DETRIMENTAL EFFECTS OF IMPLEMENTING COMPULSORY LICENSING IN THE REGIME OF INTELLECTUAL PROPERTY RIGHTS

By Aatif Rahnuma & Isha Tiwari
From Symbiosis Law School, Pune.

“That he, the Inventor, ought to be both compensated and rewarded...will not be denied...it would be a gross immorality of the law to set everybody free to see (or use) a person’s work without his consent, and without giving him an equivalent.” - John Stuart Mill (1848)

ABSTRACT

In amidst of the Covid-19 Pandemic that has engulfed almost every inch of this world, the noval virus has not only put the human life at verge of uncertainty, in spite of that it has additionally broken off the algorithm of currently existing Intellectual Property Rights Law across the world. An intellectual right owner enjoys a huge set of rights as a catalyst towards his time, resources and money invest in her research and development of the noval item. However, such catbird seat is often compromised under certain life and death situations as like in this pandemic. Added to it paper thoroughly researches on, regimes like “Compulsory Licensing” that might lead to misapplication of licensing sympathy by market organizations. Further the concept of “Open Pledge” may be two sides of a same coin with one side of it be towards the philanthropist enhancement and added to its other side owing to perfunctory of major tycoons of disinvesting for the sake of advert laws. Further, the impact of using “Intellectual Property Rights as collateral” is also researched on along with the pattern of “Patent Pool”. The presented papers attempt to conglomerate all the evidences and research procurable to get to its depth.

KEYWORDS: IP rights, Compulsory Licensing, Open Pledge, Patent Pool, I.P as collateral, Covid -19

PROBLEM STATEMENT (HYPOTHESIS)

- H1: Is issuance of CL and quashing patent holder right is justified?
- H2: Is Compulsory licencing working as a barrier and demotivating world tycoons from initiating multibillion-dollar research for pandemic and epidemic vaccines?
- H3: Is the threat of CL capable to hinder the pace of research and quality of vaccines?
- H4: Is Open pledge, Patent Pooling and use of IPR as Collateral will act as stimulant to uplift Covid -19 pandemic situation?

RESEARCH OBJECTIVE

Q1. How covid-19 effected the Intellectual property rights?

Q2. What all action can government must take to quash patent holder right in the time of emergencies?

Q3. What is the alternative that can not only prioritize public health but also keep in mind the profit needed for a company to recover its cost of research and also serve as incentives to other?
Q4. Will the threat of CL hinder the company’s motivation and speed who work with a goal to earn profit from patent?

RELEVANCE AND IMPORTANCE OF RESEARCH
Through this paper, we will be able to contribute the implication above and beyond to the current schemes of sanctions, relaxations and restrictions relating to Intellectual Property Rights with its immediate effect to Covid – 19 status quo and its future implications as such. Through our rigorous research in the field will help to bring out the both positive and negative implication of existing laws in consideration to Intellectual property scheme in national as well as international market. This paper will be relevant for academicians, students and Professionals working in the field of Industrial Property information and documentation (IPID)

RESEARCH DESIGN, METHODOLOGY AND TOOLS

Research design
The research paper has been designed with Qualitative research pattern. Paper primarily relies on the laws and response of the selected crowd predominantly affected by Intellectual Property Rights. The paper consists of hypothesis and research question to be investigated. Takes into account precise examination of Intellectual property rights during never seen before pandemics like situations, Its implication on both ends with the help various international and national forums.

Methods and Sources
With an objective best justify this research paper, Fundamental & Doctrinal Research Methodology is being used. Where the data comprises mainly of secondary data collected from legal propositions, periodicals, legislations and websites which has been cited as References.

Practical Consideration
The research scope is restricted in the consequence of limited data available on internet and trusted journals. Further, Quantitative research couldn’t be conducted on the account of non- availability of statistical data.

LITERATURE REVIEW

Key concept, theories and studies
• **CL prioritise human life above profit making.**

The basic aim of CL is to value human life above the profit maximization goal of companies. CL basic intention is public welfare but while doing so it act as a deterrence for big business tycoons from investing huge sums in research and development of drugs that are bound to come under CL

• **Negative impact of CL on the patent holder company.**

CL will affect companies adversely who work for the profit, which will be derived from the patent. As patent serve as an incentive and motivates them to invest more and speed up their research.
Key Debates and Controversies

- **Can CL be misuse to break the right of patent holder?**

CL has acted and been a reason for friction between countries, as first world countries who spend billions on research and development wants protect their patent rights but third world countries often rely on CL to avail the patented goods at cheaper rates. If the company investing time and money for researching a particular drug and such drug then is availed to other by invoking CL, then such company is bound to sustain losses and will lose further motivation to develop such drugs in future. Not only that company but other companies will also feel demotivated as there is no attractive incentive in researching and developing such drugs.

- **Who will reimburse the patent company losses and expenses in research and development?**

If there is no incentive for research and development of a new product then no big company will initiate such expensive research. As the main goal of CL is to prioritise the human wellbeing above profit making, but while doing so it jeopardizes the speed of research and development of such life saving drugs.

For example, after Italy enforced Drug Patent Law 1974, which enables the patent holder to retain a limited exclusive right which help them to recover the cost of invention and capitalize reasonable profit. This alone results in 600 percent increment in pharmaceutical research in a decade.

