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Patent Law and Compulsory Licensing: Indian Perspective

Abhinav Gupta[1] and Aqa Raza[2†]

[1]Dr. Ambedkar Government Law College, Kalapet — 605 014, Puducherry, India

[2]Jindal Global Law School, O.P. Jindal Global University, Sonipat — 131 001, Haryana, India

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This Paper seeks to critically analyze and evaluate the concept of compulsory licensing under the Indian Patents and Designs Act, 1911, and the Patents Act, 1970. The Paper further: (i) traces its evolution from the French Patent Law of 1791 to the amendment of the TRIPS Agreement in 2017 that introduced Article 31*bis*; (ii) analyzes the detailed procedure and consideration for the grant of compulsory license in India; and (iii) in the light of *Natco*v *Bayer* decision, discusses the rejection of the compulsory license applications on the grounds of procedural non-compliance. In the end, paper develops an argument that the provisions relating to compulsory license under the Indian patent regulatory framework have remained a *dead letter* during COVID-19 pandemic at the cost of public health and welfare.

Keywords: Patent, Compulsory License, TRIPS, Article 31*bis*, Conventions, Doha Declaration, Labour Theory, Utilitarian Theory, The Patents and Designs Act, 1911,Bakshi Tek Chand Committee, N Rajagopa Ayyangar Committee, The Patents Act, 1970, Controller of Patents, IPAB, *Natco*v *Bayer*, Supreme Court of India, COVID-19, India

Intellectual Property (*hereinafter*, IP) is a product of human intellect and creativity, which has commercial value and can also be described as '*knowledge goods*'.[1] IP were initially kept secret by the inventors and authors to prevent others from exploitation. It forced the State to provide state-sanctioned protection to the inventors and authors with an exclusive right to use, sell, gift, license, or assign their IP. However, such State-sanctioned protection to the inventors and authors was provided on the condition of '*quid pro quo*', *i.e.,* the inventors and authors shall disclose their IP to society and work their IP in the interest of society. Thus, the State-sanctioned monopoly rights to the inventors/authors of IP are a societal bargain between the inventor/author and society. This societal bargain ensures that social progress is not stalled due to the non-disclosure of IP. At the same time, reward the inventors and authors for their creative efforts to develop Intellectual Property and provide legal recognition of their rights. IP are intangible assets categorized into Industrial Property and Copyright. The Industrial Intellectual Property would include patent, trademark, trade secret and industrial design.

Whereas, Copyright shall comprise literary and artistic work. However, like any other tangible asset, IP could also be transferred by the inventor and author to another person by sale, mortgage, gift, or license.

For the first time, multilateral efforts to protect IP were in the form of the Paris Convention for the Protection of Industrial Property (1883), which limited itself to protecting the Industrial Intellectual Property. After three years, the Berne Convention for the Protection of Literary and Artistic Works (1886) was concluded, extending Copyright protection to literary and artistic works. The Paris Convention and the Berne Convention established the International Bureaus to facilitate the effective implementation of the Conventions, which were amalgamated in 1891 to establish a common International Bureau. The joint International Bureau was replaced by a UN body, *i.e.*, World Intellectual Property Organization (WIPO) in 1970, established under the WIPO Convention (1967). The primary function of WIPO was to facilitate global cooperation for policy formulation and establishment of an effective and balanced international Intellectual Property System. WIPO was succeeded by the Trade-Related aspects of Intellectual Property Rights (*hereinafter*, TRIPS) Agreement, which came into effect on 1 January 1995. The World Trade Organization (WTO) regulates the TRIPS Agreement. The TRIPS Agreement is considered to be the most comprehensive multilateral agreement regulating IP at the global level.

