



COMPULSORY LICENSES AGAINST PATENTED MEDICINES UNDER TRIPS: A CASE STUDY OF PAKISTAN IN COMPARISON OF OTHER COUNTRIES

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Abstract

Pakistan is a poor country where poverty stands at 78.4% when World Bank utilized the upper middle income rate (\$5.5 per day) translating 179 million people. How such people can afford expensive medicines when they are even not able to feed themselves for satisfying their hunger. On the other hand, the prices of medicines have risen 80% in last four years. Such unjustified price hike is caused by many factors including taking benefits of loopholes in policies, regulatory failures and most importantly remaining silent spectator. Government of Pakistan can play a vibrant role by invoking such permissible options under the national as well as international law. Apart from all other regulatory and procedural flaws, granting of frequent patents against pharmaceutical products also a main reason in price hiking. A state can put barriers against unqualified rights of patent holders by invoking TRIPS Flexibilities like issuing of compulsory licensing on its own terms for meeting medical emergencies. When covid-19 hit the world we witnessed various such emergency responds from the world which will be discussed in this article and what role Pakistan should have been played like other countries. This article special focuses on compulsory licensing under the TRIPS with respect to Pakistan. How it can be issued and what benefits it imparts in the way of access to medicines.

Keyword: Compulsory License, TRIPS Flexibilities, Pharmaceutical Products, Patents, Intellectual Property Rights etc.



Introduction

In the times of outbreaking of any pandemics like covid-19, governments feel immense pressure how to tackle such extraordinary circumstances at emergency basis because the lives of people are at risk. In such times every government adopt extraordinary measures to deal with extraordinary situations. In view of such health crises and seriousness along with economic pressures, especially poor countries, prospect of compulsory patent licensing arise in various ways. It becomes more attractive when international as well as domestic laws allow for issuing compulsory licensing. Section 58 of Pakistan Patent Ordinance 2000 authorises Pakistan's federal government to grant compulsory license in "the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires". When Covid-19 hit the world, the Ministry of Health of Israel on March 18, 2020 authorized importation of a generic version of 'AbbVie's Kaletra' from India for the treatment of coronavirus patients. Canada also introduced Covid-19 Emergency Response Act, on March 25, 2020 which gave range of powers to the Federal Minister of Health for the purpose of tackling coronavirus. According to this Act Health Minister was empowered to issue compulsory license against any patented invention when he thinks necessary. This new law exempted all previous legal requirements of negotiation with patent owner and any compensatory amount the said Minister determines will be final. Likewise, the Germany one of the largest economies of Europe passed "The Prevention and Control of Infectious Diseases in Humans Act on 28 March 2020. This Act also gave extra powers to its Health Minister to declare emergency for issuing compulsory licensing. Although this law gave permission patent holder to challenge it administratively but the issued license could not be suspended.

More on, France introduced new law with more sweeping powers giving powers of Prime Minister to seize and control temporarily prices of any kinds of goods and services necessary to fight pandemic. He was authorized to take any measure necessary to make relevant medicines available for coronavirus patients. According to some experts it was well beyond the compulsory licensing and measures taken elsewhere. According to article L. 3131-15 to the country's health code, "From a practical standpoint, the Prime Minister would now be allowed (i) to permit the seizure of drugs and/or (ii) to direct the launch of generic products on French territory before the expiry of patents/SPCs, if necessary (Adam, 2020)." Similarly there were also many other countries who adopted such lawful measures to deal with such pandemic in the need hours but unfortunately in our country no such action was taken ever in the history of Pakistan. "While in India cancer patients' access to medicines is ensured through cheaper generics made possible under compulsory license, in Pakistan a generous subsidy is provided by multinational pharma companies to afford branded patents for the poor patients (Dawn, 2012)."

The inventors get monopoly by registering their invention and getting a patent certificate which allows them to exclude all others from its selling, purchasing and any other dealing except with their permission for the period of 20 years. This exclusivity empower them to fix their prices higher because they eliminate all those factors which play vital role in lower downing prices in a competitive



market setting. Consequently, most of the consumers become unable to purchase such patented products despite their dire need even sometime it costs their life; in case of patented medicines. Historically, medicines were deliberately excluded from the subject of patent due to this reason because it was firm believe that if patent is allowed it would definitely hike up prices of patented medicines and most of the people will not be able to afford them. There are almost more than 40 countries who had not allowed patent protection for pharmaceutical products or process (Boulet et al., 2000). Subsequently, medicines were also started patented and it was intensified when TRIPS Agreement was formed in 1995. There was a huge concern from developing nations that the pharmaceutical products should not be included in the subject matters of patent but ultimately it was added with the certain exceptions; compulsory licensing, parallel imports and technology transfer incentives etc. (Scherer & Watal, 2002). Here the question arises: whether these exceptions are sufficient to cope up the problems and needs which the poor people will face. What if even these facilities are also not been utilized as like Pakistan has not issued any single compulsory license despite all the prevailing situations in which TRIPS allows.

