

# INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS



Open Access, Refereed Journal Multi-Disciplinary  
Peer Reviewed

[www.ijlra.com](http://www.ijlra.com)

## **DISCLAIMER**

No part of this publication may be reproduced or copied in any form by any means without prior written permission of Managing Editor of IJLRA. The views expressed in this publication are purely personal opinions of the authors and do not reflect the views of the Editorial Team of IJLRA.

Though every effort has been made to ensure that the information in Volume II Issue 7 is accurate and appropriately cited/referenced, neither the Editorial Board nor IJLRA shall be held liable or responsible in any manner whatsoever for any consequences for any action taken by anyone on the basis of information in the Journal.

Copyright © International Journal for Legal Research & Analysis

## **EDITORIAL TEAM**

### **EDITORS**

#### **Dr. Samrat Datta**

*Dr. Samrat Datta Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Samrat Datta is currently associated with Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Datta has completed his graduation i.e., B.A.LL.B. from Law College Dehradun, Hemvati Nandan Bahuguna Garhwal University, Srinagar, Uttarakhand. He is an alumnus of KIIT University, Bhubaneswar where he pursued his post-graduation (LL.M.) in Criminal Law and subsequently completed his Ph.D. in Police Law and Information Technology from the Pacific Academy of Higher Education and Research University, Udaipur in 2020. His area of interest and research is Criminal and Police Law. Dr. Datta has a teaching experience of 7 years in various law schools across North India and has held administrative positions like Academic Coordinator, Centre Superintendent for Examinations, Deputy Controller of Examinations, Member of the Proctorial Board*



#### **Dr. Namita Jain**



*Head & Associate Professor*

*School of Law, JECRC University, Jaipur Ph.D. (Commercial Law) LL.M., UGC -NET Post Graduation Diploma in Taxation law and Practice, Bachelor of Commerce.*

*Teaching Experience: 12 years, AWARDS AND RECOGNITION of Dr. Namita Jain are - ICF Global Excellence Award 2020 in the category of educationalist by I Can Foundation, India. India Women Empowerment Award in the category of "Emerging Excellence in Academics by Prime Time & Utkrisht Bharat Foundation, New Delhi.(2020). Conferred in FL Book of Top 21 Record Holders in the category of education by Fashion Lifestyle Magazine, New Delhi. (2020). Certificate of Appreciation for organizing and managing the Professional Development Training Program on IPR in Collaboration with Trade Innovations Services, Jaipur on March 14th, 2019*

## Mrs.S.Kalpana

Assistant professor of Law

*Mrs.S.Kalpana, presently Assistant professor of Law, VelTech Rangarajan Dr. Sagunthala R & D Institute of Science and Technology, Avadi. Formerly Assistant professor of Law, Vels University in the year 2019 to 2020, Worked as Guest Faculty, Chennai Dr. Ambedkar Law College, Pudupakkam. Published one book. Published 8 Articles in various reputed Law Journals. Conducted 1 Moot court competition and participated in nearly 80 National and International seminars and webinars conducted on various subjects of Law. Did ML in Criminal Law and Criminal Justice Administration. 10 paper presentations in various National and International seminars. Attended more than 10 FDP programs. Ph.D. in Law pursuing.*



## Avinash Kumar



*Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship. He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi. Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi. He has qualified UGC – NET examination and has been awarded ICSSR – Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.*

## **ABOUT US**

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANALYSIS  
ISSN

2582-6433 is an Online Journal is Monthly, Peer Review, Academic Journal, Published online, that seeks to provide an interactive platform for the publication of Short Articles, Long Articles, Book Review, Case Comments, Research Papers, Essay in the field of Law & Multidisciplinary issue. Our aim is to upgrade the level of interaction and discourse about contemporary issues of law. We are eager to become a highly cited academic publication, through quality contributions from students, academics, professionals from the industry, the bar and the bench. INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANALYSIS ISSN 2582-6433 welcomes contributions from all legal branches, as long as the work is original, unpublished and is in consonance with the submission guidelines.

# **A STUDY ON COMPULSORY LICENSING OF PATENT: INDIAN PERSPECTIVE.**

AUTHORED BY - CHITRA C

LL.M in Intellectual Property Rights (1<sup>st</sup> Year)

Tamil Nadu Dr. Ambedkar Law University-School of Excellence in Law.

## **ABSTRACT:**

*The Patent is a legal framework that establishes a system which supports and encourages the technological innovations and promotes economic development. Patent is an important criterion as it gives the inventor a monopoly over their invention and restricts the use of the invention by others as it confers exclusive rights on the patent holder. In some cases, the rights patented may be exploited. The Indian Patents Act provides for the prevention of misuse of compulsory licensing provisions. Compulsory license allows a third party to use, sell, and make the patented invention without the patent holder's consent. The predominant purpose behind the grant of the compulsory license is to ensure the supply of the patented invention in the Indian market. The present paper discusses in detail about the provisions related to compulsory licensing in the Indian Patent Act, 1970, the grant of compulsory licensing, the various issues and challenges, the compensation which are need to be issued to the inventor for their effort, and contribution of human ingenuity in creating the invention.*

**Keywords:** *Compulsory Licence, Patent, Invention, Compensation and Monopoly.*

## **CHAPTER I**

### **INTRODUCTION:**

Intellectual Property Rights is a special genre of rights which protects the result of intellectual and creative labour and like all other Intellectual Property Rights, patents too offer protection for the creative labour for a specific period of time. A Patent is a form of Intellectual Property Rights protected and granted by the law. The word “patent” refers to monopoly right over an invention. Not all invention is patentable nor it is essential to over an invention. Not all inventions are patentable nor is it essential to protect inventions solely through patents.<sup>1</sup> The final product that results from an invention may be protected through other forms of Intellectual Property Rights. Pharmaceutical products which are not protected under Patent can be protected to a limited extent by the use of trademarks. Invention may also be protected through trade secrets and confidential information even if they are already protected by patents. In case where the novelty of the product test in its design and not in its function, the product can be the subject matter of a registered design or a copyright.

A Patent is a grant of right, privilege or authority over an invention. In a sense, it is a limited monopoly granted by the State under the statute in return for the disclosure of technical information. The law relating to patents in India is governed by the Patents Act 1970 as amended and the rules made under it. The Patents Act is a legislation passed by the Central Government in pursuance of its power under Entry 49 of the List I of Schedule VII of the Constitution of India that deals generally with the Intellectual Property Rights including patents.