†Corresponding author. Email: aqaraza@outlook.com

During the COVID-19 pandemic, in the context of the global public health emergency, India and South Africa on 2 October 2020, proposed to the Council for Trade-Related Aspects of Intellectual Property Rights to recommend the WTO General Council to waive the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement dealing with prevention, containment or treatment of COVID-19. The objective of the proposal was to ensure an effective global response to the COVID-19 pandemic by facilitating access to pharmaceutical and medical products, especially to developing and least-developed countries, in light of Article 31*bis* of the TRIPS Agreement.[2] In the light of the above, paper critically analyze the relevance and requirement of compulsory licensing under the Indian patent law.

For convenience, Paper has been further divided into seven parts. Part II shall elaborate on the relevance of patent law and justification for a compulsory license. Part III shall discuss the origin of compulsory license and the evolution of the regulatory framework from the Paris Convention till the Doha Declaration in 2001. Part IV shall deliberate on the regulatory framework relating to compulsory licensing in India. Part V shall enumerate a detailed procedure for the grant of compulsory license in India. Part VI shall review the first compulsory license case, *i.e., Natco Pharma* v *Bayer Corporation*,[3] in detail and compare it with other Indian cases dealing with compulsory licensing. Part VII shall conclude and suggest alternatives available under the Patents Act, 1970, to deal with extraordinary circumstances like COVID-19 pandemic.

Patent: Tool of Social Progression

The patent is an IP which protects the rights of an inventor with respect to patentable subject matter, *i.e.*, a new product or process, which fulfils the requirement of '*novelty*', '*inventive step*' and '*industrial use*'. The State-sanctioned protection provided to the inventor is for a limited period, *i.e.,* 20 years. After the protection period, the invention becomes generic, and anyone can use such an invention. Therefore, the patent system is carefully crafted to reward the inventor for her intellectual efforts and contribution to scientific research and societal development. The protection provided to the inventor includes exclusive rights of "*making, using, offering for sale, selling and importing of the invented product*" or "*using, offering for sale, selling and importing of the invented process*". However, from its very nature, the monopoly right is not absolute, and the inventor has an obligation to disclose her invention to enrich the existing knowledge in the public domain.

The object of the patent law is to encourage technological innovation, promote scientific research, develop new technology and support industrial progress. Adequate protection for inventions will prompt the inventor to disclose her invention to the public rather than keep such an invention a trade secret. Such disclosure will ensure the effective dissemination of such technology and facilitate further research and innovation. It will also induce capital investment in research and development to produce new technologies, products and processes that promote the social and economic welfare of the State. Thus, the patent law fosters the balancing of rights and obligations of an inventor *vis-à-vis* society.

The Labour Theory by John Lock also supports incentivizing human labour. Therefore, patent protection rewards the inventor for her creative efforts by facilitating monopoly rights to exploit the invention commercially for a limited period. Bentham's Utilitarian Theory also backs the idea of protecting the inventor's rights, as it would encourage others to undertake scientific research and develop new products and processes.[4] In this context, Isaac Newton said, "*I have been able to see further than others is because I stood on the shoulders of giants*".[1] Thus, the patent law is seen as a tool of social progress as it balances the economic interests of the inventor against the socio-economic well-being of the Society.

As a result, all the exclusive rights conferred on the inventor are not without duties. Instead, an inventor can enjoy her privileges only if she fulfils her commitments to society. In consideration for her monopoly rights, an inventor shall promise that:

(i) The patented inventions shall be worked in the country for social progress;

(ii) The patented inventions shall be made available in adequate quantities to the public; and

(iii) The patented inventions shall be made available to the public at a reasonable price.

Suppose the inventor breaks her promise or refuses to fulfil her commitments under the patent law. In that case, the State shall have the right to withdraw privileges of monopoly rights and grant a compulsory

license. In extreme cases, the State may even revoke the patent protection granted to the inventor for her invention.

