this purpose, it was more important to list many countries as subject to the watchful gaze of USTR than it was to actually impose sanctions.[10]

Compulsory Licensing, Special 301 and India

India was one of the first countries to be included in the Priority Foreign country list in 1991. The report specifically stated that India had overly broad compulsory licensing provisions,[11] triggering the 301 investigation in May 1991. Following a 9 month, 301 investigation and after determining India's action as unreasonable and burdened or restricted US commerce, the USTR terminated its investigation and USA imposed trade sanction on India. In April 1992, the United States suspended duty-free privileges under Generalized System of Preferences (GSP) for $60 million in trade from India. This suspension applied principally to pharmaceuticals, chemicals and related products. Benefits on certain chemicals added to GSP in June 1992 were withheld from India, increasing the trade for which GSP is suspended to approximately $80 million.[12] India's priority 'Foreign Country' status continued in 1992 and 1993.

India issued its first ever compulsory license in 2012. Though from 1994 India was designated in the 'Priority Watch List' till 2017, from 2012 issuance of compulsory license was cited as a major patent deterioration causing India to be continued in the List.[13] The 2012 Special 301 Report stated that the United States will closely monitor developments concerning compulsory licensing of patents in India following the broad interpretation of Indian law in a recent decision by the Controller General of Patents.[14] The same reason had made India to be remained on the Priority Watch List in 2013.[15] Thus when the Indian Intellectual Property Appellate Board (IPAB) upheld the Controller's Decision in 2013, this was taken note by the USTR and stated in its 2013 Report that 'the United States will also continue to monitor closely developments concerning compulsory licensing of patents in India, particularly following the broad interpretation of Indian law in a recent decision by the Indian Intellectual Property Appellate Board (IPAB)'.[16]

In its 2014 submission, the Pharmaceutical Research and Manufacturers of America (PhRMA) had urged the elevation of India into the Priority Foreign Country List citing the reason of compulsory license and the likelihood of Indian Government to issue more compulsory licenses. Though not labelled as a Priority Foreign Country, in the 2014 Special 301 report India remained on the Priority Watch List and the report had noted almost all the issues raised by the PhRMA and an out-of-Cycle Review was planned against India which was rejected by India.[17] It is thus clear from this inclusion that the USTR supports the pharmaceutical multinationals rather than the interest of WTO members in protecting right to health. Continuing on the 'Priority Watch List', the Report stated that it continues to monitor India's application of its compulsory licensing law.

It is noteworthy that in its 2015 submission PhRMA exposed its dissatisfaction with India's compulsory license episodes. Starting from the only one compulsory license granted way back in 2012 PhRMA blamed the Indian Government for even considering the patented medicines for compulsory license under Section 92 of the Patent Act. They argued that these are against the TRIPS Agreement and they had also appreciated the Government for rejecting the compulsory license applications.[18] When the compulsory license applications were rejected by India in 2015, this was appreciated by the USA in 2016 Report.

In this regard it is notable that in 2016 public hearing U.S.-India Business Council (USIBC) stated that "the Government of India has privately reassured

India it would not use Compulsory Licenses for commercial purposes. USIBC would be further encouraged if the Government of India made a public commitment to forego using compulsory licensing for commercial purposes and in public emergencies only, which would greatly enhance legal certainty for innovative industries."[19] This was condemned by various public groups. But later on 22 March 2016, the government press office made a brief statement that such reports are factually incorrect and it also stated that India retains the sovereign right to utilize the flexibilities provided in the international IPR regime.[20] But doubts still exist as to this assurance especially because of the fact that India had issued only one compulsory license and rejected all other applications.[21]

At the same time the Union for Affordable Cancer Treatment (UACT) alleged that the United State Trade Representative Ambassador Michael From an that "the DIPP is reportedly opposing the compulsory license, motivated primarily by concerns that a compulsory license would create trade and foreign policy problems with the United States".[22] It also contended that "the decision to put off judgement on issuing a compulsory license came during a period when the USTR officials have criticized the Indian government over two other disputes involving drug patents, including the US government criticism of the rejection of the Novartis evergreening patents on *imatinib*, and US government criticism of the Comptroller of Patent's decision to grant a compulsory license on Bayer's patents on sorafenib, a $65,000 per year drug for kidney and liver cancer."[23] Thus it allege that the USTR put pressure on the Indian government, and to influence the intellectual property policy of India in such a way as to severely restrict access to newer medicines for cancer patients and to restrict the use of compulsory license by the developing countries.

