# COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS[1]

## INTRODUCTION

Compulsory Licensing of Pharmaceutical patents as a concept has run into several debates in recent times, be it pro-patent groups or pharmaceutical companies or for that matter even public health advocates, all have had a fair share of criticism for the current system. In light of all this, it is important to first understand the exact nature of the debate and then to dive into the complexities of the same.

*"Compulsory Licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner."*[2] Article 31 of the TRIPS agreement[3] deals with compulsory licensing, though the title of Article 31 is "Other use without authorization of the Right Holder" and there is no explicit mention of the term Compulsory Licensing but if we read Article 31 Article 2(1) of the TRIPS Agreement, and Article 5A (2) of the Paris Convention[4], then it will successfully culminate into Compulsory Licensing. This should further be read with Article 8[5] and 27 of the TRIPS Agreement which will lead us to the reasons for granting compulsory licenses, one of which is public health.

In light of the increasing importance of pharmaceutical patents in the 1st decade of the coming into being of the TRIPS Agreement, the Doha Declaration sought to expand the rights of the countries with regard to compulsory licensing of pharmaceutical patents which again was done on the pretext of public health.[6] Further, in 2005, **Article 31bis** was agreed upon which was enforced in the year 2008. *The fundamental implication of this Article is that it allows for*

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[1] Apurv Tyagi, IV Year, B.A LL.B. (Hons.) , National Law School of India University, Bangalore.

[2] Compulsory Licensing of Pharmaceutical and TRIPS, available at http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm last visited on May 1, 2012.

[3] Article 31, available at http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5, last visited on May 2, 2012.

[4] Article 5A (2) of the Paris Convention, available at http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P123_15283, last visited on May 2, 2012.

[5] Article 8: Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect health and nutrition.

[6] Philip W. Grubb, Peter R. Thomsen, PATENTS FOR CHEMICALS, PHARMACEUTICALS, AND BIOTECHNOLOGY 49 (2009).

*developed countries to issue compulsory licenses to domestic generic pharmaceutical manufacturers, thereby permitting the domestic manufacturers to export medications to developing countries.*[7]

Through this we can gauge the importance of compulsory licenses of pharmaceutical products at both levels, national and international. While we have entered the domain of compulsory licensing vis-à-vis pharmaceutical patents, it would be pertinent here to briefly outline the special case of pharmaceutical patents.

Pharmaceutical Products have had special treatment both in terms of patent and compulsory licensing primarily because of their role in promoting public health. Japan and Switzerland are two notable examples where pharmaceutical patents were not issued till 1977. Spain, Portugal, Greece and Norway introduced the same only in 1992.[8] Thus the amendments to the TRIPS Agreement have adopted a progressive tone which according to the author is correct and should be supported by the developed countries as well because as will be seen, Compulsory Licensing does not hurt innovation.

## CERTAIN PERTINENT ISSUES

As has been observed, "*the issue of compulsory licensing or price control holds unique significance in the area of pharmaceuticals. Unlike consumer products, where the elasticity of individual human-need varies with affordability, the demand for pharmaceuticals is independent of affordability.*"[9] In the light of the above mentioned observation, the remedy of compulsory licensing gets further weakened. So it is important to understand why and how compulsory licensing can be defended.

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[7] Mike Gumbel, "*Is Article 31bis enough*?" available at http://www.temple.edu/law/ticlj/ticlj22-1Gumbel.pdf, last visited on May 10, 2012.
[8] Colleen Chien, *"Cheap Drugs At What Price To Innovation: Does the Compulsory Licensing Of Pharmaceutical Hurt Innovation: Does the Compulsory Licensing Of Pharmaceuticals Hurt Innovation?" BERKELEY TECHNOLOGY JOURNAL (2003).*
[9] Srividhya Ragavan, AIDS As A Detriment To India Shining, available at http://www.law.ou.edu/faculty/facfiles/Vivek-NALSAR.pdf, last visited on May 10, 2012.

Now, it is quite often argued that compulsory licensing hurts innovation, in the sense that it disincentivises inventions thereby causing a great dent on the economy as well. This may not necessarily be true as can be proved from the study given below.

