COMPULSORY LICENSING UNDER PATENT LAWS AND PHARMACEUTICALS: IMPACT, ISSUES AND WAY-OUT

Mayuri Ramchandra Taware, LLM, BBA LLB, DCL, DFS, Assistant Professor at KLE Law College, Kalamboli Navi Mumbai

ABSTRACT

Patent is a very important intellectual property as it encourages the inventor by providing monopoly right for commercial exploitation of his invention. But this scenario gives rise to high cost of product for the purpose of profiteering. However, in case of pharmaceuticals the patent owner cannot be permitted to exploit the patent unreasonably and to restrict the access of those in need. It has been observed that many companies with view to earn huge profits, sell their products only in developed countries which in turn results in shortage and overpricing in developing and underdeveloped countries.

The TRIPS agreement and Doha Declaration have thus proposed for provision relating to compulsory acquisition of certain patents on specified grounds. In tune with this, the Patent Act,1970 incorporates same provision.

There has been an instance of compulsory acquisition of patent relating to pharmaceuticals which has been discussed latter in this paper. The current pandemic situation has again given rise to debate about compulsory licensing of patented drugs considering the prevailing emergency like situation. Even the Supreme Court of India has asked the government to look into the viability of the option for procurement of life saving drugs.

Through this paper, it proposed to examine the various provision relating to compulsory licensing in international agreements and domestic legislations. Along with the challenges and the possible solutions for those challenges.

Keywords: Compulsory license, drugs and pharmaceuticals, TRIPS Agreement, DOHA Declaration, Indian Patents Act

INTRODUCTION

India is a one of the important countries in the pharmaceutical production around the globe. It is at the third rank in terms of volume production and its worth is $ 41 Billion and is expected to grow with the rate of 8-14% over next 3 years. However, prior to TRIPS agreement, the drugs were not covered under patentable innovations. In simple words, patents couldn't be granted. This made the pharmaceutical industry vulnerable. This led to the booming of generic-medicines sector. Which eventually provided ample supply of drugs at much lower prices, fulfilling the needs of a commoner. But due to vulnerability of Pharmaceutical Industry, no new drugs were launched in India, creating threat to long term goals of healthy Indian society. It is where TRIPS helped Indian Government. This increased the patentee's power by accepting drugs as patentable. Three amendments were made in order to effectuate the Agreement. The Agreement came into full force in 2005. Indian patent Act, thus, has comprehensive provisions regarding compulsory licensing. Due to this, patentee could enjoy restricted monopoly.

As per the Act of 1970, the license can be issued only after expiry of three years from date of registration of such patented drug. It is important to take a glance at prevailing legal framework. *Sec.84* empowers Controller to issue licenses on the ground of non-satisfaction of public demand, over-pricing and the '*invention is not worked in India*'. *Sec.90* provides '*terms and conditions*' for license, which includes, Royalty for patentee based on nature on invention and expenses incurred along with reasonable profit for licensee and affordable public price, 'non-exclusivity' and 'non-assignability' of the license, etc. Special provision was provided under Sec.92 controller can seek for the license on the grounds of national emergency or extreme urgency or for non-commercial public use. Sec.92A is also of grate importance as it authorizes the issuance of license of patented pharmaceuticals for the purpose of exporting to the needy countries. The revocation of license by controller was provided under Sec.94 and it can be revoked on the ground that, the licensee is violating the requirements set while issuing license or the need for which the license was issued is no more exists; here the licensee has the right to contest against such order. Sec.100, on the other hand, provides for acquisition of patents for governmental use; however, in return it has to pay compensation to the patentee. Moreover, patentee can challenge the acquisition. Sec.102 authorizes governmental acquisition of patent for public use. Under previous sections, patentee cannot challenge acquisition but can claim higher compensation.

ANALYSIS

A. INTERNATIONAL PERSPECTIVE

1. ICESCR:

Art. 12 which is included in *Part-III* of the covenant forms the basis for the one of the important international law provisions. It sets out the goal for the parties to the covenant, to create such conditions, which would ensure '*medical services and medical attention*' for all so that, the standards of mental and physical health be attained.[1] This provision is a human right based approach toward health. This fact gains the importance because though, there is sufficient material available on health much less had nexus with the human right. This improved the importance of '*health*' in international sphere.