The US pressurisation tactic continued in 2017 also whereby the report noted that innovative companies remain concerned about the potential threat posed to their IP through the possible use of compulsory licensing and patent revocation, as well as overly broad criteria for issuing such licenses and revocations under the India Patents Act.[24] It is also noteworthy here to mention here that in the public hearing process for the 2018 Special 301, Pharmaceutical Research and Manufacturers of America (PhRMA), Biotechnology Innovation Organization (BIO), Alliance for Fair Trade with India (AFTI)are alleging that India's compulsory licensing provisions provide wide authority to grant compulsory license, especially the working requirement. They have also pointed out the Draft National Pharmaceutical Policy, 2017 in which reference is made of usage of Compulsory licensing or Paragraph 19 to control prices for patented products as against the principles of the patent laws as well as against India's WTO TRIPS obligations.[25] The U.S.-India Strategic Partnership Forum (USISPF), while pointing out the development in the Indian IP system, acknowledged that India should desist from issuing compulsory licensing of patented technologies and also acknowledged that the recognition of compulsory license as mechanism of price control of patented medicines in the Draft National Pharmaceutical Policy, 2017 as against Patent Law and TRIPS.

At the same time NGO's such as Public Citizen, Knowledge Economy International (KEI), Federation of Indian Chambers of Commerce and Industry (FICCI) stressed the point that countries have enough freedom to use the compulsory license flexibility and there are no limited grounds specified in the TRIPS under which a license can be issued. Therefore no citation of TRIPS compliant compulsory license should be there in the 2018 Special 301 Report. KEI also noted that the United States has at least 15 separate statutes that are used to permit non-voluntary use of patents and also by far, the most frequent user of compulsory licenses.[26] These organisations have noted that India had issued only one compulsory license which is TRIPS complaint based on the rational of public policy and access to affordable life-saving drug to the citizens. Therefore India cannot be blamed on the same. In its report was prepared by the Department of Industrial Policy and Promotion (DIPP) in the Ministry of Commerce on 2018 Special 301 Report, it noted that "The provisions relating to Compulsory Licenses under the Patents Act are fully compliant with Articles 30 and 31 of the TRIPS agreement and Article 5 of the Paris Convention."[27]

Thus as far as India is concerned though it had issued only one compulsory license USTR continues to mention India's 2012 compulsory license as a major concern for USA till the very recent 2017 Special 302 Report. The main reason is to put pressure on India so as to restrict the issuance of

compulsory license in India which is the "pharmacy of the developing countries".

India is not the only country that faced such intimidation by the USA for its public health protective policies. Brazil is the country which had successfully used the compulsory license threat to reduce the price of life saving drugs for a number of times. But in all these cases Brazil had to accept the price reduction instead of issuing compulsory licenses because Ministry of Development, Industry, and Trade was under pressure from other economic sectors that believe that compulsory license may cause loss of exports and/or foreign investments.[28] Along with this Brazil had been brought before the WTO DSB by the USA after being put on the special 301 report, for the local working requirement in its patent law which was one of the primary grounds for granting compulsory license till the TRIPS Agreement and following compulsory license threat by Brazil in 2000.[29]

Another country is Indonesia where it was put on the priority watch list in the 301 report from 2013 to 2017 due to its compulsory license for Government public non-commercial use in 2012. Adding to the list is Thailand. Following its public non-commercial compulsory licensing in 2007, Thailand was elevated to priority watch list from watch list. Following this in July 2007, the USTR withdrew duty-free access to the United States (US) market for three Thai products under the US Generalized System of Preferences (GSP).[30] Thailand continued to be one of the priority watch list countries till the 2017 Special 301 Report.