In 1977, F.M. Scherer conducted a major study of antitrust, consent related CLs. The sample set was around 400 companies, 42 of which had been subject to CLs. Scherer calculated the ratio of each company's R&D expenditure to its sales for the year 1975 and compared companies that had been subject to CL and the ones which had not and the result which he found was contrary to the widely held belief. He found that the firms subject to CLs spent almost the same amount on R&D as the companies which had not been subject to CLs.[10]

Parallel Importation is again one area, where significant numbers of debates have been generated, at the time when the issue of parallel importation was hotly being debated, Perez Motta came out with a draft providing solutions for the problems ailing the system but the same was criticized and thus not accepted.[11]

Bayer has had a fair share of trouble in this area, on account of different health policies in different member states in Europe, for the drug, *Adalat*, Bayer was charging 40-50% less in Spain and France than what it was charging in Britain. Worse still was the commission's move to fine Bayer 3 million Euros when, in order to curb parallel importation, it ceased fulfilling the large wholesale orders from France and Spain.[12]The way in which the government has utilized pharmaceutical patents has also been a contentious issue, especially in cases where the government tries to unduly exercise its right under the prevailing law or sometimes under some or the other principle.[13]

The threat of compulsory licensing has been used for a very long time for various reasons, the government always considered itself the first owner of everything that was within its jurisdiction, this can be seen from the examples of CIPRO and tetracycline, So in the 1960s and 1970s, the U.S. Government made and used tetracycline and meprobamate for the military without

[10] *Supra* note 7.
[11] INTELLECTUAL PROPERTY RIGHTS; A GLOBAL VISION, 115 (S.K. Verma & Raman Mittal eds., 2004).
[12] D.G. Goyder & Joanna Goyder, COMPETITION LAW, 218 (2009).
[13] Neil Davenport, THE UK PATENT SYSTEM, 82 (1979).

permission from the patentees. Similarly, in the fall of 2001, the threat of a compulsory license was used to drive down the price of CIPRO by around 50%.[14]

Some scholars believe that the 'problem' of compulsory licensing is linked to the patent regime in the United States.[15] The others consider compulsory licensing as a boon and they state that this remedy would increase output and decrease costs thereby benefitting the public at large.[16]

But the argument of public health has to be balanced with the Research and Development wing of the companies as well. As is understood, the chances of a compound becoming a product are 1:4000, out of this, imagine the range of successful products,[17] thus some leeway should be given to the pharmaceutical companies and that perhaps is the reason for the absence of compulsory licensing in the U.S.

If we were to take a North American perspective, then it would be found that while Mexico allows for compulsory licenses and Canada also has a limited use of the same, these are not available in the U.S. except for in certain cases.[18]

Antitrust orders have generated many more CLs and have been used to remedy patent misuse and the use of patents in price fixing, entry restricting cartels and market concentration schemes, compulsory licensing can also be used as an antitrust remedy, which can be justified when another big firm refuses its rivals the access to essential resources which is controlled by this firm thereby harming competition.[19]

Compulsory Licensing, it is argued, should form part of the essential facilities doctrine,[20] while there is huge controversy regarding the status of essential facilities doctrine itself but if compulsory licensing were to be brought within the ambit of essential facilities doctrine then it would lead to a double whammy (in the positive sense). First, a legal jurisprudence would be provided to the uncertain future of compulsory licensing as it lacks any directions as of now,

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[14] *Supra* note 7.
[15] Alan M. Fisch, "*Compulsory Licensing of Pharmaceutical Patents*" 34 JURIMETRICS 295, 296 (1993-1994).
[16] *Supra* note 7.
[17] *Id.*
[18] Background of Compulsory Licenses in U.S., available at www.aipla.org/resources/intlip/Documents/TRIPs_Ryan.ppt, last visited on May 4, 2012.
[19] Jay Pil Choi, "*Compulsory Licensing as an Antitrust Remedy*" 2 W.I.P.O.J (2010).
[20] *Supra* note 18.

second, compulsory licensing, as an antitrust remedy would be accepted by the states for the sole reason that it is going to positively balance the rights of the public with the pharmaceutical companies in particular.