The inventor must ensure that the invention includes one or more new components so that the invention is eligible for a patent otherwise the invention will not be eligible for a patent. This means that someone with expertise in the field of innovation should not find the invention simple and obvious to implement. The method/methods of making an invention must have the commercial market to be classified as service models; otherwise they will be considered inappropriate. Patentability is determined by whether the invention is new and non-obvious has an industrial use. If this is the case, the invention is patentable and therefore complete Patentability criteria.

---

<sup>1</sup> Elizebeth Verky & Jithin Saji Isaac, Intellectual Property, Eastern Book Company (EBC), Second Edition, 2021.

Everything was previously known in the public domain is ignored by the innovator. The patent has a duration of 20 years which starts on the day of its presentation of patent application. It can only be used in the country where it is licensed. Therefore any legal action aimed at the infringement or violation of patents rights be taken in this country. Each Country must file a patent application to obtain patent protection in other countries. The Patent Cooperation Treaty (PCT) provides a global patent filing strategy in which a patent can be filed in a large number of countries using a single patent application. The PCT of a patent on the other hand its discretion of the specific patent office only after the filing of the application.

### REVIEW OF LITERATURE:

- ***Patent Law and Compulsory Licensing: Indian Perspective, Author: Abhinav Gupta and Aqa Raza, Journal of Intellectual Property Rights Vol 29, pp 5-17 January 2024.***

*This article aims to analyse and critically evaluate the concept of compulsory licensing under the Indian Patent Act, 1970. This article understands about the evolution of the concept of compulsory licensing and how the TRIPS agreement got introduced and also about the inclusion of Article 31 bis. It also discussed in the light of Natco v. Bayer rejecting compulsory license application due to procedural inconsistency.*

- ***Compulsory Licensing of Patents in India, Author: Rajeshkumar Acharya and Girishchandra Tanna, SSRN Publications, December 2019.***

*Compulsory licenses are permits granted to a third party by the Controller General of Patents to make, use or sell a particular product or to use a particular process that has been patented, without needing the permission of the patent holder. Provisions for compulsory licensing are contained in Article 31 of the TRIPS Agreement (Trade Related Aspects of Intellectual Property Rights) and also under the Indian Patent Act, 1970. A compulsory license may be granted subject to certain conditions set out in the Agreement and the provisions and it has been discussed in a clear manner in this article.*

- ***Pharmaceutical compulsory licensing in emerging market-Is it a welfare licensing or threat: Author: Ritika Sharma, Smith Shau, IntJPharm Bio Science, July 2014.***

*India took its first compulsory license in 2012 because till 2005 Indian Patent Act does not have provisions of pharmaceutical and health related patent. This decision also came up with the future prospective of generic companies to take the initiative in the R*

& D as well as drug development for their own. Also the compulsory license burdens the foreign patentees to commercialize the patented drug in pharma industry.

- **Compulsory Licensing of Pharmaceutical Innovation: Price to Innovation, Author: Collen Chien, June 2003.**

The Patent system is built on the premise that the patents provide incentive for an innovation by offering a limited monopoly to the patentees. The inverse assumption that removing patent protection will hurt innovation has largely prevented the widespread use of compulsory licensing-the practice of allowing third parties to use patented inventions without the patentee permission. In this article it discusses about the concept of compulsory licensing and how it is been effective.

- **Compulsory Licensing of Pharmaceutical Patents in India: Issues and Challenges, Author: Dr. Payal Thaorey and Anushree Mukte, IPR Journal of Maharashtra National Law University, Nagpur Volume I | Issue I | June 2023, pp. 1-15.**

- *The importance of patents in various aspects of human life, especially in the field of healthcare and pharmaceuticals, is well ensured by the granting of patents for drugs and related processes. Patents are governed by the Indian Patents Act, 1970, which allows the patent holder to explore the commercial benefits of their inventions in an exclusive manner. It goes without saying that such a monopoly right encourages innovation and research. The Indian Patent Act does not distinguish between pharmaceutical and non-pharmaceutical materials for the grant and license of patents. However, the pharmaceutical patent involves technical details and rapid technical progress, which sometimes overwhelms the judiciary with litigation. It is essential to consider what to give Pharmaceutical patents are never intended to create a barrier to availability, to the access and accessibility of medicines, which is against the notion of monopoly right. So, this document focuses on all issues related to the compulsory license of pharmaceutical products in India.*

- **Compulsory Licensing of Pharmaceuticals Under TRIPS: What Standard of Compensation?, Author: Susan Vastano Vaughan, Hastings Int'l & Comp. L. Rev. [Vol. 25:87], 2001.**

A compulsory license is an involuntary contract imposed on a patent owner by a government entity; Compulsory licensing gives a government entity or a third party permission to use IPR to promote a political or social goal. The compulsory license is a public right reserved by many countries to protect against the dangers inherent in the monopoly granted by a patent. Compulsory licenses may also be granted when a

*patentee refuses, usually for economic reasons, to use the patent to make the product or process protected by the patent available to the public. This present article discusses about the compensation or adequate compensation rendered to the inventor.*

### **OBJECTIVES OF THE STUDY:**

- To understand about the concept of compulsory licensing and its related provisions under the Indian Patent Act, 1970.
- To study about the issues and challenges involved in the compulsory licensing.
- To discuss about the compensation for the inventors.

### **RESEARCH QUESTIONS:**

1. Whether fair compensation to patent holders be ensured while still promoting public health access?
2. Whether the implementation of compulsory licensing provides unique challenges and opportunities in pharmaceutical products?
3. Whether compulsory licensing can be used to promote technology transfer in developing countries?

### **HYPOTHESIS:**

Compulsory Licensing plays a crucial role in ensuring fair compensation to patent holders by maintaining a balance between public interest and private rights.

### **SCOPE OF THE STUDY:**

The main scope of the study is to analyse the present status of the compulsory licensing and to understand about the inventor's status for his contribution of human ingenuity in creating various invention where he is rendered with the compensation in the situation of where his invention has been fallen under compulsory licensing.

### **RESEARCH METHODOLOGY:**

This study is based on Doctrinal method. The work is relied upon the primary and secondary sources which includes various research articles, journals, books and newspaper.