IMPLICATIONS AND CONTRIBUTIONS TO KNOWLEDGE

**Practical Implications**

Sec 31 of TRIPS define compulsory licensing, its basic goal is to priorities the Humanity above the profit making. It basically deprive the patent holder of its right and allow others to produce the patented products. It is generally invoked during health crises in order to make the necessary drugs available to the general masses at low cost. In India CL can be applied under sec. 84.

**Theoretical Implications**

New alternative must be found which not only prioritize the Human life but also keep in mind the efforts and capital spent by the patent holder in order to acquire such drugs. An alternative that balances between the two goals must be found, because if the sword of CL hangs on any patent related to life saving drugs, then it will act as a hindrance for many other big companies to initiate research and development for the same, as they will fear even after spending billions they at last found the cure then it will be handed over to other.

New alternative can be-

- Subsidising the drugs by government
- Reimbursing the company in alternative ways apart from just money.
  - Tax relief for upcoming subsequent years.
  - Leasing land for the company use.
  - Etc.
1. INTRODUCTION

It's been said that humanity has evolved and thrived on this planet only because of its capacity and ability to innovate. Innovation in every age and century has been the central pillar of the development of the society hence there have been certain rules, regulation and laws that guide and incubate the innovator and his inventions in order to foster them from others. These laws also provide these inventions and their inventors a safe space to not only invent but also to thrive upon these inventions by earning profits and retrieving the time and money spent in order to develop such inventions.

The inventions which are tangible in nature are easier to protect then compared to inventions which are intangible or intellectual such inventions are most critical to preserve. As these inventions have no practical form but it is merely a product of human intellect. Such inventions are known as intellectual property. The concept of intellectual property was developed in 17th and 18th century in England but only in the 19th century the terminology intellectual property was used and in late 20th century the word intellectual property was commonly known in legal world.¹

Few basic types of intellectual properties are copyright, patent, trademark and trade secret. In this research paper we will be concentrating on patents. It basically gives exclusive right to the owner to produce and sell the specific goods or commodity for a certain period of time which is usually 20 years, it also bars others from producing and selling such or similar goods or product. For instance, if someone has a patented drug for certain medicine then no other company can make or sell these patented drugs without the prior permission of the patent holder. Such laws have been created in order to promote the inventors for new inventions, as any new invention cannot be commenced without thorough research and development process and such research and development required a humongous amount of investment.

In other words, a patent is provided to the patent holder to earn profit from his invention. To be more precise it is to safeguard the monetary interest of patent holders. So that the patent holder can recover the cost included in research and development and also on a substantial amount of profit that will work as incentive.

In certain cases, the right of the patent holder is dissolved, like in the situation of a pandemic or epidemic when a pharmaceutical company has invented a composition of drugs that act as a vaccine against such deadly disease. Then even after patenting such lifesaving drugs by that pharmaceutical company will not be able to preserve the exclusive right to manufacture and sell such drugs. Under the circumstances the basic principle of humanitarian law suggests that laws can be broken when necessity arises.

The core behind the patent law is to secure the monetary interest of the patent holder but when the human lives are at stake than such laws need to be diluted, this is where instruments like compulsory licensing comes into picture.

The principle behind compulsory licensing is that it prioritises human life above profit.

making; hence it is a law that dilutes the rights of patent holders and distributes the rights to other Pharmaceutical manufacture to produce the generic drug with the same patented composition in order to meet the demand in the face of the crisis. In compulsory licensing, the patent holder has no say at all, undoubtedly such measures will hurt the patent holder interest as there is a huge amount of investment involved in research and development and without the patent right the monetary interest cannot be secured therefore Capital invested cannot be retrieved.

In this research paper we will thoroughly discuss the positive and negative aspects of compulsory licensing in the face of the Pandemic and epidemic crisis.

2. COMPULSORY LICENCING

Sec 31 of TRIPS define compulsory licensing, its basic goal is to prioritise the Humanity above the profit making. It basically deprive the patent holder of its right and allow others to produce the patented products. It is generally invoked during health crises in order to make the necessary drugs available to the general masses at low cost. In India CL can be applied under sec. 84. There are several remedies available to government apart from CL 2 some of them are as;

Sec 102- Government can acquire relevant patent for public purpose

Sec 100- Government can acquire relevant patent for the purpose of government

Sec 92- Government in the event of national emergency government can issue CL without following the procedure.

In 2012 CL was granted to Nacto3 to make anticancer drug (Sorafenib), this was originally patented by Bayer AG. The generic version of same drug after invoking CL was available to the general masses for one fourth of its original price in India. This all seems good until we take a look on the back of this law which on one hand provide cheaper medicines to the people but on the other hand it sabotage the capitalistic pillars on which such pharmaceutical giants are built.

The principle behind compulsory licensing is to value human life above the profit in the making, in the face of an endemic when the masses of people's life is at stake than under these circumstances the right of patent holders can be forcefully dissolved by the government in order to preserve human life. Although the government provides royalty as a compensation for using the patented product without the patent holder authorisation, but usually this amount is hardly a fraction of the profit that company would have made through the patented goods.