Origin of Compulsory Licensing

The compulsory license under the patent system is an involuntary contract between a willing licensee and an unwilling patentee (licensor) imposed and enforced by the State.[3] Therefore, compulsory licensing refers to the authorization given by the State to an individual for commercial exploitation of a patented invention without a voluntary license from the inventor in exceptional circumstances, as enumerated in the patent law. Compulsory licensing is not a new concept, and its origin can be traced back to the French Patent Law of 1791. The most striking feature of the French compulsory working system was the invalidation of the patent if the patent holder failed to work on the invention within two years of the grant of the patent without any justification.[5] The concept of compulsory license has existed in Great Britain since the 1830s and had been prevalent in Great Britain as early as the 1850s.[5]

However, the international community recognized compulsory licensing to prevent the abuse of patent protection by the inventor through the Paris Convention for the Protection of Industrial Property (1883). The concept of compulsory licensefor the first time found a reference in an international instrument in the form of "*Article 5 Part-A: Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses*" of the Paris Convention for the Protection of Industrial Property (1883). Article 5 Part-A(2) of the Paris Convention empowers the Legislature of the contracting parties to make provisions for compulsory licensing to prevent abuse (like failure to work patent) of exclusive rights by the inventor conferred by the respective patent laws. Article 5 Part-A(3) of the Paris Convention also enables the contracting parties to revoke or forfeit the patent in exceptional circumstances where granting the compulsory license would be insufficient. Although the Paris Convention provided for compulsory licensing, it did not elaborate on the circumstances under which such compulsory license may be granted and did not lay down any guidelines or principles for the grant of compulsory license. However, Article 5 Part-A(4) of the Paris Convention states that failure to work or insufficient working of the patent without any legitimate justification could be grounds for the compulsory license. The Paris Convention also clarified under Article 5 Part-A(1) that importation of the patented invention, which does not amount to an abuse of the patent, by the patent holder into the country where the patent has been granted would not entail revocation or forfeiture of the patent.[6]

The TRIPS Agreement came into force on 1 January 1995. The Preamble of the TRIPS Agreement recognized the public policy objective of member states to protect Intellectual Property, including developmental and technological objectives.[7] Article 7 of the TRIPS Agreement states that the objective of the TRIPS Agreement is to protect and promote Intellectual Property and, at the same time, encourage innovation and technology transfer to further social and economic welfare. The principles of the TRIPS Agreement are enumerated under Article 8, which empower the member states to prevent the abuse of Intellectual Property Rights by patent holder without compromising the international trade or transfer of technology.

According to Article 2 of the TRIPS Agreement, Section 5 of Part II of the TRIPS Agreement deals with '*Patents*', which is to be read in the light of the Paris Agreement. Article 27 of the TRIPS Agreement deals with the '*patentable subject matter*' and prohibits discrimination on whether patented products are locally manufactured or imported. Article 28 of the TRIPS Agreement provides for the rights conferred on the patent holder, which is qualified by the exception of Article 30 and Article 31 of the TRIPS Agreement. Article 31 of the TRIPS Agreement lays down that a member state may permit the use of the patent, *i.e.,* compulsory license, by the Government or the third party. Thus, Article 31 of the TRIPS Agreement provides for justified differential treatment for the use of patented inventions without the voluntary authorization of the patent holder. However, such differential treatment by a member state under Article 31 of TRIPS has to satisfy the Three-Step Test as elaborated under Article 30 of TRIPS, which is as follows:

Step 1: The exception must be "*limited*".

Step 2: The exception must not "*unreasonably conflict with normal commercial exploitation by the inventor of the patented invention*".

Step 3: The exception must not "*unreasonably prejudice the legitimate interest of the patent owner but at the same time must also take into account, the legitimate interest of third parties*".

Thus, in light of the Three-Step Test provided under Article 30 of TRIPS, compulsory licensing could be granted by taking into consideration clause (a) to clause (l) of Article 31 of the TRIPS Agreement.

