Journal of Intellectual Property Rights
Vol 30, May 2025, pp 361-375
DOI: 10.56042/jipr.v30i3.9402

Contemporary Stance of Compulsory Licensing in Indian Pharmaceutical Industry

Sushma Singh[1], Anushka Singh[2], Ravi Chandra Prakash[3] and Raj Kumar Yadav[4†]

[1]School of Law, Sharda University, Knowledge Park III, Greater Noida — 210 310, India

[2]CPGLS, Babasaheb Bhimrao Ambedkar (Central) University, Lucknow — 226 025, India

[3]Advocate, Supreme Court of India, New Delhi — 110 001, India

[4]Department of Law, School of Legal Studies Central University of Punjab — 151 401, India

Received: 8th March 2024; revised: 11th October 2024

Patent is a monopoly given to prevent the patent holder's hard work from being wasted and to encourage innovation. In contrast, compulsory licensing occurs when a government authorizes a third party to use a patented product or method without the patent holder's approval under certain conditions. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, the Doha Declaration, and the Indian Patent Act of 1970 (herein referred to as 'the Act') contain provisions for the patenting of pharmaceuticals, as well as provisions for a compulsory licensing system to prevent patent rights misuse. In India, as well as the rest of the globe, there has been an imbalance between profits and medicine availability. Existing global structures were put to the test by the extraordinary period of time the human race endured as a result of COVID 19. The same was seen for the obligatory licensing arrangement for drugs under patent law. In this article, the authors proposed to discuss the existing legal system for Compulsory Licensing in India, followed by an examination of the TRIPS agreement's requirements. Further, the authors explained the status of compulsory licensing in COVID-19. Thereafter, the authors analyze the intersection of compulsory licensing with competition law and conclude with identified issues and recommendations.

Keywords: Compulsory, Licensing, Patent, Pharmaceutical, Medicine, Industry, COVID-19

The Indian pharmaceutical business supplies almost 50 percent of the global demand for different vaccines, 40 percent of the generic demand in the United States, and twenty-five percent of all pharmaceuticals in the United Kingdom. According to the *Indian Economic Survey 2021*, the domestic market is anticipated to triple during the following decade. Domestic pharmaceutical sales in India totaled US$ 42 billion in 2021, and are projected to reach US$ 65 billion by 2024 and US$ 120-130 billion by 2030.[1]

Compulsory licenses are authorizations granted by the Controller General to a third party to manufacture, use, or sell a patented product or to apply a patented method without the patent owner's consent. This idea is acknowledged at both the national and international levels, since it is expressly mentioned in both the Indian Patent Act of 1970[2] and the TRIPS Agreement of 1995. In the Indian context, granting forced licenses has been fraught with technical and legal obstacles. In the past, India has disregarded and even mocked pharmaceutical patents. In reality, India did not provide patent rights for pharmaceutical businesses until 2005. This has resulted in violations of the World Trade Organization's compulsory licensing agreement and in significant critiques of other multinational pharmaceutical corporations such as Pfizer, Roche, and Bayer. The World Trade Organization, the TRIPS agreement, and the Doha Declaration all permit the use of compulsory licensing (temporary patent rights for life-saving medications), however India has recently been more flexible in its use of this provision. In reality, the first usage of "*Nexavar"* occurred in 2012. Since then, India has seldom utilized forced licensing. In the era of COVID-19, the conflict between commercialization and the demand for pharmaceutical goods impeded the grant system of compulsory licensing, in which governments were forced to choose between economic exclusivity and the need for pharmaceuticals.[3]

Meaning of Compulsory License

A compulsory license is a contract between a willing buyer (third party) and an unwilling seller (patentee) that is imposed and enforced by the state government without the patentee's agreement. It is one of the patent protection flexibilities contained in the World Trade Organization's (WTO) intellectual property pact, the TRIPS Agreement.[4]

†Corresponding author: Email: rajkumar.yadav@cup.edu.in

A compulsory license stipulates that the owner of a patent or copyright licenses the use of their rights in exchange for a fee that is either statutorily or arbitrarily determined. Under a compulsory license, an individual or company seeking to use the intellectual property of another can do so without the consent of the rights holder, and pays the rights holder a set fee. This is an exception to the general rule under intellectual property laws that the owner of intellectual property has exclusive rights that it may license to others or refuse to license to others.[5]

These are authorizations granted by the Controller General of Patents to a third party to manufacture, use, or sell a patented product or employ a patented process without the patentee's consent.[6] This idea is acknowledged at both the national and international levels, since it is expressly mentioned in both the (Indian) Patent Act of 1970 and the TRIPS Agreement. In accordance with Sections 84-92, several prerequisite requirements must be met before a forced license may be issued in favour of someone.

Evolution of Compulsory License Regime in India

Post-independence, international corporations dominated the Indian pharmaceutical sector. The pharmaceuticals were imported at a higher price, and India ranked among the countries with the most expensive drugs. It was determined that the former "*Indian Patents and Designs Act of 1911"* did not meet the needs of the Indian populace. Therefore, the *Justice (Dr.) Bakshi Tek Chand committee* was established to evaluate the Indian patent system in detail. The committee correctly pointed out that the Patent Act should contain clear recommendations to ensure the needs of the Indian population with regard to food, medicines, and medical devices, and that these should be made available to the public at the lowest price commensurate with their value, while also providing patentees with a reasonable compensation. The 1950 (Act XXXII of 1950) amendment (focus on functioning of inventions and compulsory license [CL]/revocation) and the 1953 law are based on these proposals (Bill No. 59 of 1953). Despite being submitted to the parliament in 1953, this measure was allowed to expire.[7]

In 1957, the Indian government took two significant actions: the first was the establishment of *Hindustan Antibiotics Limited* (as per an agreement with UNICEF), and the second was the appointment of the *Justice Rajagopala Ayyangar* Committee to revise patent law and develop a locally sustainable market. This committee's report (1959) served as the foundation for the IPR revolution in India with important innovations such as the "process only patent framework" and is the backbone of the "Patents Act, 1970" (in force since 1972), which superseded prior patent laws (except designs). This updated statute remained in effect for the following 24 years, until 1994.[8]

In 1999, 2002, and 2005, amendments were made to the Indian Patent Act of 1970. On 1 January 2000, the second amendment to the Patent Act included substantial revisions to the statute. Redefining patentable subject matter, extending the length of patent protection to 20 years, and modifying the compulsory licensing system were the key problems addressed by the Second Amendment. Following India's accession to the TRIPS Agreement, the Indian patent rules were altered to permit product patenting.[9] This phase also provided patentees with greater options over medicine availability, quantity, and pricing. As a result, the Indian Patent Laws included very extensive mechanisms for compulsory licensing to combat patent rights abuse.