Before addressing what TRIPS permits with respect to compulsory licenses, it is important to first define the term. A compulsory license as its name suggests is authorization of use of a patented invention by a state beyond the will of its owner in exchange for payment of royalty fixed by the state. The license is compulsory in a sense that it is forced upon the owner of patent. Further, the patent owner has no choice except to accept the government's compensation obviously that would be likely a far less than potential income which the patent holder could earn in free market. The issuance of compulsory license does not mean that the rights of patent owner are ceased to exist and the patent is going to end by its issuance. The patentee can also claim exclusion besides the authorized licensee against all others because patent is still valid and in force but he has no longer exclusive control over the market in the same way. When any state issues compulsory license it simply means that the government wants the main purpose i.e. more production and cheap price patented invention. Patent owner can also sale the patented product at preferred price because the cheaper versions sold by the government licensee will likely drop the patent owner's sales and profits. The pharmaceutical companies are not happy that compulsory licenses should be issued and utilized although permissible under TRIPS. It is worth to discuss that during the negotiation for the formation of TRIPS in Uruguay Round; the parties discussed in length and rejected proposals to eliminate compulsory licenses (Anna Niesporek, 2005).

It is open for all members countries, irrespective of their economic static, of the TRIPS to issue compulsory license if the there are grounds available which TRIPS recognizes them as valid for compulsory licensing which have been described under Article 31 of TRIPS Agreement. It also gives only option and not imposes upon any country. It only sets conditions which have to be justified in case of dispute over the issuance because the patent owner compromises his exclusivity and monopoly. It is also worth to mention that any country can issue compulsory license not only for its domestic needs but also for exporting purposes but there are different requirements and here in this article it will be focused only on issuance of compulsory license for its own people and domestic



urgency by the Pakistan. If the other counties like India, Thailand, Kenya, Ghana or even Canada can issue compulsory licenses than why not Pakistan.

The requirements TRIPS demands are that every nation that allows compulsory licenses comply with certain procedural requirements. It does not dictate what subject matter should be licensed, but only imposes procedures to follow making sure that the compulsory licenses are fairly issued along with reasonable consideration of patent owner interests. The main purpose of describing procedural requirements is that patent owner has been provided compensation and an opportunity to challenge it. Otherwise, the TRIPS is a brief document which only set minimum standards and rest upon the members to explain within the broad scope but the provision on compulsory licensing is the most lengthy and complex patent provision. This is for clarity and to address misinformation. This section first clarifies what subject matter may be subject to a compulsory license, and second, it also clarifies that what countries may issue them. To solving these key issues, it explains the basic procedures which must be followed for issuing a TRIPS-compliant compulsory license. It also describes the appropriate scope of a license and the rights of the owner. At the end, this section also explains special situations, such as compulsory licenses for blocking patents and anticompetitive use.

What Patents can be Compulsory licensed?

It is a common confusion that what patents can be subject to a compulsory license. The answer is any type of patent can be subject to a compulsory license under the TRIPS Agreement (TRIPS, 1994). The relevant article 31 of TRIPS Agreement consist many subparts but none of these contains any provision that limits the type of patent or invention that may be licensed. Earlier international covenants (Paris Convention, 1883) were not in such form because they had only limited categories of permissible subject matter for compulsory licensing. Some pro patent proponents might have some opposite views but subsequently Doha Public Health Declaration 2001 provided additional support to this conclusion (WTO, 2001). This Declaration is very important document because it clearly affirms in the words that “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses were granted.” More on, the issue of access to medicine is also demands that all drug patents must be subject to compulsory license under TRIPS and there must not be any exclusion. In contrast, the compulsory licenses against medicines are vehemently opposed by the pharmaceutical lobbies and they regularly campaign against it that drug patents should not be compulsory licensed ignoring that TRIPS considers such licenses to be perfectly legal. Furthermore, these medicines can save many lives which otherwise cannot be purchased due to their higher prices. However, TRIPS where it allows compulsory licensing it also restrict some previous practices of automatic licenses of drugs. Before TRIPS, some countries (such as India and Canada) had provisions in their domestic laws which allow compulsory licenses automatically granted on a set royalty rate relating to pharmaceuticals or food. Although, theoretically it is still possible that every drug patent could be subject to compulsory license because TRIPS does not prohibit it specifically, but it is highly unlikely according to the TRIPS requirements that the members must treat each patent separately and if a license is appropriate to issue there must be proper chance