The TRIPS Agreement was supplemented by the "*Doha Declaration on TRIPS and Public Health*" on 14 November 2001, which was meant to fulfill the goal "*to promote access of medicines for all*". Clause 4 of the Doha Declaration provided that the TRIPS Agreements should not prevent member states from protecting public health and promoting access to medicine for all.[8] Further, Clause 5 of the Doha Declaration provides flexibility to member states, including the right to grant compulsory license and determine the grounds upon which compulsory license is to be granted.[8]

Article 31 (f) of the TRIPS Agreement allows the compulsory license of patented products to supply such patents to the domestic market only. However, after the Doha Declaration, the members of the WTO, on 30 August 2003, agreed to temporarily waive the strict requirement of a compulsory license for the production and export of pharmaceutical products under Article 31 (f) of the TRIPS Agreement.[9] On 6 December 2005, the WTO unanimously adopted the Protocol for amending the TRIPS Agreement to replace the temporary waiver, which was in force since 30 August 2003.[10] Thus, the temporary mechanism was made permanent, allowing poorer WTO Countries to access generic medicines at affordable prices produced in other countries. The decision regarding "*patented drugs and public health*" was based on the principle that the rules of the global trading system shall keep in mind the public health needs of people in developing and emerging countries, especially those with inadequate or no manufacturing capabilities.[11]

The Protocol of 2005 was replaced by the amendment to the TRIPS Agreement on 23 January 2017, by inserting Article 31*bis* to the TRIPS Agreement, which permitted the grant of compulsory licenses to the generic drug makers to manufacture and export pharmaceutical products to countries that lack manufacturing capabilities.[12]

Compulsory License in India

The first patent legislation in India was the Act VI of 1856. However, the Indian Patents and Designs Act, 1911 (Act II of 1911) replaced all the previous Acts. For the first time, the Indian Patents and Designs Act, 1911 established a patent administration system under the Controller of Patents.[13] Section 22 (1) of the Indian Patents and Designs Act, 1911 provided for the grant of compulsory licensing on the ground of the reasonable requirement of the public not being satisfied. However, after the independence, it was felt that the Indian Patents and Designs Act, 1911, did not fulfill the requirement of India due to substantial changes in the political and social conditions in the country.Therefore, a committee under the chairmanship of Justice (Dr.) Bakshi Tek Chand was established on 1 October 1948, to review the patent laws in India.[14] In its interim report dated 4 August 1949, the committee suggested changes to the various provision of the Indian Patents and Designs Act, 1911, including Section 22 dealing with compulsory licensing and revocation to prevent abuse of patents in India. Accordingly, the Government of India amended the Indian Patents and Design Acts, 1911 in 1950 by Act XXXII of 1950. The Justice (Dr.) Bakshi Tek Chand Committee submitted its final report in late April 1950. The Indian Patents and Design Acts, 1911 was amended again by Act LXX of 1952 to provide compulsory license with respect to food, medicines, insecticide, germicide or fungicide and the process for producing substance or any invention relating to surgical or curative devices.[13] Based on the Justice (Dr.) Bakshi Tek Chand Committee, Bill No. 59 of 1953 was introduced in Parliament to replace the Indian Patents and Designs Act, 1911; however, the bill lapsed.

In 1957, the Government of India appointed the Justice N RajagopalaAyyangar Committee to examine the patent law in India and suggest changes accordingly. The Justice N RajagopalaAyyangar Committee submitted its report in September 1959. Consequently, the Patent Bill, 1965, was introduced in Lok Sabha on 21 September 1965, which lapsed. In 1967, an amendment bill was introduced and resulted in the Patents Act, 1970, replacing the Patent and Designs Act 1911, as far as patent law was concerned.[13]

The Patents Act, 1970, came into effect on 20 August 1970, and continued to provide compulsory license, as in the Indian Patent and Designs Act, 1911, under Chapter XVI titled *'Working of Patents, Compulsory Licences, Licences of Right and Revocation'*. India became a signatory of the TRIPS Agreement and, being a developing country, was required to comply with the TRIPS obligation by 1

January 2005. Consequently, the Patents Act, 1970 was amended thrice in 1999, 2002 and finally in 2005. The Patent (Amendment) Act, 2002, wholly substituted Chapter XVI of the Patents Act, 1970, which now reads as "*Working of Patents, Compulsory Licenses and Revocation*". The Patent (Amendment) Act, 2005, permitted the product patent for pharmaceutical drugs, which was earlier not permitted under the Patents Act, 1970.[3]