## **CHAPTER II: COMPULSORY LICENSING OF PATENT:**

### **LEGAL LANDSCAPE**

#### **COMPULSORY LICENSING:**

Patent right is granted to an inventor as a bargain for disclosing the invention. The ultimate beneficiary of an invention apart from the patent owner is the public and hence the invention should be available for the public. There has always been a danger that the proprietor of a patent will abuse the monopoly granted to him.<sup>2</sup> Abuse of patent rights can be by refusing to grant license, imposing unreasonable terms on the licensee or restrictive conditions on the use of the patented articles. The provisions of compulsory licensing in the Patents Act prevent this situation. A compulsory license is an authorisation given by an authority allowed by law to grant license, without or against the consent of the title holder of the for the exploitation of a subject matter protected by the patent. The birth of the concept of the compulsory licenses is linked to the obligation introduced by the UK Statute of Monopolies in 1623.

Compulsory licenses are license that are granted by the government to use patents or other types of intellectual property. Governments issue compulsory licenses to broaden access to technologies and information in order to achieve a number of public purposes. Many countries have provisions in laws for compulsory licensing if the patent owner refused to make the invention available for dependent patents or for various public interest reasons. Patents and other intellectual property rights are the creation of government policy. Nations currently have the right to issue compulsory license on patents.<sup>3</sup>

Compulsory license for a patented invention is a part of the Paris Convention, accepted the working obligation. The Paris Convention for the protection of Industrial Property states each country of the union shall have the right to take legislative measures providing for the grant compulsory licenses to prevent the abuses which might result from the exercise of the exclusive right conferred by the Patent for example failure to work. The Paris Convention recognises the right of member countries to establish compulsory license but certain limitation under the Convention. Member States may provide for the grant compulsory licenses to prevent abuse of the exclusive rights conferred by the patent.

---

<sup>2</sup> Feroz Ali Khader, *The Law of Patents with special focus on Pharmaceuticals in India*, Lexis Nexis Butterworths, 2007.

<sup>3</sup> Rajeshkumar Acharya and Girishchandra Tanna, *Compulsory Licensing Of Patents In India*, SSRN, 2019.

Forfeiture of patent will not be provided for except where the grant of compulsory licenses is sufficient to prevent abuses. Forfeiture of revocation of patent will not be instituted before the expiration of three years from the grant of compulsory licence.

1. A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of four years from the date of application for the patent, or three years from the date of the grant of patent whichever period expires last. It shall be refused if the patentee justifies his/her inaction by legitimate reasons.
2. A compulsory licence shall be non-exclusive and shall be transferable even in the form of grant of a sub-licence except with that part of the enterprise or goodwill which exploits such license.

## **COMPULSORY LICENSING OF PATENTS UNDER THE INDIAN PATENT ACT, 1970:**

After discussion the Constitutional validity to the grant of compulsory license to pharmaceutical patents, the Indian Patent Act, 1970 does provide provisions for consideration of compulsory licenses in India. Grant of compulsory licence aims unquestionably to prevent abuse of patent by patentee.<sup>4</sup>Hence it is imperative that patentee must exercise his invention for benefit of society. Such requirement is always a part of consideration for grant of patent. It is an inevitable positive incident of the grant hence licensing of patents is closely associated, that is, the exploitation of patents. Here are some important provisions of the Patents Act, 1970 discussed in relation to pharmaceutical patents.

### **GROUNDS FOR THE GRANT OF A COMPULSORY LICENSE:<sup>5</sup>**

The grounds for granting a compulsory license are set out in Section 84(1) of the Patents Act are the following:

- The reasonable demands of the public regarding the patented innovation have not been met.
- The patented innovation is not easily accessible to the general public at a reasonable cost.
- The patented invention is not being used in India.

---

<sup>4</sup> LOWIA PAUL, COMPULSORY LICENSING OF PATENTS IN INDIA, JETIR, Volume 6 Issue 3, March 2019.

<sup>5</sup> SHAMNAD BASHEER, The Compulsory License Regime in India, SSRN Publications, December 2020.

The controller takes into account the per capita income and purchasing power of the people of India/or use, cost of production, availability and affordability of any alternative to product, etc. to establish a reasonable price. Section 83 of the law must be examined to determine the feasibility of the invention. For innovation to be effective in India, it must be used to its full commercial potential and technological innovation must be encouraged. The patent holder does not have a monopoly right over the patented technology. This is especially true in the case of medical innovations: patent rights should not endanger public health or prevent the government from encouraging them. Medical inventions should not only promote the financial benefits of the patent holder, but also the health of the country's citizens. The price of innovation must be such that it is accessible to people of all socio-economic strata.

*The public's aforementioned "reasonable requirements" as specified under the act are not fulfilled as per Section 84(7) when:<sup>6</sup>*

- I. The patent owner refuses to grant one or more equivalent licenses and, therefore:
  - An industry suffers.
  - The request for the patented article may not be completely fulfilled.
  - There is no provision or development of a market for proprietary products made in India.
  - In India, the formation or development of business operations is prohibited.
- II. A condition is placed on the patent license by the patent owner:
  - This causes problems with products that are not protected patent.
  - Industrial and commercial activities are suffering in the country.
- III. The patent is not being used in India commercially to a satisfactory level or not used to the highest extent.
- IV. Importation from abroad prevents the use of the patented innovation for commercial purposes in India.

## **FACTORS FOR DETERMINING THE MATTER OF GRANTING A COMPULSORY LICENSE**

When analyzing a file related to the granting of a compulsory license, the controller must take into account the following factors:

---

<sup>6</sup> Deepak Kumar Dash, A Review on the Indian Patent System and Its Implication on the Pharmaceutical Industry, JHSMR, 2023.

- The nature of the innovation, the time elapsed since obtaining the patent and the steps taken by the patent owner or any licensee to fully exploit the invention.
- The candidate's ability to put innovation at the service of the general public.
- The applicant's willingness to take the risk of investing funds and putting the innovation into production if the application is approved.
- If the applicant tried to obtain a license from the patent owner under acceptable terms and circumstances and did not do so within a reasonable time determined by the Controller.

However, in cases of extreme urgency, anti-competitive practices of the patent holder or extensive non-commercial use, the above provisions do not apply.

### **REVOCATION OF A COMPULSORY LICENSE:**

After two years of issuing the compulsory license, the central government or any interested party may apply to the Controller for an order cancelling the patent. The reasons for removing the compulsory license are the following:<sup>7</sup>

- That the patented invention has never been used in Indian soil.
- That the reasonable demands of the public regarding the patented innovation have not been Patented.
- The patented innovation is not accessible to the general public at a reasonable cost.