CL have some drawbacks too, it works as a deterrence for the company who have spent billions in research of such drugs only to end up their final product in the hands of other. These company faces difficulty after invocation of CL, as now it’s much harder for them to make profit and recover their research and development cost. The different companies who start mass production after receiving CL, usually results in degradation

2 T. Jain, Compulsory licenses under trips and its obligations for member countries, ICFAI, 231, 1 (2009).

of the quality and sustainability of the products, these products are usually end up being inferior to the products of original patent holder company. It is no wonder that “Corporate Giants” find this practice of compulsory licensing demotivating as it is unfair to distribute the right of production and sale to others who have absolutely invested nothing in the research and development of the said product.

2.1 Pros & Cons Of Compulsory Licensing

ADVANTAGES:

• Compulsory licensing prioritise human life above profit making.

In a civilized society we are governed by humanitarian law and the basic philosophies dictates that human life should always be measured and valued above anything else. The concept of compulsory licensing is a clear example of privatising human life above profit making goals. As when a medicine is researched then there is a huge amount of capital involved in research and development, amount which later on is recovered by pharmaceutical companies by selling the printed medicine at much higher rate than of the cost of production. This is done in order to recover the capital invested for research and development and also to earn substantial profit. But in times of medical crisis for life saving drugs these rights and the policy of profit maximization should be set aside for the good of humanity. On this very philosophy the compulsory licensing was introduced and is implemented when needed.\(^4\)

• Patents can be harmful for developing nations.

Patent bars other from manufacturing the same product that would otherwise have been available at a cheaper rate but due to patent these products are now bard for others from using them without the consent of patent holder and such consent only be given in the form of patent licencing to the third party from patent holder in exchange of certain sum of money. This process itself increases the cost of the product as now the final cost of the product will not only include production cost but also include capital paid to receive patent licensing for producing and selling such products. In such situation issuing CL and distributing the rights to manufacture and sell to others could very provide the much-needed help to such developing and underdeveloped countries.\(^5\)

• Compulsory Licensing in pharmaceutical sectors.

Third world countries or developing or underdeveloped countries face critical issues regarding patents, especially in the pharmaceutical sector. As these developing or underdeveloped nations don't have infrastructure to research such drugs therefore, they are totally relying upon the developed Nations for such lifesaving medicines. These Developing or underdeveloped nations usually do not have much per capita income hence the majority of citizens residing in the developing or underdeveloped Nation cannot afford the

\(^{4}\) R. C. Bird, Developing nations and the compulsory license: maximizing access to essential medicines while minimizing investment side effects, JLME, 210-12 (2009).

\(^{5}\) J. Kuanpoth, Proceed with caution on compulsory licensing, IPRJ 26 (2011) .
costly lifesaving drugs. In such a situation compulsory licensing comes as a life saver by distributing the manufacturing and selling licence to other manufacturers that could now produce generic versions of the same lifesaving drugs. These generic versions are usually way cheaper than the original and therefore it can reach the majority of the citizens residing in developing or underdeveloped nations.6

DISADVANTAGES:

• Negative impact of CL on the patent holder company.

CL will affect companies adversely who work for the profit, which will be derived from the patent. As patent serve as an incentive and motivates them to invest more and speed up their research. A multinational corporate giant who has invested in the pharmaceutical sector has only one intention and that is to generate profit. We need to keep in mind that while research and development there are numerous researches and development has been undertaken in order to achieve success and invent a composition of drugs that is suitable to treat the patient and cure the disease. Large amounts of undertaking of research and development cost in millions and billions, these expenses can only be retrieved from the market by selling these patented drugs with sole right to manufacture and sell and such rights are provided by patent laws. But when compulsory licensing is applied to a certain drug then these pharmaceutical companies are obliged to possibly give licence to other manufacturers to produce such drugs and for this they are given a minimal amount of royalty that would not be more than a fraction of profit that they could earn by selling these drugs under patent licence.7

• Compulsory licensing will demotivates the inventors.

This will surely result in the demoralisation of such pharmaceutical companies to initiate “Mammoth size research and development” for pandemic or epidemic diseases as they know that these drugs that they will find after investing millions and millions of dollars will end up in compulsory licensing and eventually will be sold by other manufacturers who has literally done nothing nor contributed anything in the process of research and development. In other word by applying compulsory licensing we are simply slowing down the process of innovation.

• Compulsory licensing will slow down the speed of inventions of new lifesaving drugs.

Patent provides the patent holder absolute right to manufacture and sell the invented commodity and also bars others from manufacturing and selling the same commodity. This work as an incentive for the pharmaceutical companies to research and develop new and advanced drugs that could save life. But after putting humongous capital and time the final composition of drug which is developed now be sold by others who have not invested time nor money, just because the said patented drugs now have been put under compulsory licensing which allows anyone to produce and distribute the patented goods. This acts as a deterrence for such pharmaceutical companies and will

result in slowing down the process of research and development as there is no such incentive now available to them.8

- **Compulsory licensing may degrade the quality of product.**

  Compulsory licensing provides anyone who is eligible to manufacture a similar product licence to produce the generic version of the patented drug. Search generic versions are undoubtedly cheaper but they are also of inferior quality. Company who has researched for years and spent Millions knows its ways around such drugs but by implementing compulsory licensing and distributing it to other manufacturers for mass production will surely degrade the quality of such drugs. In other words, by implementing compulsory licensing and producing generic drugs will provide such drugs at a much cheaper rate but also of much inferior quality.