The compulsory licensing provisions under Chapter XVI of the Patents Act, 1970, which could have been employed by India to deal with the extraordinary situation of COVID-19, especially relating to pharmaceutical drugs and medical/curative equipment, are as follows:

1. *Compulsory Licensing in the case of abuse of patent rights by the inventor or patent holder under Section 84*: Section 84 of the Patents Act, 1970 is in accordance with the exception to patent rights under Article 30 of the TRIPS Agreement. Any interested person, upon expiry of three years from the grant of the patent, may apply for the compulsory license on any of the following three grounds:

(a) Section 84 (1) (a): The reasonable requirements of the public are not satisfied. The cases in which the reasonable requirements of the public shall be deemed not satisfied have been elaborated under Section 84 (7) of the Patents Act, 1970; or

(b) Section 84 (1) (b): The patented invention is not available to the public at a reasonable and affordable price. The cases in which the patented invention is not available to the public at reasonable prices is to be determined by the Controller/Courts based on facts and circumstances of the case; or

(c) Section 84 (1) (c): The patented invention is not worked within the territory of India. The cases in which the patented invention is not worked within the territory of India are to be looked through the prism of clauses (a), (b), (c) and (f) of Section 83 of the Patents Act, 1970.

2. *Compulsory Licensing in the interest of the Public under Section 92*: Section 92 of the Patents Act 1970 complies with Article 31(b) of the TRIPS Agreement. If the Central Government is satisfied that it is prudent and necessary to grant a compulsory license in respect of any patent, including pharmaceutical drugs and medical/curative equipment, then the Central Government may, by notification in the official Gazette, grant a Compulsory License for working such a patent on any of the following grounds:

(a) In the situation of National Emergency, as was the situation in the case of the COVID-19 pandemic, public health crisis; or

(b) In the situation of extreme urgency; or

(c) In the case of non-commercial public use.

3. *Compulsory Licensing for the export of patented pharmaceutical products under Section 92-A*: Section 92-A was inserted by the Patent (Amendment) Act, 2005, to comply with Article 31*bis* of the TRIPS Agreement. Compulsory licensing under Section 92-A shall be available for manufacturing and exporting patented pharmaceutical products or medical equipment to developing and least developed countries with insufficient or no manufacturing capacity in the pharmaceutical sector. However, such a compulsory license under Section 92-A can be granted for manufacturing and exporting pharmaceutical products and not for domestic use.

The compulsory licensing provisions under Chapter XVI of the Patents Act, 1970, comply with the prerequisites specified in the Three-Step Test of Article 30 of the TRIPs Agreement.

Step 1: The exception must be "*limited*". The grounds for the grant of the compulsory license under Chapter XVI of the Patents Act, 1970, are limited and aimed at preventing the abuse of patent rights by the patent holder. Under Section 84 (1), the grounds are non-satisfaction of reasonable requirements; affordable price of the patented invention for the public; or non-working of the patented invention in India. Similarly, under Section 92 (1), the grounds are a national emergency; or situation of extreme urgency; or non-commercial public use. Even under Section 92-A, the compulsory license could be granted for the manufacture and export of pharmaceutical products and not for domestic use, which is in compliance with Article 31*bis* of the TRIPS.

Step 2: The exception must not "*unreasonably conflict with the normal commercial exploitation by the inventor of the patented invention*". The provision for the grant of the compulsory license under Chapter XVI of the Patents Act, 1970, is accompanied by reasonable royalty or adequate remunerations, and other necessary conditions as may be imposed by the Controller, as per Section 90 (Terms and conditions of compulsory licenses) of the Patents Act, 1970.