to the owner to negotiate upon the terms which the relevant state demands and there also proper remuneration.

Therefore, a nation may not mechanically issue compulsory licenses against an entire class of technology, such as all drugs. It is also not consistent with the article 31 requirements, which focus on what steps must be taken to issue a specific license. Also, this meaning can be confirmed by the negotiating history which shows that this was the exact proposal of India to automatically issue licenses for food and drugs patents but it was declined.

What can be the Possible Grounds for Issuing of Compulsory License?

Every patent has commercial utility and state grants it for the benefits of both the parties; the patent owner in the form of exclusive rights and the public which receives its benefits in the form of its industrial application because every patent invention reduces hardship of public in certain way. The owner of patent is expected by the state certain things which he have to meet in otherwise state also reserves some rights against the patent. State can also revoke its patent and can also issue compulsory license when it seems proper. The question is whether there are certain and fixed grounds and is TRIPS describes those grounds? Although TRIPS allows its signatories to issue compulsory licenses on any kind of patent and to decide the reasonable grounds and therefore it is wise able to make a brief discussion of the possible grounds including ones that have historically been recognized. Compulsory license is not a novel concept it has a long history and when TRIPS was finalised many countries had provisions authorizing them.

Failure to Work

When patent owner fails to exploit its invention in the local market and does not provide reasonable ground for its failure then the state which has given him monopoly and no one is allowed to make except him, may grant compulsory license to any other third party for its working. This is the oldest basis upon which compulsory licenses were issued. Basically the granting of patent is a privilege which were started historically in a sense of giving honor to its owner as a reward along with an expectation the patentee will make the patented invention in the local market (Paul Champ & Amir Attaran, 2002). As well as, one of the logics behind the granting of patent is promotion of technology so therefore when patent is not commercially utilized promotion of technology seems mired. In some countries, if patent owner does not produce locally and only imports the product, it will be treated failure to work it will also amount to abuse of patent right. Granting of compulsory license in case of failure and only importing the products seems moderate than the previous practice which was prevailing in certain countries in the form of forfeiting the right of patent.

In addition, there is a requirement under the TRIPS that the rights of patent holder should be available without discrimination. In particular of this statement there is dispute in the interpretation of the word discrimination means. Pharmacists and USA interprets that if you grant compulsory license on the



ground that the owner does not produce locally and only imports it is discrimination under the patent rights. This confusion has also led toward a legal action took by USA against Brazil on this ground before WTO Panel. The said Panel is a competent forum which can provides definitive guidance. Experts are also divided on this issue and some says that TRIPS does not intend discrimination in a way as USA and some Pharma industry takes (Daniel Gervais, 2008). However, that particular interpretation is not squarely intended by the actual text. The meaning of nondiscrimination clause seems to affirm the patentee's exclusive rights from making, selling, and importing without specifically describing whether the patent owner would lose his right of exclusion in case he is failed to make the product locally.

Another very important aspect regarding the possible interpretation of nondiscrimination clause meaning is the reference of Paris Convention which is the main document applies as a main source toward the patent rules. Paris Convention is an international agreement that has been expressly incorporated by reference into the TRIPS Agreement so therefore, TRIPS should be read as only providing additional procedural requirements. It cannot be taken as removing prior bases for issuing compulsory licensing. Paris Convention expressly envisages lack of local working as an abuse of patent rights and treats it as a ground for issuing compulsory licenses. Granting compulsory licenses on this issue would be consistent with the fundamental cannon of treaty. Thus it can be safely said that the signatories of Paris Convention are bound of the clause on non-working locally, so the nondiscrimination clause should be interpreted in the light of the main Paris Convention and not to nullify this requirement. This is true from this perspective and TRIPS does not consists any explicit word which repeal expressly local working. Similarly, the failure of local working should be continue as a prevalent norm as a ground of compulsory license. And this conclusion is also supported by the fact that the particular proposal advanced by the stake holders to expressly exclude local working from the grounds of compulsory licenses was not adopted in the negotiation and WTO Panel is also not agreed with this opinion.