2. TRIPS AGREEMENT

As seen above patent rights can outweigh the right to health and this issue is not only limited to India, rather this issue is faced by every country around the globe. It was TRIPS agreement which tried to upheld the health as compared to the patent right. It did so by allowing issuance of compulsory licenses of patented inventions on the basis of '*Public Morality*'.[7] Art. 31 of the Agreement, though doesn't use the word 'Compulsory License' in its literal sense, but it authorized the Government to use the patent or a third party who receives such authorization from the Government, can use an invention without authorisation of patentee. There are certain grounds on basis of which such license can be granted. They are –(a) non-commercial use, (b) extreme urgency and (c) previously applicant has approached patentee for issuance of license, etc. The agreement takes into consideration the economic facets involved in such issuance, as the patentee might suffer from economic loss due to market sharing with that of the licence holder. However, this right is not unfettered. The clause (f) of the said Article that, the countries which have efficient mechanism for manufacturing, . However, it is to be borne in mind that, countries which are suffering from the health crisis or emergency are mostly the underdeveloped or developing countries with the worst healthcare

[1] International Covenant on Economic, Social and Cultural Rights, United Nations Human Right available at https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx (last visited on 3rd May, 2023).

services and insurance.[8] Doha Declaration actually was made in furtherance of this agreement and this regime of Compulsory licencing was made stronger.

3. DOHA DECLARATION, 2001-

TRIPS agreement was one of its kind and it needed certain changes. These changes were carried out by Doha Declaration. This declaration authorised the member parties for the issuance of license in order to help to the countries which are suffering due to lack of manufacturing ability or capacity, by way of exporting drugs.[2] The declaration recognises the importance of public health and proposes and affirms the access to medicines for everyone.[10] Despite its adoption in 2001, it came into implementation in 2003. It appears that, this system is too idealised.

ISSUES AND CHALLENGES:

Pricing mechanism:

The first purpose for which the compulsory license can be granted is to regulate and control the expensive prices of life saving drugs. Moreover, access to a drug is directly concerned with the its price and financing mechanism, varying from country to country. Absence of secured/nationalised healthcare system, particularly in underdeveloped or developing countries, ends-up burdening the pockets of end-consumers of drugs, i.e., patients. The factors like, level of competition and IP rights, such as patents enabling monopoly, etc., are the price deciding elements in the market. This ultimately also decides, whether a person below certain financial income level will survive due to accessibility to a particular drug or not? In this regard, an international IP regime is vital. It provides the incentives required for the development and marketing of new pharmaceuticals. After the '*Doha Declaration*', many countries, including US, is showing concerns regarding their '*trading partner's*' right and requirements for the purposes of public health protection and also, access to medicines for all, was promoted. This enables recognised and helps countries (Trading Partners) to procure the pharmaceuticals. Also, there is a need for an IP regime which promotes manufactures for innovations in the field of commercial pharmaceuticals and manufacturers of generic medicines

[2] Declaration on the TRIPS agreement and public health https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (Last visited on May 3, 2023; 4:03PM).

at municipal level. Indeed, it is equally important for the Government of the country to invest and encourage the investment in healthcare sector; so that, irrespective of an income group, an individual should have an access to the medical drugs.

National and International pressures:

International and National Pressures also play an important role in the issuance of compulsory licenses. Thus, it is needed for us to consider and understand hindrances which occur in the path of developing countries to access patented drugs by means of licenses. The '*Multi-National Pharmaceutical Companies*' (MPNCs), has always addressed the concept of licensing as an inherent threat to patentee as it tinkers with the monopoly and thus, it should governments should restrict themselves and issuance of License be resorted to only as a last option. Let us consider an example of an international pressure. Under *Section 301* of the '*United States Trade Act, 1974*', the executive office of the US President has established an office known as '*United States Trade Representatives*' (USTR). It issues a yearly report under the name of '*Special 301*' it is no less than a threat to the foreign countries. The report has alleged that, there exists inadequate protection of IP Rights for the Companies with US origin, and in turn it has threatened for sanctions on unilateral trade. Such reports created the chilling effect on the countries, who encourages the licensing for betterment of society. It is evident from the report published by '*USTR*' that, it has listed *eleven-countries* under the title of '*Priority Watch List*' which includes India. It has also listed other *twenty-five-countries*, under the title of '*Watch List*'. The '*USTR*' is of the opinion, particularly pertaining to India that, the business of US origin functioning in India, is suffering for non-protection of innovations and faces difficulties in receiving and maintaining patents for such innovations, particularly in pharmaceutical field, is not the exhaustive list of challenges. Briefly speaking the legal framework is insufficient.[14] It is where the political strength of any given country matters. Irrespective of that, it harms the image of India as a country, when it comes to both IP regime and pharmaceuticals.