Step 3: The exception must not "*unreasonably prejudice the legitimate interest of the patent owner but at the same time must also take into account, the*

legitimate interest of third parties": The compulsory license can be granted after an application is filed. This application can only be filed after three years from the grant of the patent and only when any of the three grounds of Section 84 (1) are fulfilled. Thus, it balances the patentee's rights and the rights of society (third party). Additionally, under Section 92, the compulsory license shall be granted only when extraordinary situations, as discussed above exist. In such exceptional circumstances, the Controller shall settle terms and conditions consistent with the patent holder's right to derive a reasonable commercial advantage from her patented invention. Finally, under Section 92-A, the Controller shall grant the compulsory license on such terms and conditions that do not prejudice the commercial rights of the patent holder.

Other provisions under the Patents Act, 1970, to prevent the abuse/misuse of the patent and to deal with extraordinary situations like the COVID-19 pandemic, especially with respect to pharmaceutical drugs and medical/curative equipment, are as follows:

1. As per Section 47 of the Patents Act, 1970, any patent granted to medicine/drug in India shall be subject to the authority of the Government to import such patented medicine/drug for its use or distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government. Section 47 is to be interpreted in light of Para 4 of the Doha Declaration (2001).[8]

2. Under Section 64 (4) of the Patents Act, 1970, High Court may revoke the patent on a petition from the Government if the patent holder fails to comply with the request of the Central Government to make, use or exercise the patented invention for the '*purposes of Government*' as defined under Section 99 of the Patents Act, 1970.

3. The Central Government may revoke the patent in the public interest under Section 66 of the Patents Act, 1970, by a declaration in the Official Gazette if the Central Government is of the opinion that the patent is prejudicial to the public interest. On 9 April 2020, the Cancer Patients Aid Association wrote to the Health Secretary, Government of India and the Minister of Chemical and Pharmaceuticals to revoke the patent granted to Gilead Sciences Inc. for Remdesivir, which was a potential cure for COVID-19 infection under Section 66 and 64(1) of the Patents Act, 1970,[15]

4. Under Section 100 (1), the Central Government may use the patented invention for the '*purposes of Government*' as defined under Section 99 and in accordance with the provision of Chapter XVII of the Patents Act, 1970.

5. As per Section 102 (1), if the Central Government is satisfied, it must acquire the patent or invention in the public's interest. Through a notification in the Official Gazette, the Central Government may transfer to itself the invention or patent and all rights attached to such invention or patent.

Thus, the Patents Act, 1970, is equipped with relevant provisions to empower the Government to take appropriate steps to grant the compulsory license or use the patent/invention by the Government without authorization from the patent holder. However, when relevant technology and prerequisite raw materials are unavailable in India, as in the case of COVID-19 drugs, vaccines and other medical/curative equipment. Then international cooperation at the World Trade Organization (WTO) level is imminent to deal with extraordinary situations like COVID-19 and for a rapid response to restrict the grave impact of COVID-19, especially in developing and least-developed nations. On 2 October 2020, India and South Africa jointly proposed a waiver of the TRIPS Agreement to prevent, contain, and treat COVID-19 infection.[2] On 17 June 2022, the Twelfth Session of the Ministerial Conference of the WTO in the exceptional circumstances of the COVID-19 pandemic adopted to waive the patent protection for the production and supply of the COVID-19 vaccines as per Article 31 of the TRIPS Agreement for five years from the date of decision.[16] It was also agreed that within 6 months of the decision, the extension of waiver to cover the production and supply of COVID-19 diagnostics and therapeutics shall also be decided.[16]

Process of Compulsory License in India

Once a patent application is filed for the invention by the inventor under Section 7 of the Patents Act, 1970, and the patent is granted for such invention to the patent holder under Section 43 of the Patents Act, 1970. The patent holder can exercise exclusive patent rights under Section 48 of the Patents Act, 1970. However, if the patentee misuses/abuses the patent, any interested person, including the licensee,[17] could apply for the compulsory license under Section 84(1) of the Patents Act, 1970, read with Rule 96 of the Patent Rules, 2003. Form 17 of the Patent Rules, 2003, provides the format for the application of compulsory

license, which must be enclosed with certified copies of documents to back the applicant's claims. Additionally, as per Section 84 (3) read with Rule 96 of the Patent Rules, 2003, the application must also state the nature of the applicant's interest and the terms and conditions that the applicant is willing to accept. The application for the compulsory license can be filed on any one of the three grounds given under sub-clause (a), (b), and (c) of Section 84 (1) of the Patents Act, 1970, as the sub-clauses are separated by the disjunctive '*or*'.[18] The application for the compulsory license to the Controller for consideration has to satisfy the following two pre-requirements/conditions:[1]