***The Controller has the authority to defer petitions for compulsory licensing:*** Where an application is made under section 84 or 85 on the ground that the invention has not been commercially used to a reasonable extent in India or has not been worked in India, and the Controller is satisfied that the time between the sealing of the patent and the application time is insufficient to meet the above conditions, can postpone the application for a maximum of twelve months.<sup>8</sup>

***Licensing of related patents (S. 91):*** After the grant of the first patent, any person who has the right to exploit the second invention, whether patented or licensed, may apply to the Controller to issue a license for the first patent. To obtain the license, the applicant must demonstrate that

---

<sup>7</sup> Kaur A, Chaturvedi R. Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma. Journal of Intellectual Property Rights, 2015; 20): 279-287.

<sup>8</sup> Gupta R., Compulsory Licensing under TRIPS: How far it Addresses Public Health Concerns in Developing Nations, Journal of Intellectual Property Rights, 2010; 15: 357-363.

the first and second patents are related and that the first patent is necessary to fully commercialize the first patent. The patent must have had a significant commercial impact. In addition, the applicant must be willing to license its patent to third parties. This is done to stimulate business growth and maximize the use of inventions.

***Grant of Compulsory License upon Central Government Notification (S. 92):*** The government may issue a notification for the compulsory grant of a license for a patented drug in cases of national emergency, serious emergency or for non-commercial public health purposes. Any person interested in obtaining a license after notification can send an application to controller. If satisfied, the controller can grant the license to the licensee and impose general conditions. The controller determines the lowest selling price after deducting the patent owner's royalties.<sup>9</sup>

***Issue of Compulsory License for export of patented medicinal products due to grave problems in a foreign country (S. 92A):*** This is a clause that allows an applicant to manufacture and export patented pharmaceutical products in a country that lacks manufacturing capacity and is experiencing a public health crisis. Such an application can be made only after the country has granted a compulsory license for the product or allowed its import from India by notification. Pharmaceuticals are defined as any product or proper method that is necessary to produce the drugs and diagnostic kits needed to solve a public health problem.

## **SETTING THE TERMS AND CONDITIONS OF COMPULSORY LICENSE SO GRANTED:**

In determining the terms and conditions of any compulsory licence, the controller shall take into account the following conditions:<sup>10</sup>

- The Controller must try to obtain an amount of royalties and other monetary benefits to give to the patent owner and / or other beneficiaries that is reasonable, taking into account the nature of the patented technology, the investment made by the patent owner to create the patent. technology and obtaining a patent, as well as other related factors.

---

<sup>9</sup> P. Narayanan, Patent law, (Eastern Law House, Fourth edition, 2017) pp 1-4.

<sup>10</sup> Dr. G.B. Reddy's, "Intellectual Property Rights And The Law", (Gogia Law Agency 2012)

- The patented technology must be used to the maximum by the person to whom the license is granted, realizing a reasonable profit.
- Patented technology must be accessible to the general public at a reasonable price.
- The license must be a non-exclusive license.
- The rights so granted by the compulsory license are not assignable.
- The license is issued for the remaining duration of the period (unless the public interest dictates that a shorter period would be preferable).
- The license should be prioritized to provide the patented technology in the Indian market and export related provisions may also be attached.
- If the patented technology relates to semiconductors, the license issued must allow patented technology to be exploited for non-commercial public use.
- If the license is granted to remedy a situation considered anti-competitive, the license holder is authorized to export, if necessary, the patented technology.

Furthermore, the Central Government may, in the public interest, require the Controller to permit any licensee in respect of a patent<sup>11</sup> to import the patented subject matter or a substance or article made by a patented method from abroad. The control may impose restrictions on the royalties and payments to be paid to the patent owner, the number of imported goods, the selling price of the imported goods and the duration of the importation.

### **POWERS OF THE CONTROLLER REGARDING GRANT OF A COMPULSORY LICENSE:**

When the manufacture, use, or sale of materials not covered by the patent is impaired due to restrictions imposed by the patent owner on the granting of licenses under the patent, or on the purchase, rental, or lease of the patented article or process, the Controller, if satisfied, may order the granting of licenses under the patent to the applicant or to the applicant's customers. When an application is made under section 84 by a person who is the holder of a license under the patent, the controller may terminate an existing license or, instead of granting a license to the applicant, may order the modification of the existing license. When the same patent holder holds two or more patents and an applicant for a compulsory license finds that the reasonable demands of the public have not been met in relation to some of the patents, if the Controller finds that the applicant is not able to use them license granted under the patents effectively or satisfactorily without infringing the other patents of the patent owner and if the patents involve

---

<sup>11</sup> V.K.Ahuja, "Law Relating To Intellectual Property Rights" (LexisNexis Third edition 2017); pg, 577, Annex7

a technological advance or are of a economic When the controller determines the terms and conditions of a license, the licensee may ask the controller for a review of the terms and conditions after using the invention on a commercial scale for a period of at least 12 months for the reasons that the terms and conditions established proved to be unnecessarily restrictive, preventing the licensee to exploit the invention and causing the loss.

### ***Compulsory Licensing under TRIPS:***

With the advent of the WTO and the implementation of TRIPS since 1995, numerous multilateral treaties have been concluded in the field of patents. As a member state, India is required to integrate and amend the Indian Patent Act in line with TRIPS from 1994 to 2005, particularly to strengthen the position of pharmaceutical patents. After the trips, patent laws in India were amended to include long-term protection, EMR, pharmaceutical product patents in its overview, etc., along with compulsory licensing. Like all other international instruments, TRIPS is also consistent with the principles of national treatment and most favoured nation. To provide a basis for national treatment in India for the implementation of TRIPS,<sup>12</sup> if a compulsory license is granted to a national applicant, equal treatment should also be provided to foreign applicants. In this case, the capacity of the Indian financial and legal system is highly questionable.

The India Patent Act, 1970 already gives wide discretionary authority to the central government and the Controller to grant compulsory pharmaceutical licences. It is clear to consider the vertical and horizontal application of the TRIPS provisions, but it is rarely practical to face the situation where one would allow a license for all or only some depending on the need. Provisions regarding compulsory authorization under TRIPS have been in force since the drafting of TRIPS, i.e. with the same compulsory license for countries that are the inability to manufacture pharmaceutical products was introduced after the *Doha Declaration, 2001*.