Public Interest

Later on, compulsory licenses were extended to meet the variety of public interest goals. The Nations started such licenses in certain areas where the public interest outweigh the patentee's economic interests meaning thereby that public at large is at stake and common welfare of public is more needed. Generally these grounds include curbing of anticompetitive practices, price reduction when public does not afford high prices and people are suffering due to their incapacity to purchase and government use etc. this is not comprehensive list these grounds may vary from country to country having different circumstance and ground realities. TRIPS Agreement also does not fix these grounds but it is always question of fact in a way that every country which issued compulsory license have to justify it in case of the patent owner challenges it. Whatever the circumstances are the element of public interest must be in every event of forced licensing. In addition, nations are not limited to these common grounds they are free to create there new grounds which seem fair to them.



Procedural requirements

Now that it is clear that any country is permitted to issue a compulsory license with respect to any technology, this section discusses some procedural requirements that do place some limitations on such licenses. This section discusses three primary types of procedural parameters: when a license is permissible, whether prior negotiation with the patent owner is required, and the parameters of the actual license.

Timeframe Requirements

It relates to a question whether there is any limitation period from granting of patent to the time when compulsory license is issued. Paris Convention does not impose any such stipulation except when compulsory license is issued against failure to work. The minimum time is three years after the patent is granted meaning thereby that compulsory license cannot be issued before passing of three years after the patent is granted. Otherwise there is not any limit and TRIPS Agreement is also silent on this issue which implies that compulsory license can be issued at any time when it seems legitimate to the concern state.

Negotiation as a Prerequisite

As it has been discussed earlier, compulsory license is always issued on certain compulsions and at that time it seems need of time for securing certain ends. The state grants it has not any adverse feeling against patent owner and there is no any personal enmity, if state takes away his exclusive rights it means patent owner is not fulfilling some legitimate works which seem necessary at that time from moral, social and humanity perspectives. It is more appropriate if that purposes are met through the real owner (patent owner) because he has invested his time, money, intellects and skills and gained exclusivity rights. Thus, it is a requirement under TRIPS that before a compulsory license is issued; the concerned government must first attempt to obtain a voluntary license from the owner of patent. In simple and clear words it can be said that compulsory licenses should not be imposed unless there are proper prior negotiations with the owner. It is also important in a way that patent owners may reduce prices themselves when a compulsory license is threatened. Although, there is an ambiguity as to what extent state has to try to secure a voluntary license; TRIPS under section 31 requires that these efforts must be to obtain voluntary authorization from the patent owner on “reasonable commercial terms and conditions” and for a “reasonable period of time.” However, it is quite clear that both of the parties i.e. patent owners and consumers are likely to have opposite concerns of what is considered “reasonable.” When Thailand imposed licenses, it asserted that it had negotiated for months with the patent owners, but they showed huge surprise because according to them they did not know that a compulsory license was being contemplated. TRIPS does not explicitly require a patent owner be informed that a compulsory license is under way as a negotiation requirement but Thailand example suggests that it is most appropriate to do so. Everything has its price and similarly



frequent and unjustified issuance of compulsory license may bring political and economic bad consequences and it may hamper invention.

When Prior Negotiation can be waived under TRIPS

TRIPS have provided certain situations when this pre-requisite can be compromised. In three separate circumstances, a country can issue a compulsory license even without prior negotiation with the patent owner in the case of “national emergency,” circumstances of “extreme urgency,” or in cases of “public noncommercial use,” and he must be notified “as soon as practicable.” These situations are basically so important and vital in nature that the state can issue compulsory license without wasting time. Owner has been removed from dissuading the nation from imposing a compulsory license because the circumstances demand more urgency. However, even if prior negotiation is waived, all other requirements remain intact, including compensation to the patent owner.

Notably, these categories do not limit the situations of issuance of compulsory licenses. In other words, compulsory licenses can be issued even if there is no national emergency, because as discussed in the previous section, TRIPS does not fortify the grounds of compulsory licenses. However, the existence of a these emergencies will remove the procedural requirements of engaging negotiation procedure with the patentee.