In 1970, Indira Gandhi established legislation prohibiting the patenting of medical items in India. In 1994, 162 nations, including India, signed the TRIPS agreement, which required patents for all discoveries, including pharmaceuticals. India and other developing nations were given an additional ten years to comply with all TRIPS terms. The third modification to the Indian Patent Act of 1970 examined compulsory licensing. In order to get approval for a compulsory license, an applicant must submit a written application to the patent controller under Section 84 (1) after the expiration of the patent term, which shall be three years from the date of the invention's patent sealing, and on the grounds listed therein. In this instance, Section 3(d) of the new legislation provided that a drug could not be patented if it did not result in *"the increase of the recognized efficacy of that substance*."[10]

Pros and Cons of Compulsory Licensing in India

Compulsory license has many advantages and that is why this concept is promulgated on a global level. During emergency situations, it is helpful for public interests, particularly the pharmaceutical industry in developed and developing nations. This is due to the fact that generic producers reduce the cost of acquiring the medication or product, in contrast to patentees, who charge higher charges. It increases the

inventiveness of businesses at a lower cost. The government will prefer to give compulsory licenses, which will facilitate the transfer of technology, over sponsoring the Research and Development of such innovations, which is always an expensive endeavour. With the growth of generic companies/manufacturers, the innovation will be rapidly multiplied; hence, as the supply increases, the price of the patented product will decrease. This compels the patent holder to lower their price position in order to remain competitive on the market. This improves competition and prices. It evaluates the effectiveness of an invention. In the process of giving a compulsory license, if an innovation is insufficient and incomplete, this deficiency may be detected, allowing the government to restrict the invention's dissemination inside the region. Final customers, particularly patients, will be able to acquire the innovation or medications at drastically reduced costs. Consequently, difficulties of affordability can be tackled through this medium.[11] The notion of mandatory licensing is unquestionably beneficial to the general public, yet there are also opposing viewpoints. There is a problem with the patentee's discontent with the payments. These royalties may not cover the costs associated with the patent's research, creation, maintenance, and acquisition. It discourages generic producers from conducting research since acquiring a required license is cost-effective.[12]

Due to the demands of their trading partners and pharmaceutical industries, poor nations have historically been prohibited from utilizing forced licensing to get access to medications. Mandatory licenses necessitate a case-by-case approach and are challenging to manage between jurisdictions. The TRIPS Agreement establishes some procedural and substantive constraints for the use of compulsory licenses by governments, some of which may impose restrictions in the event of a worldwide pandemic.[13] If the ineffectiveness of compulsory licensing as a solution for developing and growing patent restrictions, after patent hurdles have been erected on particular medical goods, halting manufacture and delivery, are fulfilled then only then is compulsory licensing a viable solution.

International Provisions of the Compulsory License Regime

Paris Convention, 1883 as Amended in 1979

It stipulated that each contracting state will implement legislative steps for the issuance of obligatory licenses. According to Article 5A (2) of the Paris Convention (World Intellectual Property Organization, undated), "*each country of the Union shall have the right to adopt legislative measures providing for the grant of compulsory license to prevent the abuses that may result from the exercise of the exclusive rights conferred by the patent, such as failure to work*". Thus, forced licensing existed prior to the advent of the WTO. In fact, the notion of obligatory license existed in the United Kingdom of Great Britain and Ireland in the 1850s.[14]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1995

The TRIPS entered into force in order to ease trade and commerce between WTO members and to improve the utilization of intellectual property rights. Consequently, the TRIPS agreement incorporates a variety of safeguards for public order, morals, and health. Article 30 of the TRIPS Agreement offers limited exceptions to the rights conferred by patents, so long as they do not "unreasonably damage the legitimate interests of the patent owner, having regard to the legitimate interests of third parties." The article establishes the foundation for the issuance of forced licenses. Article 31, defines compulsory licensing as "other use without the rights holder's consent," but only under particular situations.[15]

The most essential restrictions governing the use of forced licensing by WTO members are outlined in Article 31 of TRIPS (which relates to the use of intellectual property without the owner's authorization):

(a) The applicant for a compulsory license must have been unable to obtain a voluntary license from the right holder on "reasonable" commercial terms; however, this requirement may be waived in the event of a "national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use." (b) Appropriate compensation must be provided to the patent holder if a compulsory license is awarded, (c) a forced license must be granted primarily to serve the local market, and (d) The usage must not be exclusive or even assignable.

Consequently, compulsory patent licensing is included into the TRIPS Agreement from the start.[16]

Doha Declaration, 2001

The Doha Declaration on the TRIPS Agreement and Public Health was agreed on 14 November 2001 at the WTO Ministerial Conference in Doha. It confirmed the TRIPS member nations' ability to

violate patent rights in order to improve access to vital medicines. As Article 31 of TRIPS does not expressly define the grounds that may be used to justify compulsory licensing, developing nations erroneously believed that compulsory licenses could only be given in emergency situations. The proclamation and following Decision on Implementation of Paragraph 6 of the Doha Declaration of 30 August 2003 requested clarification on the matter. [17]

In particular, the Doha Declaration includes: Paragraph 4, which affirms that the TRIPS Agreement "does not and should not prevent member countries from taking measures to protect public health"; Paragraph 5(b), which recognizes that certain flexibilities are built into the TRIPS Agreement, including the right of each WTO member to grant compulsory licenses and the freedom to determine the grounds on which such licenses may be granted; and Paragraph 5(c), which further clarifies the TRIPS Agreement's provisions regarding these flexibilities; and Paragraph 6, which acknowledges that WTO members with little or no manufacturing capacity in the pharmaceutical sector may have difficulty utilising compulsory licensing under the TRIPS Agreement effectively. It directs the TRIPS Council to find a prompt solution to this issue and report back to the General Council by the end of 2002.[18]

National Legal Provisions of Compulsory License

In India, only six sectors are subject to compulsory licensing. These are the brewing and distillation of alcoholic beverages; tobacco-based cigars and cigarettes, as well as artificial tobacco replacements; all sorts of electronic aerospace, and defense equipment; industrial explosives, such as detonating fuses, safety fuses, gunpowder, nitrocellulose, and matches; hazardous substances and pharmaceuticals (As per the modified Drug Policy issued in September 1994).[19]

The Indian Patent Act, 1970, Chapter XVI (Sections 84-94), in conjunction with the Indian Patent Rules, 2003, provides the legal foundation for forced licensing (Indian Patent Rules). Relevant sections of the Indian Patents Act, 1970 pertaining to forced licensing include:

(a) Chapter XVI, which addresses the subject of compulsory licenses. Four major provisions of the Patents Act concern the same: Section 84, under which the Controller issues general compulsory licenses on application; Section 91, under which the Controller issues compulsory licenses for a related patent on application; Section 92, under which the Controller issues compulsory licenses based on a notification by the Central Government of circumstances of national emergency or extreme urgency or in the case of public non-commercial use; Section 92(A), In order to address public health issues, Section 92(A) permits the Controller to issue obligatory licenses for the manufacture and export of patented pharmaceutical goods to any nation with insufficient or no manufacturing capacity in the pharmaceutical sector for the relevant product.

b) Chapter XVII (Sections 99-103) includes provisions for the purchase and utilization of innovations by the Central Government.

(c) Chapter VIII of the Patent Rules 2003, as revised in 2006, governs the issuance and renewal of compulsory licenses (Department of Industrial Policy and Promotion, 2010)[20]

In accordance with Section 84, any person, regardless of whether he is the holder of the patent's license, may make a request to the Controller for a compulsory license upon the expiry of three years, if any of the following conditions are met: the reasonable requirements of the public with respect to the patented invention have not been met; the patented invention is not available to the public at a price that is reasonably affordable; and the patented invention is not commercially viable.[21]

While granting compulsory licenses, the authority must consider the following additional factors: the nature of the invention, the length of time since the patent's issuance; the steps already taken by the patentee or any licensees to make full use of the invention; the ability of the applicant to work the invention to the public's benefit and the applicant's capacity to assume the risk of providing capital and working the invention; and the efficacy of the invention.[22]

The application submitted under section 84 of the Act must demonstrate that the grounds listed in Section 84(1) have not been fulfilled. The application must be submitted on Form 17 or Form 19, as applicable. Along with the application, the applicant must demonstrate his aim and competence to implement the invention in question. The applicant must also demonstrate that he or she attempted to secure the license from the licensee on fair terms and within a reasonable timeframe (i.e. six months).