TRIPS is the acronym for "*Trade Aspects of Intellectual Property Rights*". This involves a balance between providing incentives for future inventions and creations in the long term and allowing the use of existing inventions and creations in the short term. In short, it aims to protect the rights of those who invent products and ensure that they receive the necessary

---

<sup>12</sup> Agreement on Trade Related aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement] Article 31.

financial support to develop their products, while allowing the use of these products to support the future development of others or of the groups. Patents provide their holders with the legal means to prevent others from making, using or selling the new invention for a limited period of time, subject to a number of exceptions. WTO members must patent any invention, whether it is a product (such as a drug) or a process (such as a method of producing the chemical components of a drug). Patent protection must last at least 20 years. However, there are some exceptions, namely:

- Inventions, the commercial exploitation of which must be prevented to protect human, animal or plant life or health.
- Diagnostic, therapeutic and surgical methods for the treatment of humans or animals.
- Some plant and animal inventions.

For example, if a country has signed the TRIPS agreement and GlaxoSmithKline invents a new drug against tuberculosis, it can ask that government for patent protection. If this was granted, this will prevent any generic production from other companies of this drug, preventing compete for awards and ensure that Glaxo recovers its money for drug research and development. TRIPS does not expressly provide for compulsory licenses. Article 31 TRIPS, however, provides for compulsory licenses authorizing "other uses of [patents] without the authorization of the right holder."<sup>13</sup> Provisions related to compulsory TRIPS licenses they have limitations the most important of which are:

- (1) The compulsory license can only be granted after the failure of reasonable negotiations (this provision can be waived in case of national emergency)
- (2) The scope and duration must be limited to the purpose for which the license was authorized and must cease if and when conditions change to eliminate that purpose.
- (3) The license must be not transferable.
- (4) the license must to be used primarily to provide of the national market of the nation that grants it and
- (5) the holder of the right must receive adequate remuneration based on the circumstances of each case. The restrictive provisions of article 31 were also described by developed countries liberal and from developing countries such as too restrictive.

The amended Article 31bis of the TRIPS giving full form legal effect to this system and allowing low cost generic medicines to be produces and exported under a compulsory license

---

<sup>13</sup> TRIPS Agreement, Apr 15, 1994, Art 30 & Art 31.

exclusively for the purpose of serving the needs of the country that cannot manufacture those product themselves. For the minority of WTO members yet to accept the amendment an interim waiver continues to apply.

### **Compulsory Licensing of Pharmaceutical Patents and Judicial Trends in India**

In the case of *Bayer Corporation v. Natco Pharma Ltd*<sup>14</sup> on March 9, 2012, Natco became the first company in Indian history to be awarded license required. Bayer is an American subsidiary of the German multinational specialist Bayer in the chemical and pharmaceutical industry. In 1990, he developed a drug called Sorafenib Tosylate which was given the brand name Nexavar in 2005. It is used to treat Cancer patients stage 4 Patented in India in March 2008. So he started importing and selling the drug in India and the monthly cost came to around Rs 2.8 lakhs per month. Natco had approached Bayer for a voluntary license, which was rejected. In July 2011, Natco applied for a compulsory license under section 84(1) of the Patents Act, which was granted in March 2012. Bayer filed a complaint with the IPAB (Intellectual Property Appellate Board) of the Bombay High Court, who was dismissed under Article 21 of the Constitution of India taking into account social and health considerations. After the process, Natco put the available medicine is about 8800 rupees per month. 6% of the net sales price and later 7% were decided by Natco to pay Bayer. The questions were as follows regarding section 84(1)(a), (b), (c) of the Patents Act if

#### *1. Whether Bayer answered the public's reasonable questions about Nexavar?*

According to the data provided by Natco, the imports of Nexavar in India were able to meet only 2% of the demand. Bayer did not provide any argument why it did not manufacture/import the required number of drugs in the previous years. Therefore, it was found that Bayer failed to respond to the reasonable requests of the public.

#### *2. Whether Nexavar was available at a reasonable price and affordable to the public?*

Reasonable and affordable prices will depend on a case-by-case basis on R&D spending and the ability of patients to pay for the drug. Bayer argued that many costs were incurred during R&D and that generic manufacturers simply duplicated the original drug. Bayer argued that it had a patient assistance program (PAP) and partnerships with insurance companies. Natco said the price was a major obstacle for patients who wanted to buy the drug. Bayer could not yet

---

<sup>14</sup> 2014 (60) PTC 277 (Bom)

prove the exact cost of drug development and simply presented general figures. The product should not be priced in such a way that all the R&D costs have been covered by the Indian market. During the planning of the PAPs, it was noted that Bayer himself had accepted the unaffordability of the drug.

### 3. *Did Nexavar work in Indian territory?*

The term "operating in Indian territory" is not defined. Bayer claimed that research and development costs were too high and global demand was low. It is therefore possible for them to manufacture the product from a single unit in Germany due to the advancement of infrastructure and supplies in the global market. Natco stated that the term should refer to the product to be manufactured in India. The IPAB considered that this question had to be decided on a case-by-case basis and that, notwithstanding Article 84, paragraph 1, the granting of a compulsory patent required compliance with a condition, whereas the Bayer company had not met all conditions. determined and that, therefore, the grant was justified.

The pharmaceutical industry is rife with debate about how to balance patient needs with respect for patent rights. However, a compulsory license is not always granted. In the case of *BDR Pharmaceuticals International Pvt Ltd v. Bristol-Myers Squibbco*<sup>15</sup> where a patent application for an anti-cancer drug by Bristol-Myers Squibb was filed, it was found that the applicant had not attempted to obtain a license from the patent owner nor had the ability to exploit the patent in the public interest. He therefore failed to establish prima facie evidence justifying the granting of the compulsory licence. Hence, his question was rejected.

In another case, *Lee Pharma Vs. Astra Zeneca AB*<sup>16</sup> - The applicant argued that the owner of the patent have not met all the requirements set out in section (84) (1) (a), (b), (c). However, plaintiff has not established what constitutes a reasonable public demand. He too observed that the price of related drugs was in the same price range and therefore the claim that it was unaffordable was not justified. The plaintiff has not yet indicated how many patients they could not take the medicine because of their lack. Hence, the question was rejected. Conscious efforts have been made to protect the rights of patent holders in any case, but where the patentee clearly abuses the available patent right and risks of endangering the national economy and the population of the country, the concession of compulsory license is justified.

<sup>15</sup> C.L.A. No. 1 of 2013, October 29, 2013.

<sup>16</sup> C.L.A. No. 1 of 2015.