- **Compulsory licensing may endangers the consumer**

  Drugs which are produced after issuance of CL By mass manufacturers are usually generic in nature and are of inferior quality. Consuming such cheap generic drugs could result in many unknown side effects that could be injurious to health. This very well contradicts the sole purpose of compulsory licensing as it is initiated to save human life but in order to do so it may very well endanger human life by providing cheap generic drugs of low quality that could be harmful to health.9

2.2 Controversies

- **Can CL be misuse to break the right of patent holder?**

  CL has acted and been a reason for friction between countries, as first world countries who spend billions on research and development wants protect their patent rights but third world countries often rely on CL to avail the patented goods at cheaper rates. If the company investing time and money for researching a particular drug and such drug then is availed to other by invoking CL, then such company is bound to sustain losses and will lose further motivation to develop such drugs in future. Not only that company but other companies will also feel demotivated as there is no attractive incentive in researching and developing such drugs.

- **Who will reimburse the patent company losses and expenses in research and development?**

  If there is no incentive for research and development of a new product then no big company will initiate such expensive research. As the main goal of CL is to prioritise the human wellbeing above profit making, but while doing so it jeopardises the speed of research and development of such live saving drugs. For example, after Italy enforced Drug Patent Law 1974, which enables the patent holder to retain a limited exclusive right which help them to recover the cost of invention and capitalise reasonable profit. This alone results in 600

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percent increment in pharmaceutical research in a decade.10

3.CRITICAL ANALYSIS OF COMPULSORY LICENSING

Following are the different aspects of Compulsory licensing taken into consideration for the scope of this paper.

3.1 Legal Aspect of Compulsory Licensing in Pharmaceutical sectors

The paper tries to address different legal aspects related to Compulsory Licensing in respect to its International Standards, treaties and National Standards.

3.1.1 International standards & Treaties of Compulsory Licensing

In today’s era of globalization and development, still exist certain unprivileged countries that fails to secure the things of basic necessities to its citizen and have no resources to treat even the basic diseases. On the other hand, with passage of time, certain developed countries have equipped themselves to treaty almost any kind of disease. Henceforth to keep the humanity intact several nations have signed treaties and conventions wherein they pledge to help the underdeveloped countries. Following are the most eminent ones;

I Paris Convention of 1883

Article 5 A (2) of the Paris Convention of 1883 grants each country of union right to adopt legislative measures for granting compulsory license to avoid misuse of monopoly. For example, during World wars, compulsory licensing was compiled to share aviation technology and drugs like penicillin.

Paris Convention applies for the safeguarding of industrial property and includes:

- Patent rights for a period of 12 months;
- Utility models which is not applicable in India;
- Provision for Industrial design for a period of 6 months;
- Trademarks, service marks and trade names for period of 6 month;
- Geographical indication of appellations

India is also party to Paris agreement.

II TRIPS Agreement, 1995

Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was enacted on January 1, 1995. Its main agenda was to minimize the impediments and risks associated with global trade and protection of IPR’s. It required all the signatories to WTO to sign the regulations related to IPR’s as laid down by the treaty. It however did not repeal the Paris agreement but rather incorporated the convention under Article 2(1)6.

Under TRIPS it provides monopoly of patent for a period of 20 years and prohibits the use of licensed patent by third party without the permission of patent holder. It works a boon for developed countries and bane for developing countries due to their lower affordability capacities. However, when it comes to the pharmaceutical companies it becomes an exception where it provides for Compulsory Licensing to override the concept of patent monopoly.

III DOHA Declaration
DOHA Declaration took place in Doha, Qatar in 2001, which was conducted to clarify the concerns related to the flexibilities in TRIPS agreement and in relation to accessibility of medicines. It emphasized on the need to balance the public health issues in developing countries.\textsuperscript{11} It grants the individual nations freedom to grant compulsory licence. Lastly, Doha Declaration address the ambiguity imposed by Article 31(f) of TRIPS relating compulsory licensing.\textsuperscript{12} As those in case of developing countries who lacks in basic infrastructure to manufacture drugs couldn’t utilise the flexibilities provided under TRIPS.

IV Universal Declaration Of Human Rights (UDHR)
Article 25 of UDHR provides for recognising the human rights of persons to have adequate standard of health and guarantees for standard of wellbeing. It emphasises on the link between health and wellbeing, which includes right to food and to medical services.

V Institution Of Essential Service Reform (IESR)
Article 12 of the IESR emphasises on the need of “right to have highest attainable standard of health and wellbeing” and lays down the principles that must be implemented to achieve them.

VI Convention On rights Of Children (CRC)
Article 23 and 24 of the acts derives the urgency for recognition of right to health for children. It further addresses the need to maintain maternity and children health.

3.1.2 National Standards of Compulsory Licensing India
In India “Compulsory Licensing” has been conceptualised under Section 84 of the Indian Patent Law. The grant is applicable for a period of three years, on the expiration of such period however any individual can apply to the comptroller.