Once the controller is satisfied with the prima facie case, he makes an order instructing the applicant to provide copies of the application to the patentee or his

representative. This is done so that the patent holder may be heard and counter the applicant's argument. When the central government directs the controller to give a forced license, a copy of the order must be immediately provided to the patentee.[23]

Form 14 (Patent rules and Section 98) of the Rules may be used to object to the application, along with the opponent's objections. The controller communicates the notice of objection to the applicant so that all parties can be heard prior to making a judgment. The controller's order giving the applicant a compulsory license has the characteristics of a deed. Such that it is, implemented by the patentee for licensing in the applicant's name and according to the terms and circumstances defined by the controller under Section 93.

Section 91 discusses the licensing of relevant patents. The licensee may seek for a license for a related patented invention if the licensed innovation cannot be utilized without the usage of a related patented invention. Such an order to grant a license for the other related invention will be issued if the controller is satisfied that the applicant is able and willing to grant or procure a grant of a license for the patentee and its licensee (if they so desire); and the invention has made a substantial contribution to the establishment or development of commercial or industrial activities in India.

Section 92 states that, in cases of "National emergency" or "Extreme urgency" or "Public non-commercial use," if the Central Government is convinced that compulsory licenses must be granted at any time after the invention's sealing to enable its use, it may make a declaration to that effect by publishing a notice in the Official Gazette. Afterwards, the Controller shall, upon application by any interested party made at any time after the announcement, give the applicant a license on such terms and conditions as he deems appropriate. Following such notice, the Controller General of Patents, Designs, and Trademarks may give licenses to applicants willing and able to manufacture the pharmaceuticals in question. The Controller has the ability to determine the terms of such a grant. Such a grant would be cost-effective for the general public and beneficial for the patentee in the form of a licensing fee.[23]

In the event of an epidemic, such as AIDS, tuberculosis, Malaria, or any other epidemic, the controller is excused from following the procedures outlined in Section 87 and must immediately notify the patentee. This is done so that generic pharmaceuticals can be provided to individuals without any process delays and in an expedient manner.

In order to give effect to paragraph 6 of the Doha Declaration, which acknowledges that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector may have difficulty making effective use of compulsory license under the TRIPS Agreement, the Indian Patent Act of 1970 was amended to include a new Section 92-A, which discusses compulsory License for export of patented pharmaceutical products in certain exceptional circumstances. It is a clause that permits an applicant to manufacture and export patented pharmaceutical items to a nation that lacks the capacity to produce the product and is experiencing a public health emergency.[24] Such a request may only be submitted after the nation has granted a compulsory license for the commodity or has authorised the import from India by notice. In this context, pharmaceutical products refer to the product or proprietary method required to manufacture the necessary medicines and diagnostic kits to combat the public health problem.[25]

Under Section 100 of the Indian Patent Act, the government may issue a compulsory license for the use of a patented medication. In *Garware Wall Ropes Ltd* v *A.I. Chopra and Konkan Railway Corp*[26], the Bombay High Court permitted third-party entities to utilize a copyrighted technology on behalf of the government. In accordance with section 102 of the Indian Patent Act, the government may acquire a pending or issued patent for public benefit. In exchange, the government must pay the patent holder royalties as agreed upon by both sides.

Landmark Cases of Compulsory Licensing in India

In the majority of cases in India, the Controller denies the issue of a forced license for a few reasons, such as when a prima facie case has not been proved or when a patent license has not been sought for while requesting a compulsory license. The legal perspective on the granting of compulsory licenses is that this provision is primarily for the public good and cannot be abused to reduce the rights of patent holders. There must be a balance between public welfare and the protection of patent holders' rights. In a groundbreaking case involving Novartis, the

Controller awarded a compelled license, marking the first instance of coercive licensing in India. In 2005, the examination of product patent applications filed in India between 1995 and 2004 began. According to patent law, registration of a patent alone is not sufficient. The Court must evaluate the entire case, including the strength of the patentee's case and the defense's arguments.[27]

In the 2007 case *Natco Pharma Ltd* v *Pfizer/Roche,* a generics producer located in Hyderabad, *Natco Pharma Ltd,* filed a CL application with the Controller General of Patents. *Natco* reportedly had a license from Nepal to import Erlotinib, which was patented in India by Swiss company Roche under the brand name *Tarceva*, and *Sunitinib*, which was patented in the United States by *Pfizer Inc* under the brand name *Sutent*. *Natco Pharma* makes generics and asserts that the generic versions may be produced for one-fifth the price of the innovators' proprietary medication. Since Nepal is one of the least Developed Country, it is not required to prove that it has insufficient manufacturing capacity; therefore, it is legally permissible for Nepal to obtain a compulsory license to invalidate the patents for reasons of public health (citing Section 92A of the Patents Act and Article 31 of the TRIPS Agreement). It was denied.[28]

In *F. Hoffmann-La Roche Ltd. & Anr* v *Cipla* Ltd [148 (2008) DLT 598], the court considered Roche's application for an ad-interim injunction to prevent *Cipla* from manufacturing, offering for sale, selling, and exporting the generic version of the drug *Erlotinib (Tarceva),* for which Roche was granted Indian Patent no. 196774. This decision was applauded by both NGOs and the general public, who referred to it as a judge-made obligatory license.[29] It is common knowledge that the scales of justice tip in favour of the plaintiff or the defendant. In this precedent-setting ruling, however, special regard was given to the Public (third-party interest), which would be denied of the generic product, so shortening the lives of several unidentified individuals. While rejecting Roche's ad-interim plea, the *Honorable Justice S Ravindra Bhat* stated that the Court could not ignore the public's right to access to life-saving pharmaceuticals, which would be denied if the injunction was granted.

In *Bayer Corporation* v *Natco Pharma Ltd.* (Order No. 45/2013), the Intellectual Property Appellate Board upheld the decision of the Controller of Patents[30] to grant India's first compulsory license and elaborated on when the conditions and grounds for compulsory licenses are met. In this landmark case, commonly referred to as the *Nexavar* case, the three grounds outlined in Section 84 of the Patents Act, 1970 were upheld, including the unreasonable requirement of the public, the inaccessibility of the drug at affordable prices, and the ineffectiveness of the invention on the territory of India. This judgement by the Indian government, which resulted in the issuance of CL, prompted other local generic producers to file further CL applications for patented pharmaceuticals. The Board determined that the Controller was correct in concluding that the appellant's sales of the drug at a price of approximately 280,000/- were the only relevant factor for determining public requirement, and that he was also correct in considering the purchasing capacity of the public and the available evidence in reaching the conclusion that the invention was not reasonably affordable to the public.

There were disagreements with this verdict, and a question was raised regarding the award of the same, as the firms contended that producing such a medication required a substantial investment of time, money, and effort in Research and Development. Therefore, they should be permitted to enjoy monopolistic rights over the drug's usage and to make a profit. Additionally, they must be able to balance and recoup Research & Development (R&D) costs. In contrast, it was asserted that the controller failed to give a fair and affordable pricing in this instance. While the controller accepted *Natco's* pricing, other segments of society may not be able to afford it. The question remains as to whether the patent holder or its licensee, and not a third party, must satisfy the demand for the claimed innovation in this instance.[31]

The Indian Ministry of Health submitted a compulsory licensing application for Roche's breast cancer medicine Herceptin (Indian Patent No. 205534), in 2013 in response to the *Nexavar* case. Interestingly, the Department of Industrial Policy and Promotion ultimately denied this application. Following the issuance of a compulsory license for *Nexavar*, there was significant worldwide scrutiny of India's intellectual property rules, and India did not want to promote more license applications, according to one school of thinking.[32]

In *M/s. BDR Pharmaceuticals International Pvt. Ltd.* v *M/s. Bristol-Myers Squibb Co.*[33], the Controller of Patents denied a compulsory license application submitted by *BDR Pharma* against Bristol-Myers Squibb's anticancer medicine *Dasatinib*. The

Controller denied this application on the grounds that *BDR Pharma* had not demonstrated a prima facie basis for the issuance of a compulsory license. In addition, it was determined that BDR Pharma had not fulfilled the criteria of acquiring a voluntary license prior to submitting an application for a mandatory license. The Delhi High Court[34] has upheld the patent of US-based BMS for *Dasatinib*, squelching the dreams of a local firm to market a generic version of the cancer medicine and offering some solace to global pharma manufacturers who are opposed to India's patent regulations. The primary reason for the rejection was that the India-based pharmaceuticals did not complete the procedure as required by Section 84, sub-section (6), clause (b), sub-clause (iv). In addition, BDR did not request a license from the patent owners within a reasonable timeframe.[35]

In *Lee Pharma Ltd.* v *AstraZeneca AB (*C. L. A. No. 1 of 2015), the applicant for a compulsory license for the drug 'Saxagliptin was denied because the applicant had failed to provide authentic evidence to satisfy the requirements of Section 84 of the Act. The Controller denied the application on the basis that the applicant did not meet any of the criteria outlined in Section 84(1) of the Act.