The mere reference in the Special 301 Report is important - it is a form of sanction and an inappropriate warning against countries exercising established rights to promote public health.[31] For instance, when the Government of India considered a compulsory license for *dasatinib*, a drug for leukaemia that Bristol-Myers Squibb priced at $108 per day, in a country with GNI per capita of $1,570, USTR was widely reported to have pressured India and the license was blocked.[32] Another worrying example was the pressure exercised by the United States on Thailand in early 2000, when the Thai government attempted to issue a compulsory license for the formulation patent of the AIDS drug *didanosine* (ddI). The US responded by threatening Thailand with trade sanctions. The Thai government consequently ended up rejecting activists' calls for a compulsory license because it was afraid of potentially serious adverse consequences for its economy as this threat came at a time when the Thai economy was reeling from the widespread South East Asian financial crisis.[33]

Conclusion

The analysis of Indian experience regarding the Special 301 for its compulsory license provision/grant shows that India is being continuously pressurised by the USA for changing its policy on compulsory licensing and to prohibit India from using the public health saviour flexibility of compulsory license. It is paradoxical that USA which always exerts pressure on the developing countries from using compulsory license, many a times utilised the same flexibility,[34] while India has issued it only once. It is not a unique case of India, but whenever a developing country use or tries to use a TRIPS compliant compulsory license, they have been listed in the Special 301 Report so as to give the feeling that they are under observation by USA. This feeling of threat from USA itself does matter for the developing countries because they always prefer to avoid the risk of any dispute with USA and therefore do some or the other modifications to their intellectual property to avoid any clash with the largest economy in the world. According to Peter Drahos & John Braithwaite, every year as the deadline for the USTR's Special 301 review approached countries would rush through some amendments to their intellectual property law, perhaps put a few more pirates in jail, increase penalties or to take some other action, all in an effort to demonstrate their commitment to respecting their US intellectual property.'[35]

This 'immediate commitment' to the US intellectual property is perceptible from the Special 301review itself and is articulated in the words of Richard W. Fisher, Deputy U.S. Trade Representative, Subcommittee on International Economic Policy and Trade House Committee on International Relations:

'One fascinating aspect of the Special 301 process occurs just before we make our annual determinations, when there is often a flurry of activity in those countries desiring not to be listed or to be moved to a lower list. IP laws are suddenly passed or amended, and enforcement activities increase significantly.'[37]

The public health will override any private interest over any intellectual property. The basis of

intellectual property itself is the promotion of useful arts and science that is the public interest and not the protection of the rights of the patentee. But for the USA, the baseline for property rights has moved quite far in the direction of private reward over public access. Therefore interest of the patentee cannot be seen above the life of the patients suffering from fatal diseases. Any such action to undermine the public health is a violation of basic human rights. Reducing the number of compulsory licenses, preventing developing countries from sourcing generic cancer drugs from the few countries that could actually manufacture them, is in fact systematically ending any hope for cancer patients to live longer and better lives. In such a line the US actions on the developing countries to restrict the use of compulsory license for life saving drugs can only be seen as a major human rights violation.

The United States shall not seek, through Special 301, negotiation, sanction, trade preference, or otherwise, the revocation or revision of any intellectual property or pharmaceutical market regulation of any developing country that promotes access to affordable pharmaceuticals or medical technologies. USA should not indulge in any activity that undermine or interfere with the rights of the WTO member countries in utilising any TRIPS flexibilities including compulsory license. The developed countries including India should be courageous enough to put the matter before WTO DSB. Another possible solution is the formation of regional collaboration by developing countries under the platform of which these countries can collectively bargain/fight against any such actions by the developed countries. This can be done either by initiating WTO Dispute Settlement Procedure against the country that implement actions to restrict the usage of compulsory license by developing countries or by resorting to the same retaliatory actions by developed countries against such countries. This mechanism is more effective as being developing countries, developed countries may not consider any retaliatory action by a single developing country as significant on it wherein the action is from a number of developing countries, developed countries might consider it as substantial and withdraw its illegal tactic against such countries.

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