Application can be made for grant of compulsory licensing to any person including the license holder. No person is restrained from applying by the virtue of lacked public interest, out of domain of Indian Jurisdiction, etc. The application must include applicant’s interest along with particulars and facts that forms the base of the application.\textsuperscript{13}

A. Factors taken into consideration for granting of Compulsory Licensing

Following factors are to be consider by the comptroller in granting of Compulsory Licensing:

- The nature of inventions and time elapsed from the date of patent user acquired its rights in full compliance to be used;
- The capacity of invention to serve the public advantage;
- Applicant’s ability of undertaking risk in providing capital and using the patent;
- Whether there were any efforts made by the applicant to obtain the grant from the


\textsuperscript{13} Cornish, W.R., Intellectual property: Patents, Copyrights, Trademarks and Allied Rights, Univ.L.J.,222, 2012
patentee or not will also serve as a point of consideration

Further the above-mentioned points can be elaborated in the light of mentioned case laws;

In F. Hoffmann-La Roche Ltd. And Another v. Cipla Limited, court observed that the intent of the legislature was to provide the Patent holder a sufficient time of at least three years to recover the cost incurred in research and development of the drug. And later on, the expiration of the above-mentioned period, it could be made available to public at large at affordable price by Compulsory Licensing.

In Franz Zaver Huemer v. New Yash Engineers, High Court of Delhi held that the ground of not using the Patent right by Patentee can be taken as a ground under section 84 of the Indian Patent Act to order for compulsory licensing of the drug.

B. Procedure of granting Compulsory License or Revocation of patents

Firstly, if the Comptroller is satisfied with application served by the applicant under section 84 and 85 of Indian Patent Act, he can direct the applicant to serve copies to Patentee and any other person concerned. Secondly, comptroller will ensure that the application is published in the official journal. Thirdly, the Patentee or the any another person interested must fill for opposition within the stipulated time. Fourthly, upon receiving the notice of opposition the comptroller must notify the applicant as to provide him with the reasonable chance of being heard.

C. Powers of Comptroller in case of Compulsory Licensing

Upon satisfaction by the comptroller served by the applicant under section 84, comptroller may grant licenses under patent to such application. Where the application made by the patent holder, and comptroller is satisfied on the merit of the case, he may order to existing license or cancel or may order to amend the existing license.

D. Grant of license in case of multiple patent holder

In case of where a single patent is acquired amongst two patent holder, in that particular case the comptroller might go into the merits of documents and utility provided by one of the patentee and must prejudicially grant the compulsory licensing against the will of other patentee if it is in better public interest and satisfies the terms and conditions of compulsory licensing.

E. Terms and Conditions of Compulsory License

Under section 90 of the Indian Patent Act, it provides for the terms and conditions for granting of Compulsory License. Following are the important terms and conditions as follows;

\[\text{[14] F. Hoffmann-La Roche Ltd. And Another v. Cipla Limited (2009) PTC 125 (Del.)}\]


\[\text{[16] The Indian Patent Act,1970, section 88 (India)}\]
• The Patent to whom right was granted has sufficiently derived profit for its invention;
• The patented article must be made extractable to the public at reasonable price;
• The license granted must be non-exclusive licence;
• The license must be non-assignable;
• The license must be granted for primary purpose of supplying in Indian Market and can also be exported upon satisfying the conditions under section 84(7)(a)(iii);

However, the Comptroller is not authorised to grant license to import patented product from abroad of any goods or substance protected under patent act. As such would amount to infringement of rights.

The central Government however as a matter of public interest might direct the comptroller to issue such importing rights to an individual in case of granting compulsory licensing to imported drugs.

**G Termination of Compulsory Licensing**

On receiving the application made by Patentee or any other person interest in the respective patent rights, comptroller if satisfied with the documents provided can cancel the compulsory license granted under section 84 of the Indian Patent Act. Mostly on the circumstances provided by the patentee as such that the respective patent is no more in use. The holder of compulsory license however has sufficient change to rise objection to such terminations. However, while terminating such compulsory license, the comptroller must take into consideration rights and interest of persons who were granted license and must not act prejudicially.  

### 3.2 Comparative Analysis with USA & EU

#### 3.2.1 Compulsory Licensing in USA

In USA under Article 1(8) authorises the US constitution regarding its patent laws. It provides its congress the power to promote, protect any progress in science and useful arts by securing exclusive rights to the creators of such inventions. The patent law is designed to protect the interest of inventor of such invention. In USA time period for protection of Patent rights are 20 years from the date of application filling. However, on the expiration of the patent term, it is free in public domain to be used freely without any restrictions.

However, USA does not impose antitrust laws either on any individual firms or monopolies. It also doesn’t caste any duty to do business with an individual as such. The same position can be briefly reflected in the line of below given cases;

In *Hartfors-Empire co. v. United States* court stated that “a patent owner does not act as a quasi-trustee for public or is under any obligation to ensure that public gets free right to use it. Henceforth he doesn’t hold any

20 *Hartfors-Empire co. v. United States* 323 U.S. 386 (1945)
obligation either in granting to use it to others”.

Although on the contrary, there are cases where the court has directed certain duty to deal with Compulsory Licenses often referred as “essential facility cases”. However, the essence of this concept is better taken up in *United States v. Terminal Railroad Association* \(^{21}\), where a group of railroads were jointly owned and was only connecting route Mississippi river. The supreme court in this case directed the them to allow the general public to use the crossing route and declared not attempting to same as illegal restraint of trade.

In *Eastman Kodak Co. v. Image Tech. Inc.*, \(^{22}\) Supreme court emphasised that power gained by the virtue of some legal advantages like patent, trademark can give right to legal liability in the case when their rights are exploited. In this case the case was decided in plaintiff’s favour where it won the monopolization claim over Kodak’s claim of refusal to sell its patented parts. Therefore, in the light of above discussed decision, it can be clearly considered that in USA although there is slight interference in “ownership” but however certain exception is considered by the court.