Recently, *Baricitinib* was utilized in conjunction with *Remdesivir* to effectively treat COVID patients during the current epidemic. Inhibiting the intracellular signaling pathway of cytokines, *baricitinib* increases the number of lymphocytes and prevents the entry of the coronavirus into the cell. The approved licensee for *Baricitinib* is Eli Lily and Company, originally located in the United States. In light of the second wave of COVID in India, NATCO Pharma petitioned the Controller of Patents for a Compulsory License (CL) to manufacture *Baricitinib* on 3 May 2021.[36] Consequently, the medicine would be readily available to a bigger proportion of the population throughout the epidemic. NATCO asserted, among other things, a national emergency under Section 92 of the Patents Act, 1970 in order to seek CL for the medicine *Baricitinib* from the Central Government of India.[37] However, the Licensee, Eli Lily, signed a royalty-free, non-exclusive, voluntary license agreement with NATCO and five other Indian pharma manufacturers for the production and sale of *Baricitinib*. Consequently, NATCO *Pharma* has withdrawn their CL appeal for *Baricitinib* on 17 May 2021.[38]

The major takeaways from the recent cases stated above regarding the granting of compulsory licenses are that the courts will assess the authenticity, proactive behaviour, and efforts of the applicant towards the patentee for the issuance of a voluntary license (Section 84(6) (iv)). Three tests apply to the meeting of reasonable requirements:

(i) whether, in addition to the patented drug, there are alternative drugs available for the same disease that could be made available to the public at a reasonable cost;

(ii) if no alternative drug is available, whether the patented drug is available to the public through manufacture or import by the patentee (commercial working in India) at a reasonable cost; and

(iii) a comparison of the cost of proposing the patented drug and the cost of proposed drug.[39]

Since the statute necessitates the annual submission of a statement of employment regardless of the condition of employment in India, the required form must be filled with attention. If a patent has not yet been developed, the owner must describe what will be done in the near future. If local manufacture is not practicable, the patent holder may consider licensing, which must be practiced concurrently. Similarly, the patentee must respond to generic company license inquiries. The patentee should examine the cost of vital life-saving pharmaceuticals by carefully monitoring the public need and economic position in India. The obligatory legislative conditions for getting a compulsory license (e.g., efforts to secure a license from the patentee and a fair timetable for discussions in light of public needs) must be carefully evaluated.

Compulsory Licensing During COVID-19

In the event of a "national emergency", "public health crisis", or "great urgency", governments have the power to offer their population with generic copies of copyrighted pharmaceuticals via domestic manufacturing and export under Section 92 of the Indian Patents Act, 1970. Given that the World Health Organization classified COVID- 19 a pandemic and that it meets the criteria of a catastrophe under Section 2 (d) of the Disaster Management Act 2005, it was appropriately labeled as a 'national emergency' or 'high urgency.'[40]

In the 2000s, developing nations such as Malaysia, Mozambique, Thailand, Rwanda, Zambia, Brazil, Zimbabwe, Ghana, and Ecuador awarded obligatory license to a few antiretroviral pharmaceuticals for their HIV/AIDS-afflicted populations. Similarly, in 1997, the South African government changed Article 15(c) of their Medicines and Related Substances Act, so permitting their government to award compulsory

permits to import cheaper and generic medications to combat the epidemic of HIV in its country. In retaliation, the United States of America and a few of European nations threatened them with ineffective penalties.[41]

The Parliamentary Standard Committee[42] proposed that the government investigate the possibility of temporarily waiving patent rights and granting Compulsory Licensing in order to address the inadequate supply and accessibility of COVID-19 vaccines and medications during a pandemic emergency.

In light of these circumstances, the Supreme Court questioned, in *Re Distribution of Essential Supplies and Services* v *Unknown during Pandemic*, in Suo Motu Writ Petition[43] why the Central Government was not considering invoking its powers for compulsory licensing or government-authorized use when evaluating a case involving COVID-19. During the hearing, the Court remarked that India was in the forefront of TRIPS talks regarding provisions on compulsory licensing, and that the current situation constituted a Public Health Emergency, making it a suitable instance for implementing these rules. The advice made by the Delhi High Court in *Dharmendra Kumar Aggarwal* v *Govt. of NCT of Delhi through the Secretary*[44] that the Centre should explore compulsory licensing of COVID-19 medications must also be included. In an order issued on April 20, 2021, the Court's Division Bench made the following observations: –

"*Looking to the present day situation, there can be no doubt that a case is made out for exercise of its power by the Central Government / Controller… At the same time, the interests of the patent holders/ licensees should be kept in mind…… the lives of thousands of people are being lost each day in the country due to COVID. The lives of the people take priority or everything else*……"

Even in the international community, the strongest opponent of CLs, the United States turned around, not only backing the use of CLs during the epidemic with its USTR Special 301 Report,[45] but also supporting a limited TRIPS Waiver. Despite this, the government was hesitant to issue a CL for COVID medications such as *Remdesivir* and *Tocilizumab*.

Further, the discussions at the 12th WTO Ministerial Conference in Geneva, prompted by a joint proposal by South Africa and India in October 2020 for a time-bound and specialized waiver about certain provisions of the TRIPS agreement administrated by the WTO, to allow manufacturers in developing countries to produce vaccines without the patent holder's consent, for the duration of the pandemic, with the aim of facilitating wider access to technologies necessary for the production of vaccines, will aim to facilitate wider access to technologies necessary for the production.[46] According to the proposal, governments are no longer compelled to abide by Article 31(f) of TRIPS; to guarantee this, IPRs must be waived for at least three years, and medical items should be considered global public goods.

A similar exception was provided to the other developing and least developed nations that lacked the industrial capacity to create medicines and medications, and hence had limited access to them. In 2003, the general council renounced the duty specified in TRIPS Article 31(f) and 31(h).