The real question of great importance is that how to define what “national emergency” means how it constitutes? TRIPS is silent and do not dictate it and it totally up to a nation to assess whether an emergency exists. There is not even a requirement of a formal declaration. Accordingly, a nation should be permitted to simply note in the license itself that it is issued based on a national emergency. In addition, the lack of a definition provides nations with discretion to decide what constitutes an appropriate emergency. This approach is not only consistent with standard TRIPS interpretation, but also explicitly endorsed in the unanimously concluded 2001 Doha Public Health Declaration. Historically, the WTO community had admitted that national emergency or situation of extreme urgency exists in the prevalent of epidemics such as HIV/AIDS, tuberculosis, malaria, or other. Covid-19 is a best current example of such epidemic. Covid-19 appeared as a big threat to the survival of human beings and it was the vaccines which saved human lives. When the vaccines was in process there was huge concern from the developing nations whose research and development has not reached to this level to develop such vaccines at emergency level, fore-sought huge fear that the vaccines developers will get patents against their vaccines. The poor nations were foreseeing that the patent will serve manifold purposes for them in a way of controlling over sale and fixation of higher prices. Keeping this fear in mind more than hundred developing nations submitted a request in the TRIPS Council for waiving patent over vaccines in the WTO.

Apart from above, these are not final grounds; the Doha Public Health Declaration plainly states that “each member has the right to determine” what constitutes a “national emergency” or situation of “extreme urgency”, and moreover these grounds are only illustrative. On a practical level, a nation



may be more vulnerable to challenge for issuing a compulsory license without negotiations on the basis of a national emergency that is *not* specified in the Declaration. However, this is no different than with any other undefined term under TRIPS. A trickier question is what constitutes “public noncommercial use.” This has never been defined, and it was subject to some controversy when Thailand issued a series of licenses on this basis. Although many key TRIPS terms are undefined, this particular one is critical with respect to potentially opening up a wide range of situations where compulsory licenses can be imposed without prior negotiation. The word *public* could refer either to a license that is for the public *benefit*, or a license that is given to a public (as opposed to private) entity. Similarly, *noncommercial* could refer to use by a public institution, or to the use being not-for-profit.

Constraints about License under the TRIPS

TRIPS Agreement is basically very brief in nature but section 31 which relates about compulsory license is very lengthy and detailed because there involve patent owner's rights which must be dealt carefully and taking consideration of the limits which TRIPS sets forth. First of all, compulsory license must be issued predominantly for domestic use. On special grounds this ground can be waived when a country has not manufacturing capacity. This has been recognized in “The Declaration on the TRIPS Agreement and Public Health” in November, 2001 later called Doha Declaration. It was recognized in this Declaration that the countries having insufficient pharmaceutical technology capacity could face problems and difficulties in utilizing effective compulsory license. Subsequently TRIPS Council made a decision on which is known as “August 30 Decision” allowed exports under compulsory license to the countries who lacks capacity. Subsequently, after passing two years on December 6, 2005 this dictum became permanent part of TRIPS as an insertion “Article 31bis”. Later on, in 2017 this system was became formal part of TRIPS after acceptance of Protocol passed by two third majority making history in WTO.

Secondly, in order to limit the impact of such licenses on the patent owner, they must be nonexclusive and nonassignable. Thirdly it must be “limited to the purpose for which it was authorized.” Once the purpose for which the license was authorized ceases to exist and it seems will never occur again the license must be terminated. After all, every license relates to a different patent and every patent differ from other in its value and scope so while granting such forced license all these factors must be kept under consideration keeping in mind the remaining length of time of patent.

Rights of Patentee when Compulsory License is issued

Originally we can see that compulsory license imposed upon patent owner when he does not fulfill the intended demands of one state which it seems necessary in broader perspective. However, patentee is most important person who has developed such needful thing which is likely to solve the immediate problem so therefore TRIPS contains many provisions whose purpose is to secure the patent owner's rights and interests. Apart from the above his rights like right of negotiation and others



there are two main rights which every state has to secure at every cost. First, he must be compensated properly and second, he must have the opportunity to challenge both the decision; issuing of license and to challenge the compensation amount when he is dissatisfied.

Right to Review

The patent owner must be able to challenge two aspects of a compulsory license. First, the patent owner must be afforded an opportunity to challenge the initial decision to issue a compulsory license. In addition, the patent owner is entitled to challenge any national decision concerning remuneration for a compulsory license. This opportunity of judicial review may within the judicial system of that relevant nation granting the license. There are concerns upon such principle arguing that any nation who is issuing compulsory license very least chance to declare it against its national interest rather in the favour of individual owner who possibly might be foreigner. Moreover, if the judicial review process is in any way inappropriate, member states can always bring a challenge within the WTO dispute settlement system. As noted earlier, individual stakeholders (such as patent owners) have no standing in that system. However, patent owners can petition their home country to act on their behalf and have effectively done so in the past when their interests were at stake.