### 3.2.2 Compulsory Licensing in EU

Under the EU treaty Article 82 is used to restrain the abusive competition policy of individual owners of Intellectual Property rights. Particular policy is more inclined towards protecting excessive pricing, however looks forward to safeguard the IPR’s of individual. This article is also responsible for regulating the monopolies or near monopolies in the market. This article protects the market against “anti-competitive practices”. Therefore, in nutshell EU treaty acts a guardian to safeguard the concept of Compulsory Licensing, which can be further understood in the line of below mentioned case laws;

In *AB Volvo v. Erik Veng* \(^{23}\) ECJ held that in the case where the proprietor of protected designs abstains from granting the rights to the third party, despite being paid a sufficient royalty will amount to “Abuse of dominant position in the market” by the virtue of Article 82 of EU Treaty. As in the present case Volvo was using its design dominance in UK over the design of its front wings for car. Therefore, this case determines the essence of “Compulsory Licensing”, where it is voluntary compelled by the court authorities not in all cases but in the case of arbitrary dominance to protect the market and its players.

In *Radio Telefis Eireann & Independent Television Publications Ltd v. Commission of the European Communities* \(^{24}\), a more intensive and broader approach was adopted by the courts. Here the court were of opinion that Compulsory Licensing can be granted to a particular company on the ground of Articles 82, and the mere copyright cannot be a sole ground for the case of refusal of licensing, since the same can be compromised in case of “exceptional circumstances”.

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\(^{21}\) United States v. Terminal Railroad Association 224 U.S. 383 (1912)


\(^{23}\) AB Volvo v. Erik Veng (1998) EUECJ R-238/87

3.3. Obstacles to better IPR Management in Pharmaceutical Sector

This section of analysis deals with the problems & impediments faced when it comes to Pharmaceutical Patent rights. These include the following as follows;

A. PROBLEM

I. Intricate Procedural requirement.
Compulsory Licensing requires a rigorous procedure to be primarily be followed prior to get the issuance of Compulsory License in all three respective areas taken for the consideration of this paper.25 “Even if a developing country is ultimately successful in authorizing a compulsory license . . . the delays in authorization due to [the mandatory] judicial review [or other independent review] may discourage licensees from producing generic versions . . . as they will have less time to recover start-up costs.”26 Additionally Paragraph 6 of the TRIPS Decision is a lengthy and impractical process due to which most of the nations prefer to have their own procedure to implement the system of Compulsory Licensing. Due to its cumbersome and money consuming procedure countries refrain from using paragraph 6 of Decision of TRIPS.

2. Ambiguity in Definition and its scope of Jurisdictional application
Owing to the ambiguity of interpretation of the legal standards laid down by the TRIPS, it decreases its effective use by the countries as it increases the risk of litigation.27 As the Doha Declaration merely stated gives permission to individual countries to decide as its discretion “what constitutes nation emergency or any circumstance of emergency” while granting compulsory license and thus lacks in clarification of this procedure in case of developing and developed nations.28

3. More Flexible terms leads to abuse of the provision
Owing to the ambiguity and its resultant creation of scope of multiple interpretation has led to severe misuse of the provision.29 For instance: In Egypt, the compulsory Licensing for Pfizer’s Viagra set an example of misuse as the erectile dysfunctionality is a situation which was not supposed to be covered under public health exception of TRIPS. Additionally, to this there is vacuum in interpretation of identifying the type of pharmaceutical products required for compulsory licensing.30 Further due to non-applicability as to the scope of applicable nations creates a chilling effect on the pharmaceutical companies in terms of their investment plan and research plans. This burden is mostly

25 Donald Harris, TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing, J. INTELL. PROP. L. 367, 390–392 (2011).
28 Ibid 25
30 Ibid 26
used on the exploitation of developing nation’s needs.\(^{31}\)

Additionally the concept of ambiguity leads to several interoperation and allowing the countries to mould in the way its suits their self interest and therefore abusing the provisions.\(^{32}\) For example USA initially used narrow interpretation of TRIPS and latter contradicted itself in 2011 by suggesting the use of compulsory licensing for Cipro, a drug for anthrax treatment, whereas at the same time challenged the compulsory licensing for HIV/AIDS drug in South Africa which affected 25 million at that time and however the anthrax affected merely eleven confirmed cases.\(^{33}\)

4. Limitation subjected to Developing nations

A huge impediment which comes during the application of TRIPS flexibilities’ and its dual goal policy are restricted to middle income and developed countries. However, due requirement of technical sophistication, intergovernmental diplomacy and legal intricacies, which are often unafforded to developing countries, it becomes almost a lack letter of law towards them.\(^{34}\) A “clean hand approach” is required to be used to ensure the drugs are used as profitable lower priced in these developing economies.