By November 2021, the original waiver proposal permitted WTO members to remove IP barriers on all COVID-19 response tools, not just vaccines, through negotiations facilitated by the European Union, the United States, India, and South Africa, as the QUAD process of the WTO waived only one of the conditions for the issuance of compulsory licenses.[47] In March 2022 The countries reached a consensus on key elements of a long-sought intellectual property waiver for COVID-19 vaccines. In March 2022, the nations established a deal on the essential features of a long-sought exemption from intellectual property for COVID-19 vaccines.[48] At a June 2022 Council for TRIPS meeting, WTO members granted a five-year patent waiver for COVID-19 vaccines. A government can provide a compulsory license to its local pharma businesses to develop the vaccine without clearance from the original maker. Vaccine export was also allowed.[49] An agreement emerged from an informal World Trade Organization (WTO) meeting on 13th November 2022 about whether an intellectual property (IP) waiver should be extended to COVID-19 therapeutics and diagnostics.[50]

Competition Regime and Compulsory Licensing

A combined reading of Section 89, 83(b), and 83(f) of the Act will reveal the goal of compulsory licensing. The goal of the approach is to avoid using anti-competitive conduct in place of monopolistic control over importation and exploitation of rights obtained from the patent. The license is granted by the controller with the intention of promoting business growth to the maximum degree possible without

unnecessary delay. In order to fulfill the public need and fully utilize the patent, this is done.[51]

The prohibition on anti-competitive behaviour in the Competition Act 2002 and the requirement for compulsory licensing in the Patent Act are not mutually exclusive, the Indian courts have held in some instances; rather, they must be interpreted in harmony with one another. The Controller may also take into account whether a patentee has used anti-competitive tactics. However, the Controller would likewise proceed on the aforementioned premise and—on the theory similar to issue estoppel—the patentee would be prevented from asserting the opposite if Competition commission of India has ultimately determined that a patentee's behaviour was anti-competitive and its decision has achieved finality.[52]

The pharmaceutical sector in India is susceptible to three primary forms of competition problems: collusions, horizontal or vertical mergers and acquisitions, and abuse of dominant position. The first concern is with actions that may be considered collusions. Although this scenario has not yet arisen among Indian manufacturers, it is undeniable that such inclinations exist in some markets with few firms competing. It raises the cost of the medication and pushes many underprivileged people beyond its means. Second, unfair business tactics may be used in mergers and acquisitions. The Competition Act of 2002 allows for the scrutiny of mergers that go over a certain point. The third issue is the abuse of power. Since the pharmaceutical sector relies heavily on information, intellectual property grants businesses monopolistic position, which is sometimes misused at the expense of customers. Therefore, it is crucial to establish a balance between IPR and the Competition Act in order to advance the common interest. The Competition Act has a number of strict provisions that can be utilized to thwart anti-competitive tactics. Many businesses believe that the pricing can only be controlled via competition. As a result, it is critical to maintain the pharmaceutical industry's competitiveness for the benefit of customers.[53]

The success of a corporation will mostly depend on its R & D activities since scientific understanding rather than industrial expertise drives competition in the global pharmaceutical sector. As a result, R&D spending in the pharmaceutical sector is very high as a share of overall revenues; some estimates put it as high as 15%. The management of creative risks while attempting to obtain a competitive edge over competing businesses is one of the major problems in this sector.

Issues and Recommendations

According to the research above, the compulsory licensing system is now a standard component of patent laws and is also commonly used in other intellectual property rights. Such licenses have been heavily depended upon by developed nations to restrict exclusive rights and stop or address unfair practices in a number of fields. Recent legislative reforms in both industrialized and emerging nations demonstrate that the obligatory licensing system is not a relic of the past. According on the analysis above, a few problems may be found that can be fixed by adding or removing phases or amending the analysis.

Frequency of Resorting to Compulsory License

The primary goal of a compulsory license is to increase public access to pricey, proprietary medications. Because a drug's dominance on the market may result in a high price and consequent misuse of the patent, this also fosters market competition and lowers the cost of patented pharmaceuticals. The public always benefits from the competition for a medicine between several corporations. Competition will increase a product's supply, bringing down its price. The government may take action to reduce costs by capping the profit margin at a certain level. By doing these actions, the price of the medicine should be under control in the beginning stages and may not require a mandatory license in the future. This might safeguard the public's right to access to healthcare and medications. Therefore, the nations should make compulsory licensing a key component of their public health strategy. We can see this in the Annual Report 301 of the United States, where they have threatened to stop trading with the countries that are issuing compulsory licenses on their patents. However, if a country goes on a spree to grant compulsory licenses as a regular measure for abuse of IPRs and anti-competitive practices, then it may shrink the foreign direct investment of a country. Therefore, mandatory licensing must only be used in dire situations when there is no other option.[54]

Singular Approach for Granting Compulsory License

Compulsory licenses must consider the "bigger picture." Medicines need to be protected and regulated, and other types of protection including know-how, trade secrets, data, and market exclusivity are important. Since Compulsory Licenses only apply to patents and since there are other forms of

protection outside patents, they must be considered before being used.[55] The local manufacturer must have access to the necessary know-how, raw resources, infrastructure, scientific and technical skills to create the medicines in issue for a compulsory license to be successful. The granting of a compulsory license in the case of the COVID 19 vaccine may prevent local producers from effectively entering the market if there is insufficient transfer of technology and know-how.

Fair Patentee Hearing and Waiver

To be compliant with the TRIPS Agreement, compulsory license provisions under Indian law will need to be restricted and conditional. The government would only give such licenses based on the merits of each case after providing the patent holder with a fair opportunity to be heard. In the case of process patents, there will also be no distinction between local and imported goods, and the burden of proof will be with the party who infringes. Furthermore, obligatory licenses should not be seen as a permanent remedy for the problem because they were only meant as a temporary waiver for the sake of convenience. As a result, the moment the conditions under which the licenses were granted ceased to be valid, the implementation of the compulsory license must be revoked. Therefore, provision is not helpful for any company's long-term planning.

Reviewing Provisions of the Indian Patents Act, 1970

India will need to be aware of any potential dysfunctions that the new patent regime may have brought about as it acquires more experience with it. While the requirements for patentability (Article 3[d]) and compulsory licensing (Article 84) have been criticised by global corporations, some small businesses appear to have suffered due to uncertainty surrounding the validity of the patents obtained (Section 13 [4][56]). It would seem desirable to evaluate these critically. The concerns about complicated patenting processes appear to be widespread across different kinds of businesses. Admittedly, the nation is still in a learning period, and the State should be adaptable enough to adjust policies to reconcile the dual goals of encouraging innovation and offering cheap health care.[57]

Rights of Patentee

The public good and patentee rights should be balanced by the government. The frequent issuance of forced licenses may discourage the patent holder and hinder innovation. To enhance citizens' access to costly and life-saving medications, the government may boost healthcare spending and broaden the insurance coverage area. Increased government funding of research facilities will enable underdeveloped nations to become self-sufficient and increase medication production. Governments of affluent nations can take similar action to aid underdeveloped nations. The cost of a patented medicine can be negotiated and set in accordance with the national economy. By doing this, the patent holder will be able to benefit more from wealthy and advanced nations. It is possible to persuade patent owners to freely distribute medications to least developed nations.[58] Tax breaks and other rewards may be provided to the patent holder in exchange for decreasing the cost of patented medicines. A costly life-saving drug's patent may be purchased by the government from the patentee and then licensed at a discount to a nearby pharmaceutical firm for convenient public access. There should be development of groups for collective rights by the state. Although the aforementioned solutions would not completely eliminate the necessity for compulsory licensing, they might be effective in lessening the negative implications of this regulation.