While applying the remedy of compulsory license remains one thing, a slightly deeper analysis would reveal as to how it is to be done, some argue that the rule of reason in antitrust law should be used as the guiding principle for granting compulsory licenses.[21]

## LEGAL POSITIONS

In U.K., the Crown has a lot of power over the patents, Section 55 of the 1977 Act empowers any government department or person authorized to do various acts in relations to a patent without the consent of the owner.[22]

In the United States of America, there is no general statutory provision requiring compulsory licensing of patented inventions. But the Department of Justice has been more than willing to provide compulsory licensing as one of the solutions where a company adopts a licensing strategy to affect public welfare.[23]

One of the earliest case involved the licensing of tetracycline ampicillin and related products as part of a judgment against Pfizer and other pharmaceutical companies in response to an antibiotic price fixing scheme.[24] In 1970, the FTC created a separate division staffed with 35 lawyers and investigators within the Bureau of Competition to work exclusively on healthcare antitrust issues. Through this we can estimate the importance of this area in the U.S. CIPRO controversy better reflects the plight of the pharmaceutical companies but then again even the profits of the companies should be balanced with public health.

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[21] Dora Kripapuri, "*Reasoned Compulsory Licensing*" 36 NEW ENGLAND LAW REVIEW 669, 672
[22] Paul Torremans, INTELLECTUAL PROPERTY LAW, 102 (4th edn., 2005).
[23] Gerald Kamstra, Henry Wixon et al., PATENTS ON BIOTECHNOLOGICAL INVENTIONS, 102 (2002).
[24] *Supra* note 7.

In case a compulsory license is granted, then the patent for that particular product/process cannot be assigned, also the amount that can be produced under the license must be specified as must the duration.[25]

No single interest group can shape a system. If there is a single justification or common purpose that underpins the system, it must be the attainment of a balance between the different interests involved.[26] It is the belief of a few that the jurisprudence which has developed in the direction of protection to research tools instead of specific application of research data must be rejected.[27]

Case: U.S. v. Glaxo Group Ltd., 1973 Supreme Court Judgment. Here ICI (Imperial Chemical Industries) and Glaxo each owned patents covering various aspects of antifungul drug, griseofulvin. They pooled their patents so that the finished form of drug was not sold in bulk form. It was licensed to be sold in finished form only. The purpose of this restriction was to keep the drug chemical out of the hands of small companies that might act as price-cutters, and the effect was to maintain stable, uniform prices. The Department of Justice Antitrust division sued, alleging violations of Section 1 of the Sherman Act. The U.S. Supreme Court held that when a patent is directly involved in an antitrust violation, the government may challenge the validity of the patent and ordinarily in a patent-antitrust case, mandatorily selling on specified terms and compulsory patent licensing at reasonable charges are recognized antitrust remedies.

India from the very beginning has played a significant role in the pharmaceutical industry as it was Dr Yusuf Hamied who took the lead in providing inexpensive drugs to African countries.[28] The World Bank's report on the Indian Pharmaceutical Sector gives insights into the importance of developing countries while policies are being formulated as they constitute the majority of the world and might be not so technologically advanced but soon will be.[29] Needless to say, that the future of India in this regard sure seems bright.

[25] THE MODERN LAW OF PATENTS, 413 (Ashley Roughton, Philip Johnson *et al* eds., 2nd edn., 2010).
[26] Holyoak & Torremans, INTELLECTUAL PROPERTY LAW, 44 (6th edn., 2010).
[27] Gustavo Ghidini, INTELLECTUAL PROPERTY AND COMPETITION LAW, 43 (2006).
[28] Hiroko Yamane, INTERPRETING TRIPS, 279 (2011).
[29] Ramesh Govindraj, Gnanaraj Chellaraj, THE INDIAN PHARMACEUTICAL SECTOR 4 (2002).

Also, with the very recent order granting the first compulsory license to Natco against Bayer's patented cancer drug,[30] *Nexavar*, India is set to come in the top league of countries with extensive compulsory license jurisprudences.

## CONCLUSION

The remedy of compulsory licensing for pharmaceutical patents as has been argued may just become one of the biggest solutions to the problems ailing the system at large but the same is yet to face the most severe of its criticisms before perhaps becoming well established. Alan M. Fisch calls this solution an unreasonable one to an unfortunate problem. Despite all this, it is the hope of the author that compulsory licensing of pharmaceutical patents would soon find its permanent place in patent law jurisprudence.[31]



[30] Breaking News: India's First Compulsory License Granted, available at http://spicyipindia.blogspot.in/2012/03/breaking-news-indias-first-compulsory.html, ;ast visited on May 16, 2012.
[31] *Supra* note 14.