5. Subjected to Corruption

Another issue of flexibilities provided under TRIPS flexibilities is high corruption in case of developing countries as the government may intend to resell the drug at higher prices rather than using it for its own citizens.\(^{35}\)

B. Impediment & Risk

1. Retaliation posed by Pharmaceutical companies

Major threats to posed by Developing countries towards the pharmaceutical companies are their alienating powers and its further repercussions often borne by these developing countries.\(^{36}\) Although new pharmaceutical companies bring significant funds and job opportunities towards the developing countries but its repercussion is worst. A suitable example of repercussion was of Thailand when compulsory licensing to a drug company named Abbott’s HIV drug, was granted and as a resultant, the company restrain itself from selling certain drug in Thailand and withdrew its seven new drug application from the country.\(^{37}\) The main pleading taken from the Pharmaceutical companies was that the provision of compulsory Licensing affects their monetary cost born on research and development of the drug in the order to treat diseases that are

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\(^{32}\) Ibid 28

\(^{33}\) Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, J. INTELL. PROP. L. 367, 390–392 (2011).


\(^{36}\) Ibid 25

specifically affecting the developing countries.\(^{38}\)

2. Retaliation posed by Developed Countries
In most of the cases the developing countries tries to amend this provision to suit it to their self-interest. Henceforth the developing nations fears the cancellation of trade sanctions in case of Compulsory Licensing as any cost that they will save on procuring cheaper medicines will be eliminated against other economic sanctions.\(^{39}\) For instance, as USA publishes Special 301 Watch-List Reports lists of countries that have inadequate IP Protection and bans them. Under the threat of trade sanction, its pressurised Thailand’s biggest export market to stop its production of generic version of HIV drugs, diagnosing and to amend its domestic law to restrict Compulsory Licensing.\(^{40}\)

Further in 2003, European Union seized most of the drugs originated in India for its consumption in developing nations primary Nigeria and Ecuador in the name of border regulations. Thus, limiting the intent of Compulsory Licensing and access to cheaper drugs.\(^{41}\) Developed countries often try to control the developing countries by making them party to bilateral and regional trade agreements (“FTAs”).\(^{42}\) Often this FTA’s restricts the TRIPS flexibility and impose stricter IP standards of these developing countries. Unfortunately, the developing countries agrees to this FTA’s despite its negative impact to develop cordial relation with developed nations. Further developing countries have fewer negotiating powers when it comes to negotiation with developed nations. An example of same is USA, which in 2011 signed the Anti-Counterfeiting Trade Agreement (“ACTA”), which was exceeding TRIP limitation and severely affected the access to medicine in developing countries under compulsory Licensing.\(^{44}\)

3. Legal Repercussions
When it comes to domestic implementations of compulsory licensing it is often faced by legal challenges, which decreases the effectiveness of TRIPS and adds to the cost of the nation to procure the drug till the time of non implementation period. Further, since


\(^{40}\) Ibid 33


the provision is in non-consonance with profit theory of pharmaceutical companies, they often end up searching for loopholes in the system and succumbed the developing countries to pressure to give decision in their favour. For Example, in 1997, forty pharmaceutical companies with the support of USA sued the South African government claiming that the South African Medicines and Related Substances Control Amendment Act of 1997 on the basis of violation of TRIPS. Further in 2012, Bayer Pharmaceuticals sued, Indian generic manufacturers Cipla and Natco for the infringement of its patent rights to manufacture cancer drugs Nexavar. Henceforth, Compulsory Licensing is a concept better said that applied in worldwide.

3.4 Current Pandemic And Its Impact On Pharmaceutical Sectors

• THE PHARMACEUTICAL SECTOR
Pharmaceutical sector is one of the world's most profitable sector at the end of the year 2020 it is assumed to be valued at 1.4 trillion US dollar. 30 billion was the turnover of only the top four companies in pharmaceuticals. And it's been clear that pharmaceutical companies are driven by capitalist mind-set, they invest tons of money in research and development and then recover the capital and substantial amount of profit by selling the drugs under patent licencing.

• WHY BIG PHARMACEUTICALS ARE HESITATING
In the current pandemic of covid-19 for coronavirus none of these top 4 pharmaceutical companies have jumped on the opportunity for development of vaccines. It was estimated that in the beginning of 2019 the projected sale of covid-19 vaccine would be approx 54 billion US dollar and by the end of 2020 it has reached to 60 billion US dollar. Then what is the reason why the Pharmaceutical Giants of the market haven't jumped on this opportunity.

It is very clear that they are simply not interested in manufacturing a drug that would surely end up in compulsory licensing. In other words, they are not motivated by the idea that a third party who has neither invested nor contributed in the research of vaccines will end up having a licence to manufacture and sell under compulsory licensing.

• CAPITALISTIC DRIVEN PHARMACEUTICAL SYSTEM
These Pharmaceutical corporate Giants are driven by a capitalistic mentality and when the incentive provided by patent law is threatened to be diluted by compulsory licensing then these corporate Giants are not so interested for researching and developing such vaccine. Irrespective of how big is the sales market, as the very well-known that after the implementation of CL they will be the one bearing the expenses and others will bear the fruit of their labour.

46 Ibid 33.
CRITICAL ANALYSIS OF SITUATION

Although this might seem to be cold-hearted behaviour of these Pharmaceutical giants but we have to keep in mind that these companies are leading today only because of their capitalistic mentality. Ethical evaluation of their act is a whole different concept but practical implication of their act is in the Regime of patent and compulsory licensing, that will either provide incentive by giving them patent rights or provide deterrence by implementing compulsory licensing and diluted their patent holder rights.