Fair Remuneration

Although the TRIPS agreement grants governments broad preferences and latitude regarding the grounds on which a compulsory license is issued, it also protects the interests of the inventor by mandating the member countries to negotiate "reasonable commercial terms and conditions" with the innovator. This is often described as fair compensation. The TRIPS Agreement omits defining words like "appropriate payment" and "fair commercial terms." WTO Members are allowed to choose how to implement the TRIPS Agreement in accordance with their own legal framework and customs, and this freedom includes the standards they use to define what constitutes "fair" royalties or "sufficient" compensation.[59] FICCI has advised adding comprehensive reference and instruction materials to the Manual of Patent Practice and Procedures (MPPP). The learning material may take the shape of a pamphlet that explains the circumstances surrounding the granting of compulsory licenses by nations such as the United States, Canada, Japan, and others. [60]

Corporate Social Responsibility

The joint efforts of the government and pharmaceutical firms will aid in creating a healthcare fund that can be utilised to deliver medications and lessen the likelihood of patent infringement. Instead of supporting product patents, the Indian government should promote process patents. Drugs are sold at exorbitant rates as a result of product patents which result in market monopolies. Since the copyrighted items are not available for the benefit of the public health, product patents have frequently been accused of infringing a number of different human rights.[61]

Enhancing Research and Development

Pharmaceutical patent research and development grants the patent holder a certain amount of monopoly rights. A decrease in research and development activity results from inadequate compensation for costs paid during the creation of a new product by the patent holder. When a compulsory license is granted without the patent holder's consent, the government compensates the patent holder in the form of a royalty for the use of inventions covered by the patent. Due to their inefficiency in meeting the demands of their populations, developing and least developed nations must enhance their mandatory licensing systems. Additionally, patent-protected pharmaceuticals must pay royalties to patented pharmaceutical businesses while being granted compulsory license. Given that India is a developing country and in light of numerous significant rulings rendered by the Indian Supreme Court regarding the production of drugs at reasonable costs, the Indian government should support process patents rather than product patents, which can lead to monopoly conditions on the market and higher drug prices. A number of rights, including public health and access to medications, are violated when product patents are granted, which eventually infringes people's human rights.

Diminishing Royalty or No Royalty

A mandatory license for the production of the generic version of a patented medicine is given out in times of crisis, emergency, or urgent need when the drug is needed extensively and at a reasonable cost. Therefore, medicine ought to be affordable for the entire people. In times of crisis, emergency, or urgency, royalties should not be excessive since the general public would be forced to pay more for them. The elements that will determine the proportion of royalty are marketing, geographic location, product amount, time duration of licensing, market value of product, and percentage of customers. Due of their low sickness rates, high- and middle-income countries are required to pay large royalties for obligatory licenses. The government can start price-control measures or negotiate with pharmaceutical corporations to make breakthroughs more easily accessible. The Government of India might create a set of recommendations addressing the interpretation and practical use of compulsory licensing in order to lessen the uncertainty and frequent worries of pharmaceutical businesses. The government may make regulations allowing for the use of various royalty payment methods based on the requirements and urgency of the required pharmaceutical product either little or no royalties are involved.

COVID-19 Conundrum

The government might create a scientific formula that aids in the distribution of vaccines, taking advantage of the monopolistic control that already exists over vaccines. The formula would ensure that each state received an appropriate number of vaccinations by exerting monopolistic control over vaccine procurement and supply while taking population growth and case prevalence into account.[62] If the lack of a registered patent for the vaccinations prevents the government from granting patents, they may file a petition under Section 100 of the Patents Act to allow anybody to produce the vaccines for the benefit of the government. The government may establish bilateral pacts with nations that have the resources and expertise necessary to produce vaccinations in large quantities. In order to negotiate vaccination prices and offer the necessary vaccines to other nations, countries might create vaccine blocks. Encourage the idea of voluntary licensing, which might expand the vaccination supply.[63]

The Indian pharmaceutical market is dominated by the generics sector, which coexists with pharmaceutical innovators. However, there have been more examples of generic and innovator businesses having competing interests, and varied court rulings have repercussions for the pharmaceutical industry. When negotiating voluntary licensing with interested parties, patent owners should take the proper safety measures. To ensure more efficient medicine delivery and to satiate public demand, license agreements may be desired. In a similar vein, it is crucial for generic producers to thoroughly research compulsory licensing before submitting an application.

Way Forward

Compulsory licensing is a prominent tool for policymakers to look up to increase the production and distribution of drugs and medicines amidst the crisis. Compulsory license is a powerful public health tool for overcoming public health emergencies and situation of either expensive pricing and shortage of supply. The main aim of the compulsory license is to improve public access to patented expensive medicines. This also increases competition in the market and cuts down the price of patented drugs, because the dominance of a drug in the market may lead to higher prices and hence an abuse of patent may result. Countries should include compulsory licensing as an essential public health policy tool, to be resorted to only in extreme cases when there is no other way out.

It has been discussed, the specific circumstances in which the compulsory licensing is invoked. Though, it is an efficient mechanism previously adopted by various governments and even the Indian government, it has to be borne in mind about the limited advantage it offers. The invention of vaccine has surely created a new hope in combating the menace of virus but, its usage and distribution to large masses still remains a challenge. The adoption of radical government policy such as compulsory licensing may not be an ideal move given the limitations. Hence, the policy makers are required to devise a balancing policy which incentives the inventors and provide necessary health care to masses at large, by creating a suitable environment for intellectual property to thrive.

In India, as well as the rest of the globe, there has been an imbalance between profits and medicine availability. Since the historic *Bayer* v *Natco* decision, the Indian patent regime has altered dramatically. It was clear that the judicial approach protected the public interest and prevented pharmaceutical firms from abusing their position. Granting patent protection to drugs, particularly essential treatments, has always been a difficult task. In addition, the following rulings on this topic have generated confusion over the position of mandatory licensing standards in India. The inherent conflict between profit-driven pharmaceutical companies and welfare-oriented governments attempting to ensure less expensive access to essential medicines has frequently attracted global attention.

The TRIPS exception and current compulsory licensing restrictions are not mutually exclusive. Every nation has the right to decide the circumstances for issuing a forced license, and in non-emergency situations, a compulsory license can be a potent and possibly adequate instrument. In accordance with the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property, the patent office, ministry of health, or competition authorities should be allowed to grant a compulsory license. However, nations must do more to guarantee that intellectual property (IP) obstacles do not impede access to COVID-19-related medical technologies.

Faced with a global health catastrophe, such as the COVID-19 pandemic, in which pharmaceutical firms refuse to engage into worldwide, non-exclusive licensing, nations should investigate automated and accelerated solutions to overcome intellectual property (IP) obstacles. This should include suspending some duties under the TRIPS Agreement and trade agreements relating to the granting and enforcement of intellectual property rights on important health technology, materials, and products in order to facilitate the open sharing of health innovations for all. South Africa and India's proposal for a temporary TRIPS exception for COVID-19 presents an opportunity for nations to unify and give a crucial legal alternative for resolving IP monopolies during a pandemic. Nonetheless, seven months after the plan's introduction, a tiny number of nations continue to use delay tactics to obstruct the initiative. As the COVID-19 epidemic continues to flare over the globe, all countries should support the passage of this crucial proposal.[64]

The legal position on forced licensing is that the issuance of a compulsory license is predicated on the goal of striking a balance between the rights of the inventor and the public, and that the public interest is paramount in determining such a grant. In the current situation, where the pandemic has infected people from all socioeconomic classes, it is imperative that any medicine or vaccine created to treat COVID 19 be broadly available and reasonably priced. However, it must also be assured that a patentee that has spent a substantial amount of money producing a treatment or vaccine is fairly reimbursed for its efforts and hard work, so that it is not dissuaded from undertaking more research in the field. A balance between the two can be achieved if a patentee acts reasonably and enters into voluntary licenses that ensure widespread distribution of the patented drug or vaccine, thereby preventing the government from issuing a compulsory

license and removing the patentee's autonomy over pricing and license terms.[65]

The provision of forced licensing must be utilised prudently, since it represents an exception and a measure of flexibility to the general patent norm. The clause sits in the middle; neither complete patent protection is provided, nor is it refused entirely. It has a direct impact on innovation financing, and the unrestricted application of this provision may discourage multinational pharmaceutical corporations from introducing novel medications in other nations. If enterprises wish to shield their products from forced licensing, they must set the price of their patented module in accordance with the economic situation of the country. Now, compulsory licensing is the only chance for financially disadvantaged patients in developing nations. The economic state of the bulk of the population necessitates this service in India. The difficulty is that, on the one hand, it must conform with international patent protection rules and, on the other, it must preserve public health.

