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Compulsory Licence as a tool of Public Interest Under Patent Law in India

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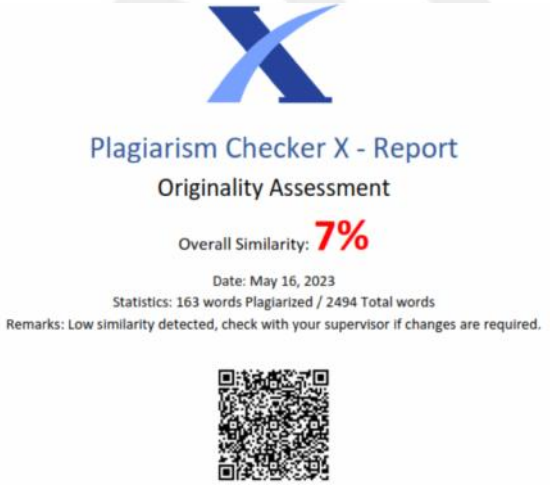

ABSTRACT

Compulsory licence is "an involuntary contract between a willing buyer and an unwilling seller imposed by the State". A compulsory licence is basically a revocation of Intellectual Property Rights - an extraordinary legal instrument that allows a country to itself or a third party (usually a competitor) to access, make, use or sell an Intellectual Property protected product or process without the consent of the owner. Mandatory and compulsory licences required by law can be granted for patents, copyrighted works or other exclusive rights. In the case of patents, the licence must protect against the misuse of the patented invention or the abuse of the patent holder's monopoly rights to protect the public interest. The same principles apply to copyright and other exclusive rights. TRIPS provides Member States with leeway to smooth out the wrinkles created by potential conflicts between competition policy and intellectual property laws. Articles 8, 31 and 40 of the TRIPS Agreement deserve special attention. Members can take steps to protect public health and nutrition and promote the public interest in sectors important to their socio-economic and technological development. In addition, TRIPS treats compulsory licences as an exception to the minimum requirement of the agreement that all member states grant exclusive rights to be patented for the entire term of the patent. TRIPS predicts a set of circumstances that will establish a minimum threshold above which each Member State is entitled to issue compulsory licences. Compulsory licences fall into two categories - if there is excessive public interest or if the patent is being used in an anti-competitive manner.

KEY WORDS

Intellectual Property Rights, Compulsory Licence, Public Interest, Patent, TRIPS.

INTRODUCTION

Compulsory licences are neither defined nor expressly mentioned in the TRIPS Agreement. They fall under a provision titled "Other Use Without Authorisation of the Right Holder," which establishes a system for the granting of licences where Member States are allowed to make "use of the subject matter of a patent without the authorisation of the right holder, including use by the Government or third parties authorised by the Government." In practical terms, this means that a third party may be permitted to use, manufacture or commercialise an invention, which de facto is still under patent and in this respect, the public interest goal of achieving broader access to the patented invention is considered more important than the private interest of the right holder in fully exploiting his exclusive rights. What this means in the context of public health imperatives is that compulsory licensing is intended to permit countries to produce generic drugs that are more affordable than patented medicines. Since this amounts to an exception to the exclusive rights of the patent holder, the TRIPS Agreement imposes specific conditions on Member States to admit compulsory licences.

Before a compulsory licence is granted, the proposed user must have first attempted unsuccessfully for a reasonable amount of time to obtain a voluntary licence on "reasonable commercial terms." Nevertheless, the requirement of trying for a voluntary licence can be waived if there is "national emergency" or "other circumstances of extreme urgency." Basically, compulsory licences could be granted by developing countries without prior negotiation with the holder of rights to pharmaceutical patents in the case of a public health crisis of epidemic proportions. However, the use of compulsory licensing shall be authorised "predominately for the supply of the domestic market of the Member authorising such use." This has the practical effect of preventing exports of generic drugs to countries that do not have significant pharmaceutical industries themselves.

Furthermore, the scope and duration of the use of compulsory licensing is "limited to the purpose for which it was authorised" and the authorisation of use can be terminated "if and when the circumstances which led to it cease to exist and are unlikely to recur." Finally, if a compulsory licence is issued, right holders shall be paid "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation."