## **CHAPTER III**

### **COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN INDIA: ISSUES AND CHALLENGES**

Compulsory licensing is recognized as an effective and justified tool against patent holders' monopolies, while cartel agreements represent a more promising and affordable way to ensure access to pharmaceutical products. For pharmaceutical patents, it is not possible to follow a global approach. Implementation requires a balanced approach between public health rights and an approach based on exclusive intellectual property rights.<sup>17</sup> This certainly provides economic growth and encourages research, but few conceptual, procedural and technical problems related to the compulsory license still need attention.

1. The granting of a compulsory license to an invention is in turn a denial of the property rights of the patent owner. The law does not specify the future of mandatory licensed patents under section 92 if, due to a change in circumstances, the patent no longer exists guaranteed for use.
2. It is necessary to analyze whether the granting of a compulsory license is a denial of the fundamental rights and human rights of the patent holder. A bargain failure to agree to share a patented invention may constitute a flagrant denial of the rights guaranteed by Section 1950. Since the right to life of a person or the public in general is in conflict with the monopoly right of the owner of the patent, the granting of a compulsory license should serve as a reasonable limitation<sup>18</sup> and not a denial of the right of the owner of the patent to realize the greatest good of the greatest number. It must serve as a legitimate limitation or reasonable limitation.
3. The granting of a compulsory license is only allowed for non-functional patents. Access to features must be more clarified: if a pharmaceutical product is readily available, accessible but not affordable, it should only lead to a compulsory license or an alternative measure, since the situation does not fully confirm the non-functional patent.
4. Regarding the procedure for granting compulsory licenses, first, no compulsory license can be granted three years before the date of sealing of the patent. This raises the question of the time lost in the patent agreement, the patent holder in some cases having a very limited period for submit an application for a compulsory license.

---

<sup>17</sup> Prabhat Kumar Saha, Aditi Mukherjee, Compulsory Licensing of Patent: Issues & Challenges, academic journal, 2019.

5. Any interested person can apply for the compulsory license, but the basis of the infrastructural and financial capacity of that person is not mentioned. These characteristics may vary from case to case, but the foundations remain to be determined. Moreover, such a requirement may serve as a means of harassment and mental anguish to the patent owner in the absence of proof of intent.
6. The patent owner may use voluntary non-licensing as a delaying tactic. A fixed negotiation period, with specifications regarding negotiation stages, can delay the submission of a viable compulsory license application.
7. The application of Section 92 dilutes the provision of Section 84, but such a clear mention is absent in the provisions, leaving room for ambiguity.
8. Finally, if the owner of a patent is not satisfied with the royalty or compensation, he can challenge the Supreme Court. This led to an increase in the legal burden and delays in the payment of amounts due to procedural failures.
9. There is no doubt that the law is underused for compulsory licensing in general and in relation to pharmaceutical patents in particular. The government has shown a proactive approach to legislation and the enforcement of provisions relating to anti-competitive practices, the regulation of companies against the abuse of dominant positions, etc., but has a passive approach to the provisions related to licenses, despite the fact that there is still. A considerable time requirement for pharmaceutical products due to population and diseases in India. It may be a lack of political will, but the main concern, the researchers say, lies in "the saga of developed and developing countries." Developed countries insist on stringent and stringent licensing provisions, which is not the case in developing countries. There is the obvious pressure of unilateral and unpleasant sanctions against developing countries if such provisions are widely used.
10. It should be understood that there is no cost-effectiveness of royalties. Pharmaceuticals require intensive research, unpredictable timing and extremely high costs. The royalties/compensations given in this way do not correspond to the resources spent on the product, leading to the failure of attempts to obtain licenses. Such inadequate compensation may discourage research efforts.
11. In view of the international approach, the question is whether universality and absolute harmony are possible with patents. Each member state it has resources, political approach, political stability, system different jurisprudence and therefore have different requirements in terms of specific drugs and quantities. Flexibility and transitional

arrangements must respond to this problem, but do not identify the possibility of an optimal harmonization.

12. One of the worst situations that can arise against the owner of the patent is a threat created in his mind on the compulsory license of his patent because of which he may be abandoned patent rights under compulsion. There is no identified process in India that allows the patent holder to negotiate the price of the compulsory license with the government. He is still the last person to set the price of a patented medicine with a compulsory license. This factor may discourage the patent owner from allowing his patent to be subject to a compulsory license.



## **CHAPTER IV**

### **COMPENSATION STANDARDS FOR COMPULSORY LICENSING**

Compensation Proposals to Meet the Requirements of Article 31(h)"adequate remuneration" for compulsory licence sit varies depending on the political issues. Developing countries, they seek to promote access and competition through minimum compensation strategies while developed countries they seek to protect the investment through compensation for waiting.<sup>19</sup>

#### ***A. Developing Nations Seek Minimal Compensation***

As a preliminary question, developing countries try to define "adequate remuneration" within the meaning of Article 31(h) based on them limited paying capacity. Most developing countries are poor and incompetent pay market prices for patented products such as pharmaceuticals. Furthermore, under Article 31(a) of the TRIPS Agreement, compulsory licenses can only be applied when the conditions present an imperative necessity. In such conditions, the resources of a developing country it is likely that he was exhausted by the effort put into it solve the problem; therefore, the country would not be able to pay compensation at the market price of the patent holder. Thus, even when a developing country overcomes the obstacle of Article 31 (a) showing a compelling need, compulsory licenses will not be available to meet that need, unless section 31(h) on "adequate compensation" is interpreted as limited based on available resources of the country.