Patient versus patent is one of the most pressing issues in the contemporary healthcare system. Although India has only issued a single obligatory license to date, the number of such licenses awarded globally is on the rise. The undeveloped and emerging nations are in favour of passing obligatory licenses, whereas the developed nations and large pharmaceutical corporations are opposed. The primary reason large pharmaceutical corporations oppose mandatory licensing is because it is expensive and time-consuming to develop new treatments, and even then there is no guarantee of success. They must recover the expenditures associated with the innovation. If enterprises wish to shield their products from forced licensing, they must set the price of their patented module in accordance with the economic situation of the country.

Unanswered is possibly whether forced licensing is the most reasonable approach of making patented pharmaceuticals available to patients in sufficient quantity, at the appropriate time, and at an acceptable price. In order to get a creative, imaginative, and industrially applicable output that satisfies public demand within the required timescale, it is vital to strike a balance between boosting R&D and pricing structures. Due to the economic state of the bulk of its population, India has a distinct difficulty. On the one hand, it must closely adhere to international patent protection requirements, but on the other, it must preserve public health. We may today state that forced licensing is the last chance for financially constrained patients in developing nations, and it has become one of the most contentious issues in International Property law.

Conclusion

In the current world, mandatory licensing is a necessary evil that cannot be avoided. In the face of ever-increasing ailments, countries are in severe need of pharmaceuticals; nevertheless, this has also given rise to the importance of research and development in the pharmaceutical industry. Patents offer exclusive rights over inventions and illustrate the biblical idea that one will receive the fruits of his effort, but a balance must be struck between the rights of the patent holder and the giving of forced licensing. In the event of forced licensing, enough remuneration should be granted to the patent holder so that he or she is not dissuaded from investing hard work in ideas.

In the future, it is anticipated that there will be a significant conversation among all stakeholders regarding how the poor and needy might buy pharmaceuticals protected by product patents. In addition, it is anticipated that corporations with product patents would collaborate with Indian generic companies to develop a licensing structure that satisfies both parties. The government cannot abdicate its obligation to the poor, and it must recognise that the issuing of obligatory licenses cannot resolve all concerns pertaining to access to high-quality medications. Government is also obligated to collaborate with pharmaceutical corporations to design programmes that allow for discounted bulk purchasing of copyrighted medications.

References

1 India Brand Equity Foundation, “Pharmaceutical Industry Report”, *IBEF*, June 2022, *available at:* https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation (accessed on 25 November 2022).

2 The Patents Act, 1970 (Act No. 39 of 1970)

3 Bindusha H C, Intellectual property rights issues in Indian pharmaceutical industry” *Journal of Pharmaceutical Research International*, 33 (38B) (2021) 281.

4 IIPTA, Role Intellectual property rights in pharma business, *available at:* https://www.iipta.com/wp-content/uploads/2017/06/white-paper-.pdf (accessed on 25 November 2022).

5 Wikipedia contributors, “Compulsory license”, *Wikipedia*, August 22 2022, *available at:* https://en.wikipedia.org/wiki/Compulsory_license (accessed on November 25, 2022).

6 Acharya R & Tanna G, Compulsory licensing of patents in India, *les Nouvelles - Journal of the Licensing Executives Society,* 4 (2019) 296.

7 History of Indian Patent System, IPI India, *available at*: https://ipindia.gov.in/history-of-indian-patent-system.htm (accessed on 25 November 2022).

8 Prakash A, Sharma P, *et.al.*, Intellectual property rights and Indian pharmaceutical industry: Present scenario, *Indian Journal of Pharmocology,* 50 (2018) 57.

9 Onderkova H, Compulsory licensing in India and changes brought to it by the TRIPS Agreement, *European Commission,* 12 October 2021, *available at:* https://intellectual-property-helpdesk.ec.europa.eu/news-events/news/compulsory-licensing-india-and-changes-brought-it-trips-agreement-2021-10-12_en (accessed on 25 November 2022).

10 Kumari K & Sharma A, Doha Declaration: Compulsory Licensing and Access to Drugs, *Amity Journal of Healthcare Management* 3 (2) (2018) 43.

11 Compulsory Licensing in India- Global Reaction, Advantages, Disadvantages, *Lawnn*, April 18, 2018, *available at*: https://www.lawnn.com/compulsory-licensing/ (last visited on November 25, 2022)

12 Agarwal Y, Reddy S, *et.al.*, A STUDY ON COMPULSORY LICENSING IN THE TIME OF COVID-19, *The Law Brigade,* 6 (5) (2020) 141

13 Abbas M Z, Pros and cons of compulsory licensing: An analysis of arguments, *International Journal of Social Science and Humanites,* 3 (3) (2013) 254.

14 Ashar D J, Submission of special 301 review, *International Journal of Law Management & Humanitie,* 4 (3) (2021) 2259.

15 Mehta P S, Trips and pharmaceuticals: Implications for India, *Open Edition Journals* 95-104 (1998).

16 Urias E & Ramani S V, Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence, *Journal of International Business Policy,* 3 (2020) 367.

17 Acharya R K & Tanna G C, Compulsory Licensing of Patents in India, *les Nouvelles - Journal of the Licensing Executives Society,* 4 (2019) 297.

18 Parthasarthi V, Analysis of Compulsory Licensing in India and its Perceived Impact During the COVID Era, *GLS Law Journals,* 4 (2022) 21.

19 Gautam, Dasgupta S & Meghna, Compulsory licensing: India's maiden experience, ARTNeT Working Paper Series, No. 137, *Asia-Pacific Research and Training Network on Trade (ARTNeT),* 2013 7.

20 Shukla N, India: Compulsory licensing in India, *Mondaq*, 18 January 2019, *available at*: https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india (accessed on 24 November 2022).

21 Mukherjee A, Compulsory licenses under the Patents Act, *Law Circa*, 21 July 2020, *available at:* https://lawcirca.com/compulsory-licenses-under-the-patents-act/ (accessed on 25 November 2022).

22 Singh A, Intellectual property rights in pharmaceuticals, *Lawctopus*, 14 Feburary 2015, *available at:* https://www.lawctopus.com/academike/intellectual-property-rights-in-pharmaceuticals/ (accessed on 25 November 2022).

23 Commentary on Compulsory Licensing under The Patents Act, 1970, *IIPR*, 22 August 2020, *available at:*https://www.iiprd.com/commentary-on-compulsory-licensing-under-the-patents-act-1970/ (accessed on 25 November 2022).

24 Parthasarthi V, Analysis of compulsory licensing in india and its perceived impact during the COVID era" *GLS Law Journals* 4 (2022) 21.

25 Shah R, Compulsory license: India, *Kluwer Patent Blog* , 16 August 2021, *available at:* http://patentblog.kluweriplaw.com/2021/08/16/compulsory-license-india/ (accessed on visited on 25 November 2022).

26 (2008) 3 MLJ 599.

27 *Franz Xaver Huemer* v *New Yash Engineers*, AIR 1997 Delhi 79.

28 Mathur H, Compulsory licensing under Section 92A: Issues and concerns, *Journal of Intellectual Property Rights,* 13 (2008) 464.

29 Nair G G, Fernandes A, *et al.*, Landmark pharma patent jurisprudence in India, *Journal of Intellectual Property Rights,* 19 (2014) 79.

30 *Natco Pharma Ltd.* v *Bayer Corporation* [Compulsory License No. 1 of 2011]

31 Unni V K, Compulsory Licensing of Pharmaceutical Patents in India: Whether the Natco Decision Will Meet the Global Benchmarks?, *European Intellectual Property Review,* 37(5) (2015) 296.