Impacts Of Compulsory Licensing

The following areas are affected by compulsory licensing:

1. **Innovation:** In developing countries like India, pharmaceutical companies will be less innovative because they rely on generic drugs. They prefer to get a compulsory licence rather than fund to R&D separately, which is often very expensive. In addition, research-based pharmaceutical companies in developing countries will not introduce patent modules because there is always a risk of losing patents and losing money in research.
2. **Competition & Cost:** Compulsory licences increase the number of generic producers of medicines. Hence, supply will increase and prices will fall. It will also force innovator countries to introduce different prices for their patented modules in order to survive in the market.
3. **Patients:** Patients receive drugs at a much lower cost. In addition, large pharmaceutical companies often introduce plans such as free access to medicines to protect their patents in developing countries.

Compulsory Licensing in Public Interest

Specific provisions for compulsory licensing on notification by the Central Government by means of a notification in the Official Gazette, the Central Government can declare that any patent must be granted a

compulsory license, regardless of the time elapsed since the grant of the patent, in the following cases:

1. National emergency, or;
2. Extremely urgent, or;
3. Public non-commercial use.

After such declaration, the Controller can, at anyone's request, grant licence to the applicant under a patent on the terms and conditions deemed appropriate.

The Controller shall endeavour to ensure that products manufactured under patents are available to the public at the lowest price commensurate with patent owners and make reasonable use of their patents.

The procedure for issuing such a licence is the same as for issuing a licence under the terms of Section 84 of the Patents Act,1970. However, the Controller will not use the procedures set out in Section 87 of the Act prior to granting such consent in circumstances that may arise or are appropriate to the case, including public health crises related to Acquired Immune Deficiency Syndrome and Human Immune Deficiency Virus, Tuberculosis, Malaria or other epidemics. The Controller shall inform the patent owners as soon as possible about patents relating to applications for such non-application processes.

Intellectual Property Rights and Public Interest

IPR is an "exclusive" right because it gives a monopoly to the right holder to exploit intellectual property commercially, such as inventions (in terms of patents) and creative works (in terms of copyrights), and whoever wants to use the invention. Creative works can only do this with the copyright holder's consent. However, the laws of India and other countries provide exceptions to this right of public interest. For example, some exceptions in Indian copyright law exist to protect certain uses of copyrighted material, usually if the work is for personal, non-commercial use. Likewise, Indian patent law allows third parties to use patented inventions in certain limited cases without the permission of the rights holder - a mandatory licensing provision to ensure drug access is one such measure.

Consideration of the public interest in intellectual property laws educates Indian courts when deciding on offence proceedings, and courts strive to uphold socio-economic ideals such as access to education and public health. Problems such as a lack of available medicines and access to knowledge are concerns that affect millions of people in a country like India and therefore cannot be ignored when deciding the extent of restrictions (if any) on private rights such as intellectual property rights. However, if the public interest exception is interpreted too broadly by Indian courts, it raises concerns about the misuse of public interest provisions by third parties, as was the case with DU Photocopy.

Public Interest in Patent Law

In pharmaceutical cases (where a prior compulsory licence has been issued), the public interest requirement essentially requires evidence of bodily injury or grievous hurt if the damaged product is withdrawn from the market. It also considers the public interest in the interests of the person being patented, including whether the patent holder owns a product that is competitive in the market. It is based on expert forensic evidence that the public interest has been confirmed that there are patients who are successfully treated alone and who experience serious side effects or treatment failure when alternative drugs are used.

The court took into account that the patent recipient did not have a competing product with the same approach to the market. In contrast, at Parlance, patent holders have their own drug Repatha on the market with (presumably) the same mode of action, and Sanofi / Regeneron failed to convince the court that Praluent reduced patient mortality in a statistically more significant manner than Repatha. This is due, among other things, to the fact that separate studies were presented at Praluent and Repatha, which the court deemed to be less comparable due to the different ways in which the research was designed and conducted. In pharmaceutical cases (where a prior compulsory licence has been issued), the public interest requirement essentially requires

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Patent Rights v/s Public Interest: An Indian Perspective

The patent system is based on the principle that innovators must be incentivized to make their technologically advanced innovations available to the public. Innovators have a limited monopoly on the findings of such research. The granting of patents has two important but contradictory consequences: on the one hand, the monopoly given to innovators and, on the other hand, the severity of its impact on the public interest. The balance between these two aspects is very important for any country. In India, where more than one third of the population lives below the poverty line, public interest is an important factor in fighting the innovation monopoly.