#### ***1. Controlled Compulsory Licensing with Minimal Compensation Will Promote, Not Stifle, Innovation***

One of the main purposes of granting monopoly rights under IPR is that provide an incentive to innovate. Developed countries have argued this Compulsory licensing will weaken this incentive. Developing countries argue, however, that mandatory limited licenses are not it will not prevent innovation, even when there is little or no compensation. In fact, most developed countries already offer licenses mandatory in certain critical areas. For example, in the United States, 35 U.S.C. § 287(c) prevents patent holders medical procedures to sue doctors for falsification. Section 287(c)it effectively grants a compulsory license without compensation the most likely users of patents for medical procedures, namely doctors. Although the bill was much contested and has been described by some commentators as harmful to innovation, its

---

<sup>19</sup> SUSAN VASTANO VAUGHAN, Compulsory Licensing of Pharmaceuticals Under TRIPS: What Standard of Compensation, *Hastings Int'l & Comp. L. Rev.*, Vol. 25:87, 2001.

approval shows that the Congress of the United States weighed the human need for access to medical procedures vs potential barrier to innovation and concluded that the human need was primordial. This is how the policies of developed countries have reflected the recognition that innovation will not be unfairly stifled by action government that provides reasonable access to important inventions. Developing countries also argue that compulsory licensing will increase in reality innovation facilitates industrial development. Rigid patent protection may hinder the development of domestic industry's research capacity innovative solutions that address national problems that are often ignored as unnecessary multinational. Some persuasive counterarguments for stronger patent protection conclude that the availability of compulsory licenses hinders local research and development and discourages foreign direct investment that could stimulate domestic industrial innovation. However, empirical evidence shows that these conclusions are not incontrovertible. For example, the elimination of patents on pharmaceutical products in Brazil in 1969 was followed by a sixfold increase in foreign investment in the domestic pharmaceutical industry. There is no doubt that the current level of technological development and innovation in developing countries is completely insufficient for this.

## *2. Compensation for Costs and Lost Profits Amounts to Compensation Where There Was No Injury*

Developing countries also argue that the refusal to grant compulsory licenses without full compensation for costs and lost sales is not sustainable because patent owners are not harmed by provisional licenses in developing countries. United States jurisprudence supports this proposition. For example, in *Leesona Corporation v. United States*<sup>20</sup>, a federal appeals court stated that compensation should be based on "what [the patent owner] lost, not what the licensee lost." Thus, the patent owners in the Leesona case have not been lost profits from sales at prevailing market rates.

Developing countries are not a real component of pharmaceutical companies' markets. "Pharmaceutical manufacturers do not depend on the profits of developing countries." Companies do not develop drugs for diseases endemic to developing countries. Companies may indeed sell drugs in developing countries, but these drugs are developed to be sold to citizens of developed countries.<sup>21</sup> Thus, the investment of pharmaceutical companies is not directed to developing countries and their return on investment is not affected by compulsory

---

<sup>20</sup> 599 F.2d 958, 970 (Ct. Cl. 1979).

licenses aimed at meeting urgent health needs in these countries. According to Leeson's reasoning, pharmaceutical patent holders do not have the right to compensation for compulsory licenses that allow the manufacture and sale of drugs in developing countries.

### ***B. Developed Nations Seek Full Compensation for Lost Costs and Profit***

#### *1. Full Compensation Is Necessary to Protect the Incentive to Innovate, Which Is the Purpose of IPR Protection*

Developed countries, especially those with large pharmaceutical industries, argue that the refusal of full compensation for compulsory licensing erodes the intellectual property policy that promote innovation. Denying full compensation for lost costs and profits will stifle innovation because it will discourage the investment so essential to research and development. A study of pharmaceutical innovation compared to drug price regulation in developed countries showed that price controls appear to have a chilling effect on pharmaceutical innovation.<sup>22</sup> The chairman of German pharmaceutical giant Bayer suggested that the research-based pharmaceutical industry no longer has much of a future. Germany if their innovation has been marred by price erosion a compulsory license with compensation below fair market value it is likely to have a similar detrimental effect on the incentive to invest and innovate.

The pharmaceutical industry relies heavily on long-term investments to support research and development during the laboratory research phase, 5,000 ingredients are tested for each ingredient approved and marketed. It takes an average of fourteen years to bring a new drug to market, and the costs to get there are staggering. On average, it costs \$500 million to bring a new drug to market, and only one new drug approved in the market. Thus, the annual balances that reflect a lot earnings, considered by some unacceptable, do not count enormous costs incurred in more than a decade of research and development. Developed countries with a pharmaceutical industry know this the need to promote investment and innovation and support a fair market value compensation for compulsory licenses. For example, in the United States, 28 U.S.C. § 1498 authorizes compulsory licenses for public use, but requires compensation, as for expropriation standard for the compensation for an expropriation is "just compensation, so that the owner is placed in the same monetary position as him would have occupied if his property had not been expropriated. The standard has it is further clarified that it requires compensation at full market value. Switzerland allows compulsory licensing of patents, but

---

<sup>22</sup> Jerry Stanton, Comment, Lesson for the United States from Foreign Price Controls on Pharmaceuticals, 16 CONN. J. INT'L L. 149, 156 (2000).

treats licensing as expropriation. The international standard for compensation for expropriation is that it be "immediately paid and fully realizable". "According to the North American Free Trade Agreement, the "adequate" compensation for expropriation is defined as the fair market value, including the ongoing value and the pre-expropriation value of the asset. Therefore, the developed countries need that the "adequate consideration" for compulsory licenses under TRIPS be interpreted as the fair market value of the license, including development costs and lost profits.

## *2. Full Compensation Is Necessary to Compensate Patent Holders for Lost Revenues Due to Resale of Gray Market Goods Produced Under Compulsory License*

The exhaustion doctrine allows for the resale of gray market goods. Under the exhaustion doctrine, once a patented product is sold with the patent owner's consent, the patent owner has no right to resell it.