1. As per Section 84 (1), the application for the compulsory license has been made after the expiration of three years from the date of the grant of the patent.
2. According to Section 84 (6) (iv), the applicant must have made an effort to obtain the voluntary license from the patent holder on reasonable terms and conditions within a reasonable period. However, the law does not require the applicant to make a second request when the earlier effort had failed.[18] A patent holder would try and prolong the process of mutual deliberation by raising unnecessary queries. However, the patent holder is entitled to satisfy herself with respect to the credentials and capacity of the applicant and finalize the terms and conditions of the voluntary license. The applicant has the right to highlight before the Controller that the patent holder, under the guise of the queries, is trying to extract confidential and private information, which may be detrimental to the applicant. Additionally, the applicant may also raise the issue that the patent holder is simply raising the queries without accepting or rejecting the application for the voluntary license is a pre-mediated and well-planned strategy to frustrate the efforts of the applicant to obtain the compulsory license. Nonetheless, the legislative intent behind inserting the explanation to Section 84 (6) (iv) clarifies that the reasonable period to engage in dialogue for the voluntary license on reasonable terms and conditions was not to be construed ordinarily exceeding more than six months. Nonetheless, if the applicant does not take any further steps under a preconceived notion that the patentee was engaging in delay tactics, then the very purpose of Section 84 (6) (iv) would be defeated.[19]

It is only upon the satisfaction of the above two pre-conditions, the Controller may consider the application for compulsory license on non-fulfilment of any of the following three grounds as laid down under Section 84 (1) of the Patents Act, 1970:

1. Satisfaction of reasonable requirement of the public under Section 84 (1) (a): The reasonable requirement of the public has to be looked at from the prism of Section 84 (7) of the Patents Act, 1970. The reasonable requirement of public with respect to pharmaceutical drug or medical/curative equipment is to be considered in the context of the number of patients requiring the patented pharmaceutical drug or medical/curative equipment. The adequate extent test may vary from article to article. However, for pharmaceutical drugs or medical/curative equipment, it has to be 100%, *i.e.,* to the fullest extent. It is in accord with the Doha Declaration (2001) to ensure medicines for all. The obligation for fulfilling the reasonable requirement of the public is that of the patent holder alone, either by itself or through its licensee. Therefore, the patent holder cannot take into consideration the actions of a third party, especially whose presence itself is litigious and not included in Form 27 by the patentee, for the fulfilment of the patent holder's obligation under Section 84 (1) (a).[1]
2. Availability of patented invention to the public at a reasonably affordable price under Section 84 (1) (b): The reasonably affordable price is a notional price and must be determined from the facts and circumstances on a case-to-case basis. The reasonably affordable price has to be construed predominantly from the viewpoint of the public and not with reference to the inventor/patentee. The Controller must determine the reasonably affordable price by considering all factors, including socio-economic condition, nature of the product, expenditure incurred by the inventor/patentee, classification as an '*orphan drug*',[20] etc. However, the Controller is not conferred with any power to direct investigation to determine the reasonably affordable price of the patented invention. Therefore, the Controller must determine the same based on the evidence led by the parties before it. Additionally, the initiatives like dual pricing, such as the Patient Assistance Program (PAP), would fulfil the reasonable requirement of the public under Section 84 (1) (a). However, it fails to satisfy the requirement under Section 84 (1) (b) as it fails to make available the patented drug at a reasonably affordable price to every member of the public ready to tender the price.[1]
3. Working of the patented invention in India: The word '*worked in India*' has to be decided on a