Pecuniary Compensation to Patent Holder

TRIPS has also emphasized upon monetary compensation to the owner of patent in the words “adequate remuneration” keeping in mind the market value of the patent. Patent owners are have not right to fix their rate but they will be provided an opportunity of negotiation and it is the relevant state which will determine the amount. TRIPS demands that the patent owner must be provided “economic value of the authorization.” Yet these phrases have not been interpreted comprehensively by a competent forum what constitutes “adequate” remuneration. According to the interest of patentee he will prefer market value but it seems difficult and some other ground realities. Why would state suggest market value compensation in the circumstances when compulsory license is itself is being issued to lower the price? However, in plain meaning of *adequate* would suggest something reasonable and sufficient on a minimal level rather than optimum but obviously it would definitely likely to be less than the prevailing market rate. Although efforts have been made to set some principles for what royalty amounts in the light of word adequate but it ultimately lies within the scope of national discretion as with all other undefined terms.

When Infringement Becomes Inevitable

It is better to adopt a legal way; compulsory license rather to infringe. To understand this ground, it is important to first understand why use of a second patent would infringe. Recall that a patent only confers a right to exclude and not an affirmative right to use; this means a patent owner could be precluded from using the patented invention if it infringes another's patent. This could happen because there is no patentability requirement that the invention not violate an existing patent. Rather,



the patentability rules are that the invention be capable of industrial application, new, and have an inventive step. Accordingly, it is possible a patent will issue for an invention that cannot be used without violating another patent unless permission to use the prior patent is obtained. Because the prior patent “blocks” use of the later patent, it is often referred to as a “blocking patent.” Similarly, because legal use of the later patent depends on the ability to use the first patent (whether through voluntary permission or a compulsory license), the later patent is referred to as a “dependent patent.” Various countries have used compulsory licenses to ensure that new innovations can be used. Some opine that a compulsory license to the later patent owner is to maximize social welfare by ensuring the subsequent invention can be used.

Conclusion

Compulsory licensing has been advocated very frequently in various places as the main alternative to avoid the potential negative impacts of patents of pharmaceutical products. For example, the study of literature pertaining to access to medicines under the TRIPS Agreement which provides current IPR system reveals that compulsory licensing is the most suggested mechanism to improve access to medicines (Urias, 2015). Patent holders sometimes recognize importance of access to medicines and therefore they license their products to generic manufacturers on voluntarily basis. They do so by either direct contractual arrangement with generic manufacturers or through the Medicine Patent Pool mechanisms. Moreover, it is common in this arrangement to restrict it territorially where these products can be commercialized. However, if such voluntary licenses are not formed and operationalized or the country is not included in a given voluntary license territory, then compulsory licensing can be a very suitable and pragmatic option for such countries under certain circumstances to improve access to patented medicines.

Issuing compulsory licenses to a local manufacturer is very useful in a numerous ways but problem sometimes arises when a country lacks in manufacturing capabilities. Currently there are new methods of medicinal formulation have been invented by advance countries like biologics rather than small molecule drugs. So in such cases where no alternative local manufacture is available compulsory license will serve no purpose. Pakistan may be having not equal R&D to certain advanced level but it is quite at satisfactory level. In Covid-19, Gilead had given voluntary licenses for Remdesivir production to a Pakistani pharmaceutical company, Ferozsons Laboratories which shows a satisfactory situation in technological capabilities. This tablet was the most wanted medicines in initial phases of Covid-19 pandemic when vaccines was not in the market and “as soon as Remdesivir was approved by the regulatory authorities, the Trump administration ordered the purchase of about 90% of Gilhead’s targeted production in July, August, and September, leaving very little for the rest of the world (Eduardo Urias, 2020).” This tablet was priced 2340\$ per patient for a 5 day treatment whereas its cost was estimated 5 to 10\$ per patient (Boseley, 2020).