Section 84 of the Patents Act,1970 grants patent holders the exclusive right to exclude third parties from making, selling, offering for sale, using, or importing a patented product or process. On the other hand, protecting the public interest by providing provisions regarding compulsory licences in accordance with the Chapter XVI, which was substituted by the Amendment Act of 2002 compliance with the TRIPS Agreement. Under Section 83 of the Act, patents are issued to encourage, innovation and ensure that patented inventions are fully functional in India. In addition, there are plans to grant patents to promote technological developments in India and to make patented inventions available to the public.

Under Section 84 of the Act, any interested person can apply for a compulsory licence after three years from the date of grant if the patented invention does not fulfil reasonable demands of the public or if the patented invention is not available to the public at a reasonable price or a patented invention doesn't work in India. The legislature's clear intention is that a monopoly should be given to promoting publicly available inventions at a reasonable price. Thus, if read together, the provisions of the law clearly align the public interest and the rights of the innovator or the person who is patentee.

The judiciary plays an important role in achieving this delicate balance, especially when it comes to medicines, especially life-saving drugs. In deciding the balance of comfort in Franz Xaver Hummer's appeal to the decision, Chief Justice M.J. Rao of the Delhi High Court said factors such as the defendant's investment, job loss, public interest that the product was a life-saving drug, the quality of the product combined with the price, or the smaller size of the defendant should also be considered could lead to a court ruling against the plaintiff.

There is nothing to deny that the majority of people in least developed countries - and in most developing countries - find the prices of many life-saving drugs a barrier. This is further compounded by weak social health infrastructure, unbearable health insurance, and unavailability of medicines in public hospitals, forcing hospitals to fund drugs at high costs. Therefore, there is a need for a paradigm shift in the way the pharmaceutical sector does business, especially in this part of the world. The downside is the enormous costs incurred by innovation organizations around the world for development, testing and patents. They want to amortize these costs through their drug pricing mechanism. Without incentives, no pharmaceutical company will invest in the development, and therefore the availability of new, stronger drugs will be disrupted. Some subjects tend to alleviate the difficulties of poor patients, even in developed countries, by selectively providing free drugs. The right model must be developed so that on the one hand the innovation offers sufficient incentives to develop new drugs and at the same time patients of different social classes have sufficient equal access to them.

Public Interest Criteria

Defining standards or criteria for the public interest is not easy because the public interest itself is a vague concept and therefore difficult to define. Also, as Kalo said, it is difficult to conceptually define the public interest in operational terms.

CONCLUSION

The compulsory licences hold the important position in patent system of any country and these provisions are the soul of the Patents Act of 1970. The Government was empowered to grant compulsory licences on certain grounds and above all the highlight of the Act was that the inventions in the field of food, drugs and chemical were already endorsed with the licence of right which allowed any interested person to have licence after three years of course on the payment of royalty to the patent holder. Ceiling rate of royalties was fixed at 4 % in such cases. The basic purpose of the Act was to work the patent in domestic country instead generating import monopoly. The non-working of the patent was made one of the grounds of revocation of the patent by the Government.

Furthermore, if seen isolated and provided that TRIPS is modified, compulsory licensing might be an effective tool to restrain and reduce drug prices. However, seeing compulsory licensing from a wider angle in addition to adopting an extended compulsory licensing system, the safeguard suffers from the risk of being detrimental to future R&D initiatives, of obscuring the potential of alternative innovative policy instruments as well as of being abused for commercial purposes. In addition, it is desirable that further recommendations are given on which generic producing companies should be awarded compulsory licences and also on which premises.

In reality, the debate about compulsory licensing is part of a much wider structural problem in development policy. The solution to the inaccessibility problem requires a mix of courses of action with a functioning compulsory licensing system included. However, disagreements such as how necessary funding should be divided equitably between developed countries could protect the reaching of a pragmatic solution.

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