32 Reuters Staff, "Roche gives up on India patent for breast cancer drug", *Reuters, 16 August 2013*, *available at:* https://www.reuters.com/article/us-roche-herceptin-india-idUKBRE97F08220130816 (accessed on 24 November 2022).

33 (CLA No. 1 of 2013 before the Controller of Patents, Mumbai)

34 Rajagopal D, Delhi High Court upholds BMS' patent for cancer drug Dasatinib, *Economic Times*, 6 July 2015 , *available at*: https://economictimes.indiatimes.com/ industry/healthcare/biotech/pharmaceuticals/delhi-high-court-upholds-bms-patent-for-cancer-drug-dasatinib/articleshow/47952559.cms (accessed on 22 November 2022).

35 Rohatgi H, Indian patent office rejects compulsory licensing application: *BDR Pharmaceuticals Pvt. Ltd*. V *Bristol Myers Squibb*, *K & K*, 13 November 2013, *available at*: https://www.khuranaandkhurana.com/2013/11/13/indian-patent-office-rejects-compulsory-licensing-application-bdr-pharmaceuticals-pvt-ltd-vs-bristol-myers-squibb/ (accessed on 24 November 2022).

36 Patent Office Branch Mumbai, "Indian Patent 270765 Formerly 1863/MUMNP/2009", *SpicyIP*, May 03, 2021, *available at:* https://spicyip.com/wp-content/uploads/2021/05/Natco-Baricitinib-CL-Application.pdf

37 Raghavendra A, India: Compulsory licensing in view of pandemic: Bajaj Healthcare requests for license to manufacture Baricitinib" , *Mondaq,* 02 February 2022, *available at:* https://www.mondaq.com/india/patent/ 1155308/compulsory-licensing-in-view-of-pandemic-bajaj-healthcare-requests-for-license-to-manufacture-baricitinib (accessed on 24 November 2022).

38 Nacto Pharma Limited, The power of tenacity, Annual Report 2020-21, *available at:* https://www.natcopharma.co.in/wp-content/uploads/2021/09/NATCO-Pharma-AR-2020-21.pdf.

39 Musyuni P, "Compulsory licensing: Law, challenges and strategies", *Lex Orbis*, 8 March 2017, *available at:*

https://www.lexology.com/library/detail.aspx?g=8efb1c00-65cd-4d66-8925-5ece8f8f2551(accessed on 24 November 2022).

40 Luthra A S, Politics, pharma, patent, profit or the people of India? A case for compulsory licensing", *Bar and Bench*, 1 May 2021, *available at:* https://www.barandbench.com/columns/patents-COVID-19-drugs-case-for-compulsory-licensing (accessed on 24 November 2022).

41 Wong H, The case for compulsory licensing during COVID-19, *Journal of Global Helath*, 10 (1) (2020).

42 Parliamentary standing committee of commerce, 161th Report on review of intellectual property rights regime in India, July 2021.

43 [Civil No 3/2021] LL 2021 SC 236.

44 W.P.(C) 5173/2021.

45 Froman M B G, Special 301 Report, Office of The United States Trade Representative", April 2015, available at https://ustr.gov/sites/default/ files/2015-Special-301-Report-FINAL.pdf (accessed on 15 February 2015).

46 Council for trade-related aspects of intellectual property rights, Waiver from certain provisions of the trips agreement for the prevention, containment and treatment of covid-19 revised decision text, IP/C/W/669/Rev.1 *WTO* (accessed on 25 May 2021).

47 Devarakonda R K, TRIPS waiver: How India Abandoned its Own WTO Proposal, *The Wire* , 15 June 2022, *available at:* https://thewire.in/health/trips-waiver-how-india-abandoned-its-own-wto-proposal (accessed on 24 November 2022).

48 Khureja K, COVID-19 vaccine and TRIPS IP waiver – Explained, pointwise, *Forum IAS* , April 05 2022, *available at :* https://blog.forumias.com/COVID-19-vaccine-and-trips-ip-waiver/ (accessed on November 24, 2022)

49 Ministerial Conference Twelfth Session Geneva, Draft Ministerial Decision On The Trips Agreement Revision, WT/MIN(22)/W/15/Rev.2, *WTO* (accessed on 17 June 2022).

50 Council for Trade-Related Aspects of Intellectual Property Rights, Annual Review Of The Special Compulsory Licensing System, Report To The General Council, IP/C/94, *WTO* (accessed on 22 November 2022).

51 Directorate for Financial and Enterprise Affairs Competition Committee, Licensing of IP rights and competition law – Note by India, *OECD*, 6 June 2019, *available at:* https://one.oecd.org/document/DAF/COMP/WD(2019)4/en/pdf (accessed on 25 November 2022).

52 *Koninklijke Philips Electronics N.V.* v *Rajesh Bansal and Ors. MANU/DE/2436/2018*

53 Singh A, Intellectual property rights in pharmaceuticals, *Lawctopus*, 14 February 2015, *available at:* https://www.lawctopus.com/academike/intellectual-property-rights-in-pharmaceuticals/ (accessed on 25 November 2022).

54 Kaur A & Chaturvedi R, Compulsory licensing of drugs and pharmaceuticals: Issues and dilemma, *Journal of Intellectual Property Rights* 20 (2015) 279.

55 Lath A, Compulsory licensing for expensive medicines: KCE report , SpicyIP, 22 June 2022, available at : https://spicyip.com/2022/06/compulsory-licensing-for-expensive-medicines-kce-report.html (accessed on 25 November 2022).

56 S 13(4), The examination and investigations required under section 12 and this section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.

57 Basant R & Srinivasan S, "Intellectual property protection in India and implications for health innovation: emerging perspectives" *Dove Press Journal: Innovation and Entrepreneurship in Health,* 3 (2016) 57.

58 Carlos M. Correa, "Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries" Trade-related Agenda, Development and Equity (T.R.A.D.E.)" , October 1999, available at: https://www.iatp.org/sites/default/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf

59 Monika Shailesh, "Fair Remuneration For Compulsory Licensing" *Mondaq* , August 03 2017, *available at:* https://www.mondaq.com/india/patent/616430/fair-remuneration-for-compulsory-licensing (last visited on November 25, 2022).

60 FICCI IPR Division, "FICCI"s Position on Compulsory Licensing" *FICCI*, 2021, *available at:* http://ficci.in/SEdocument/20143/Compulsary-Licensing.pdf (accessed on 25 November 2022).

61 FICCI, "Submission of Special 301 Review", FICCI 15-19 (2018) *available at:* https://ficci.in/sector/24/add_Docs/FICCI_2018-Special-301_Review_Comment.pdf

62 Swamy R N, Compulsory licensing of drugs and vaccines in the backdrop of the pandemic: Pros and Cons, *Lex Forti Legal Network*, 14 July 2021, *available at*: https://lexforti.com/legal-news/compulsory-licensing-of-drugs-and-vaccines-in-the-backdrop-of-the-pandemic-pros-and-cons/ (accessed on 24 November 2022).

63 Tahir Amin and Aaron S. Kesselheim, "A Global Intellectual Property Waiver is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness" *INQUIRY* (2022).

64 MSF Briefing Document, Compulsory licenses, the trips waiver and access to covid-19 medical technologies, *Acces Campaign*, May 2021, *available at:* https://msfaccess.org/sites/ default/files/2021-05/COVID_TechBrief_MSF_AC_ IP_ Compulsory Licenses TRIPSWaiver_ENG_21May2021_0.pdf (accessed on 24 November 2022).

65 Khaitan & Co, Compulsory licensing amidst the COVID-19 Pandemic, *Lexology*, July 16, 2020, *available at:* https://www.lexology.com/library/detail.aspx?g=253ff273-55fb-46cf-9331-04d632ac055e (accessed on 25 November 2022).