For instance in 1974 Italy has imposed a new law that granted the patent holder to retain some exclusive and limited right which cannot be taken away in any circumstances, this was done to make sure that the pharmaceutical company can recover the capital invested in research and development and also to generate a reasonable product. This act itself has immensely changed the situation in Italy within a decade there has been a noted growth of 600% in the field of pharmaceutical development. This shows that people in the areas of pharmaceutical are a little cautious while initiating research and development programs for new diseases and it is mainly because of compulsory licensing as it will dilute their right which will end in demotivating such inventors and hindering the pace of invention. As in Italy this hindrance was removed in 1974 and the result was a bombastic 600% increment in pharmaceutical research.

3.5. Loopholes & impediments of Compulsory India, USA, EU

As according the provisions of US patent laws, it does not provide for any dedicated statute to protect the Patent rights of its individuals, however the protection is guided by their Constitution, which provides very narrow protection to their individuals. However, in case of EU, it although restricts the abusive commercial conduct & monopoly of individual by the virtue of Art 82. Whereas in case of India despite the strict regime of Compulsory Licensing, there lacks any provision for interpretation in case of violation of patent Laws. Henceforth, it can be inferred from the above analysis that in all of them lacks a dedicated legislature to have strict and conclusive system while dealing with provisions of compulsory licensing.

3.6. Recent Development

In the recent years there have been some eminent changes as to deal with compulsory licensing relating to pharmaceutical sectors. One of such notable development is as follows;

3.6.1 THE NEW IPR POLICY (2016)

Under new policy India has achieved the compliance to WTO’s agreement as laid at TRIPS. Accordingly, India will utilise all the legislative creativeness and flexibilities provided under international agreements and TRIPS agreement. Flexibilities including sovereign rights provided to countries to use Section 3(d) and Compulsory licensing for availing the lifesaving and essential medication at reasonable cost to public at large. In regards to the pharmaceutical sector India has clearly taken its firm stand in not
changing the current policies. In reiteration to
the same many USA based companies has put
forward its concern on grant of compulsory
licensing. Currently India is using
Compulsory licensing for manufacturing of
generic drug for cancer. The major focus of
these new policy is to strengthen IPR laws in
India and to protect its intent. 47

4. SUGGESTIONS

Under compulsory licensing the royalty paid
should also include a compensation amount
for infringing the patent holder’s right this
amount should be subtotal of the capital
invested in research and development by the
company and also include a reasonable
amount of profit. This would provide some
sense of security to the companies especially
in the pharmaceutical sector that even if
compulsory licensing is applied on their
patented drug, then also they will earn the
capital invested and a certain amount of profit
too.

As these companies invest billions of dollars
in research and development hence it is not
feasible for a single country to bear the entire
expense, there must be a compensation pool
created by all the countries with equivalent
standards per se underdeveloped or
developing countries.

This pool will calculate the compensation
amount for a company that will include
research and development cost and
reasonable amount of profit and the subtotal
will be divided among all the other countries
who wish to apply compulsory licensing on
such lifesaving drugs in order to avail generic
versions of such in their respective countries.

This will result in a win-win situation as big
pharmaceutical companies with capitalistic
mind-set will earn their share amount of
profit and recover the capital involved. On
the other hand the underprivileged will be
provided with the cheap substitute of the
patented drug in the form of generic drugs.

There should also be a regulating body
created under the guidance of the patent
holder company that can check and verify the
generic drugs are as per the required standard
and are not harmful in any nature, this will
help to safeguard the Welfare of people
consuming these generic drugs.

5. CONCLUSION

On the one hand patent encourages the
practice of monopoly as the patent holder
enjoys exclusive right to manufacture and
sell the patented good this also leads to the
overpricing problem of the commodity. this
may seems a bit negative in the perspective
of consumers but it is an essential practice
that keep the inventors going on inventing
new innovation, because such undertaking
required huge amount of capital for research
and development and no corporate giant will
initiate such task without the absurdity that
they could not only recover the capital
invested but also gain certain amount of
profit from the invention. In return
consumers get more efficient and better
products time and time again. It is because
the inventors are given the incentive in the
form of patents to continue inventing new
innovations that will ultimately help the
human race thrive.

on the other hand this practice is only suitable
enough for the developed nation but for the

47https://pib.gov.in/Pressreleaseshare.aspx?PRID=15
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developing or underdeveloped Nation where per capita income is relative low and people usually cannot afford these prizes commodities especially in pharmaceutical sector where these commodities are lifesaving drugs and in certain way an essential element for survival of an individual from illness. The full philosophy of compulsory licensing evolves on the principle of human life values more than the goal of profit maximization. With the said principal at its core compulsory licensing allows other manufacturers to produce similar drugs of generic nature at a cheaper price. It goes without saying that the generic and cheaper drugs are relatively inferior to the original one.

These are the two sides of a coin: one that gives rights to the companies and protects their interest of monetizing their invention and the other safeguards human life by sacrificing the profit-making agenda of a company. These two factors are balanced on a very fine line as without a patent no further incentive will be available for the company to develop any newer invention and without compulsory licensing there would be no relief for the underprivileged who cannot afford expensive drugs.

In order to balance it we can look into the example of Italy which in 1976 has introduced a new law that save guard certain rights of the patent holder exclusively providing them t right to retain in any circumstances with the motive that these inventors will be able to recover the capital invested in in research and development and also on reasonable amount of profit out of it. This action of Italy has resulted in more than 600% growth in pharmaceutical research in nearly a decade.

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**International Declarations**


**Official Governemnt websites**


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