To understand the dual face of developed nations in the context of corona virus vaccines we have to go through the request made by poor countries to TRIPS Council (WTO) for waiving intellectual



property rights i.e. patent, against upcoming vaccines which was not considered and allowed. “It makes little sense that the United States, Britain and the European Union, among others, are blocking a proposal at the World Trade Organization that would allow them, and the rest of the world, to get more of the vaccines and treatments we all need (The New York Times, 2020).”



Image source: want Vaccines Fast? Suspend Intellectual Property Rights, New York Times, December 7, 2020.

On the other hand, although developing and least developing states are considered having very poor medicinal facilities and ability to produce, it has been witnessed that even developed states like USA, Canada, Germany and Israel have issued compulsory licenses at the time of need. For example, German Federal Court of Justice in 2017 confirmed a compulsory license which was issued for an antiretroviral drug for the HIV/AIDS patients. Similarly Netherlands also announced his intention to use it for highly expensive medicines in the same time (Cappuyns & Vanherpe, 2018). Senator Bernie Sanders of USA in 2015 formally requested to its Veterans Affairs Secretary to issue compulsory licenses against Sofosbuvir patent which was very expensive tablet whose price was US\$1000 per tablet at that time (Sanders, 2005). Canada had a long history of compulsory licensing against pharmaceutical products. It was admitted in WTO Panel Report on Canada Patent Protection of Pharmaceutical Products, in the following words, “it was certain that the Canadian regime on compulsory licences for pharmaceutical products existing in the pre-C-91 system would have been incompatible with Article 31 of the TRIPS Agreement. This had been expressly admitted by the Canadian Government.” (WTO, 2020) On March 25, 2020, the government of Canada had acted swiftly to enact legislation in response to COVID-19. The legislation, which was introduced into Parliament, brought sweeping changes to various aspects of Canadian law, including expanding the compulsory licensing framework in the Patent Act. (Daphne Lainson, 2020).



There are other options for improving access to medicines; some patent holders voluntarily grant license to generic manufacturers of their products. However, it is common in voluntary licenses that it is restricted territorial wise where such licensed product can be marketed. Similarly in Pakistan when Gilead Sciences Inc. gave voluntary license to Ferozsons Laborites Limited for generic production of famous tablet of Hepatitis C Virus (HCV) 'Sovaldi' its price was reduced five times (Dawn, 2016). So if such license is not issued then compulsory license can be a viable and better option in time of need for some countries under prevailing and justified circumstances like pandemics for the availability of medicines to save lives.

Apart from a legitimized instrument of industrial policy to create local manufacturing capacity through voluntary licensing compulsory licensing can also plays an important role of price reduction of patented medicines at unimagined low. Indeed, when patent owner does not lower prices sufficiently, and he is not willing to grant voluntary licenses, then what else remains either let the people die or issue compulsory licensing which is not illegal. When India issued compulsory license of a cancer treatment drug Sorafenib in 2012 and give license to generic medicines Producer Company 'Natco' its price was reduced 97% (Eduardo, et.al, 2020).

Canada passed a special law with purpose to cope up with COVID-19 Emergency Response Act on March 25, 2020, which authorizes the state to produce, sell, and use a patented invention. This act cannot be treated less than compulsory licensing in any manner rather it is above and beyond. Under this law, the license for production of intended (patented) medicines can be issued without even negotiating with the patentee or rights holder. In addition it also authorizes whether the owner has local manufacturing ability, but the patentee must be compensated. This legislation was to be revoked when the crisis is over (Houldsworth, 2020). Similar to this, France enacted a new law (No. 2020-290) on March 23 that allows the Prime Minister to implement price control and introduce generic medications to solve the health issue before the patent expires. More on, an Act was also passed in Germany on 28 March with the name of "The Prevention and Control of Infectious Diseases in Humans Act", which allowed the issuance of compulsory licensing. Likewise, on March 18, Israel also issued a compulsory licence for the purchase of Kaletra, a combination of the antiviral medications lopinavir and ritonavir created by AbbVie. The patent for Kaletra expires in Israel only in 2024, despite the fact that its beneficial effects on COVID-19 patients have not been independently verified. These acts affirm that adjustments to national legislation that permit patent protection to be flexible, particularly compulsory licensing, are crucial for promoting speedy access to therapeutic choices in emergency situations (OECD,2020).

At the end no single compulsory license was issued by Pakistan having similar or even worse situations but other developing countries like Pakistan and even developed states mentioned above have been reported total 74 compulsory licensing events of medicines since the TRIPS Agreement came into force according to The TRIPS Flexibilities Database developed by Medicines Law & Policy reports.



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