Coming to the domestic example. Recently, a three-judge Bench of the SupremeCourt has asked the Union Government to consider the option of compulsory licenses to secure the required amount of life saving drugs during the prevailing pandemic. The observations were made on the premise that, in such health-related crisis the Government enjoys and should use the flexibility offered under Patent Act. This has led to the public outcry for issuance of license.

Government of the day should be kept aloof from such kind of pressures and should act consciously.

Determining as to when Compulsory Licensing is to be given:

The issue has been raised from time to time in this regard on international front regarding the standard situation in which compulsory licencing can be issued. Trying to define or attempting to recognize a universal situation which can be termed as 'national or regional emergency' will have zero practicality. The various factors will influence this kind of determination, including health problems, diseases, lifestyle, population etc. and agreeing on, even if made possible, such common conditions, will give us a very narrow and limited understanding of the possible situation.

To make the picture better, let us assume, the prevailing situation. The number of persons infected in India is around 2.23Cr causing 2.42Lakh deaths which is 1.632% and 0.177% respectively of the total population of India. Whereas, if we consider Canada as another example, the number of people infected by Covid-19 virus are 12.8Lakh causing 24,568 deaths which is 3.404% and 0.065% of the total population. This leads to the conclusion that, the Canada is more affect during this pandemic as compared to India, in terms of population. However, the volume in India is way more than that of Canada, which cannot be ignored and steps has to be taken on part of India, because irrespective of figures every life matters.[15]

Considering this illustration, it is amply clear that, the volume of patients may be very less as compared to the total population of the country. However, the ratio of availability of drugs to the volume of patients, does or does not necessarily is the sign of situation of national emergency in any country. For example, in India, lack of medicines was more widely in question as compared to Canada. This leads us to safe conclusion that, situation talks more effectively than numbers. Thus, while granting or refusing to grant compulsory licensing there are no fixed standardized definition or universal situation of national health emergency.

Discouraging Patentee

The Government or applicant seeking compulsory license, both, had nothing to do with or has never had spent any amount for the invention. Thus, they can never be equated with the inventor. More frequently, patentee pleaded that, licensing will discourage the inventors and

innovations specifically. It is because patentee invents a lot of money along with his time and efforts to develop a particular invention and in the cases of companies it has a specialised unit for carrying these functions in the form of Research & Development and collective efforts of members of such unit. However, the license holder enjoys the benefits arising out of such unique inventions, without any efforts whereas, the patentee hardly yields any profit of it. Sometimes even the amount invested in Research is unrecoverable. To take care of this situation, compulsory licenses should be granted only in the cases such as inadequacy of drugs or shortage in supply, etc. Increasing the role of patentee himself, in granting the licence can be good solution. Such as, making it mandatory for the applicant to apply to the patentee first and in cases of rejections only, making the governmental interference justifiable. The patentee can be conferred with some royalty in exchange of the licence for his innovation, to which he was only entitled to enjoy. This will help to smoothen the situation. After taking such steps only, for protecting the public health on the basis of morality, Government can take actions.

CONCLUSION

It is necessary for every member of the society to have an access to such drugs which are essential for life saving, whether it is patented or not. The concept of compulsory licensing intends to do the same. It does so by creating a competition between the patentee and the license holder. Increase in competition will restrict the monopoly and abuse of patent by the patentee and eventually it will reduce the prices of expensive drugs. Competition will also improve the quality and supply in the market. Thus, taking all these things together, the competition created by grant of compulsory license is good for society. Government has to take the steps to control and regulate the profit percentage such that, the patentee will get smaller percentage but steadily for the longer tenure, this will help to reduce the price. Also, by adopting and implementing the above-mentioned recommendations, the price of the drugs can be controlled and there is lesser possibility of demand for compulsory license in future. Indeed, as the compulsory licensing has direct nexus with the right to health, as it facilitates the same, procurement of medicinal drugs is of utmost importance. Hence, compulsory licensing can turn out to be an effective and essential weapon for the countries. However, if start to grant compulsory licenses as a regular measure it will be an abuse of IPRs and anti-competitive practices. It may have serious repercussions on economy as well. It will shrink the foreign investment in such countries.[16] Therefore, the option of compulsory licensing should be resorted only in such cases when there is no possible way out.