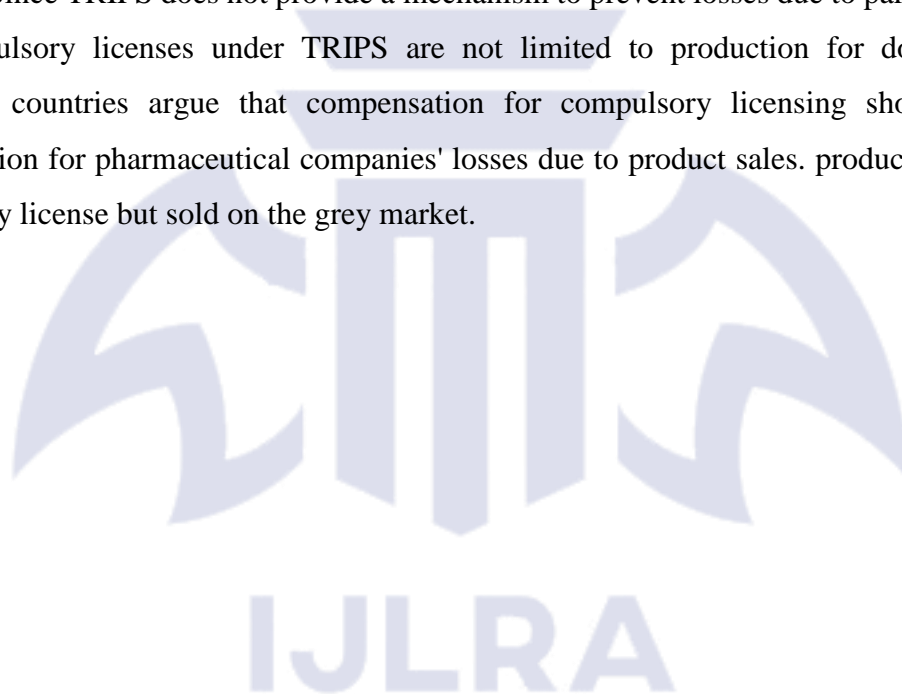
To control the further resale of the product, both nationally and internationally, in the absence of protective law. Thus, a patented product can be purchased abroad and imported for sale at a price lower than the domestic market price, unless a local law prevents the unauthorized importation of patented products. Large pharmaceutical companies, concentrated in a small part of developed countries, depend on a significant income from sales in foreign markets; American pharmaceutical companies estimate that foreign sales represent forty percent of their annual revenues.<sup>23</sup> However, revenues from overseas sales have been significantly reduced, up to \$5 billion per year, by the parallel importation of gray market products. Thus, the grey market has a significant impact on the gross income of pharmaceutical companies and, therefore, reduces the resources that can be reinvested in future research and development. In 1996, the International Trade Commission estimated that the revenue losses from the sale of pharmaceutical products on the grey market resulting in a shortfall in reinvestment amounting to approximately \$1 billion annually. Assuming an approximate cost of \$500 million to bring a new drug to market, annual grey market losses represent a lost opportunity each year to bring to the market two new drugs to fight and human diseases. However, TRIPS expressly avoids addressing the international regulation of grey market products and parallel imports. Article 6 of TRIPS states that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights. TRIPS specifies that there will be no obligation to

---

<sup>23</sup> Gerald J. Mossinghoff & Thomas Bombelles, The Importance of Intellectual Property Protection to the American Research-Intensive Pharmaceutical Industry, COLuM. J. WORLD Bus., Spring 1996, at 39.

apply [border control measures] to imports of products placed on the market in another country by or with the agreement of the patent holder. The United States prohibits the importation of patented products without the patent owner the authorization.

However, many industrialized countries do not have one protective laws and TRIPS do not require their approval Therefore, currently TRIPS does not in any way restrict the parallel importation or resale of grey market products. Furthermore, under Article 31 of TRIPS, products manufactured under a compulsory license may be exported from the country that grants the compulsory license. Therefore, TRIPS does not prohibit the use of compulsory licenses to exploit international markets of the patent holder through grey market sales. products. Since TRIPS does not provide a mechanism to prevent losses due to parallel imports and compulsory licenses under TRIPS are not limited to production for domestic use, developed countries argue that compensation for compulsory licensing should include compensation for pharmaceutical companies' losses due to product sales. produced under the compulsory license but sold on the grey market.



## **CHAPTER V**

### **CONCLUSION:**

Compulsory license plays a vital role where there are certain patented inventions that are important in health and well being of the community. The license is granted only when certain conditions are satisfied, which is provided under the Indian patent Act. The Act also provides about the revocation of the compulsory license when the subjected invention is not worked in a proper manner within sufficient time period. In such cases the granted compulsory license can be revoked. Compulsory licenses can be used to decrease the burden of cost of the production, and reduce the barriers to innovation, and ultimately providing greater access to these tools for public at large. Compulsory license in India is still an emerging concept and it exists in the Indian patent laws. Compulsory licenses of patented invention grants exclusive rights to the applicant but such rights are granted only in certain situations. The concept is still growing and till now only one compulsory license is being granted by the India. With the development some changes always occurs and hence let's hope that the compulsory license always works in a positive manner in India and thereby the IP remains protected.

### **REFERENCE:**

1. Elizebeth Verky & Jithin Saji Isaac, Intellectual Property, Eastern Book Company (EBC), Second Edition, 2021.
2. Feroz Ali Khader, The Law of Patents with special focus on Pharmaceuticals in India, Lexis Nexis Butterworths, 2007.
3. Rajeshkumar Acharya and Girishchandra Tanna, Compulsory Licensing Of Patents In India, SSRN, 2019.
4. LOWIA PAUL, COMPULSORY LICENSING OF PATENTS IN INDIA, JETIR, Volume 6 Issue 3, March 2019.
5. SHAMNAD BASHEER, The Compulsory License Regime in India, SSRN Publications, December 2020.
6. Deepak Kumar Dash, A Review on the Indian Patent System and Its Implication on the Pharmaceutical Industry, JHSMR, 2023.
7. Kaur A, Chaturvedi R. Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma. Journal of Intellectual Property Rights, 2015; 20): 279-287.

8. Gupta R., Compulsory Licensing under TRIPS: How far it Addresses Public Health Concerns in Developing Nations, *Journal of Intellectual Property Rights*, 2010; 15: 357-363.
9. P. Narayanan, *Patent law*, (Eastern Law House, Fourth edition, 2017) pp 1-4.
10. Dr. G.B. Reddy's, "Intellectual Property Rights And The Law", (Gogia Law Agency 2012)
11. V.K.Ahuja, "Law Relating To Intellectual Property Rights" (LexisNexis Third edition 2017); pg, 577, Annex 7,
12. Agreement on Trade Related aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement] Article 31.
13. TRIPS Agreement, Apr 15, 1994, Art 30 & Art 31.
14. 2014 (60) PTC 277 (Bom)
15. C.L.A. No. 1 of 2013, October 29, 2013.
16. C.L.A. No. 1 of 2015.
17. Prabhat Kumar Saha, Aditi Mukherjee, *Compulsory Licensing of Patent: Issues & Challenges*, academic journal, 2019.
18. SUSAN VASTANO VAUGHAN, *Compulsory Licensing of Pharmaceuticals Under TRIPS: What Standard of Compensation*, *Hastings Int'l & Comp. L. Rev.*, Vol. 25:87, 2001.
19. 599 F.2d 958, 970 (Ct. Cl. 1979).
20. Jerry Stanton, *Comment, Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 *CONN. J. INT'L L.* 149, 156 (2000).
21. Gerald J. Mossinghof & Thomas Bombelles, *The Importance of Intellectual Property Protection to the American Research-Intensive Pharmaceutical Industry*, *COLuM. J. WORLD Bus.*, Spring 1996, at 39.