case-to-case basis and interpreted in light of Section 83, which contains the legislative guidelines to govern the meaning of '*working of patented invention*'. Section 83 (b) says that the patents are not granted merely to enable the patent holder to enjoy a monopoly for importing patented products. Section 83 (c) refers to the transfer and dissemination of technological knowledge. Section 83(f) provides that the patentee shall not abuse the patent rights to impact international trade. In light of Article 27 of the TRIPS Agreement, the word '*working*' has a flexible meaning. Therefore, '*working*' could mean local manufacturing entirely, and in some cases, it could mean only importation. It depends on the facts and circumstances of each case, and it is for the patentee to show why it is impossible/prohibitive to manufacture the patented invention in India. A mere statement of inability to locally manufacture patented invention is insufficient, but the assertion must be backed by evidence. However, when the patentee satisfies the Controller of the reasons for not manufacturing in India, the patented invention shall be deemed to be worked in India even by import.[18]

Thus, the Controller has to consider the requirement of the public, purchasing capacity of the public and the working of the patented invention on a commercial scale in India before granting the application for the compulsory license under Section 84 of the Patents Act, 1970. While considering the application for the license, the Controller is also mandated under Section 84(6) to take into consideration the following aspects:

1. The nature of the patented invention.
2. The time elapsed since the grant of the patent and measures undertaken by the patentee and its licensee for full use of the patented invention.
3. The capacity of the applicant of the compulsory license to work the patented invention in India for public advancement.
4. The capacity and working capital of the applicant to work the patented invention in India.

However, the Controller shall not consider any matter or steps taken by the applicant or the patent holder after applying for the compulsory license. Therefore, the Controller is only required to consider the state of affairs that existed on the date of filing the application for compulsory license and not beyond.[19]

After considering the application for compulsory license and accompanying documents and evidence submitted by the applicant, the Controller is satisfied that a *prima facie* case for the compulsory license is not made out, as per Rule 97 (1) of the Patent Rules, 2003. In that case, the applicant is notified of the same. Unless the applicant requests a hearing within one month from the date of notification, the Controller refuses the application. If the applicants request a hearing within the stipulated time of one month, the Controller shall accept or reject the application after hearing the applicant.

However, after hearing the applicant, the Controller accepts the application, or after considering the application, the Controller is satisfied that a *prima facie* case for the compulsory license is made out. Under Section 87 (1), the Controller will direct the applicant to serve copies of the application to the patent holder or any other interested party and publish the application in the official journal. Upon receiving the application for the compulsory license, the patent holder or any interested party may submit a notice for opposition in the format of Form 14 of the Patent Rules, 2003, under Section 87 (2) of the Patents Act, 1970, read with Rule 98(1) of the Patent Rules 2003, to the Controller within two months from the date of publication of the application in the official journal. As per Section 87 (3) of the Patents Act, 1970, read with Rule 98 (2) of the Patent Rules 2003, the patent holder or any interested party is required to set out grounds for the opposition of the application for the compulsory license. The notice of opposition and evidence are also required to be served upon the applicant by the patent holder or any interested party under Rule 98(3) of the Patent Rules 2003. When the notice of opposition is duly served to the applicant, the Controller may fix a date and time for hearing the case and give at least ten days' notice to the concerned parties under Rule 98 (5) of the Patent Rules, 2003. As per Section 87 (4) of the Patents Act, 1970, the Controller may decide the case by either refusing or granting the application for the compulsory license after hearing the parties.

Under Section 86 (1) of the Patents Act, 1970, the patentee may apply to the Controller to adjourn the application for the compulsory license filed under Section 84 (1) (c) or Section 84 (1) (a) read with Section 84 (7) (d). The Controller may adjourn the further application hearing for the compulsory license for a period not exceeding 12 months in aggregate.[18] However, the discretionary power of the Controller shall be exercised subject to Section 86 (2) and the fulfilment of the following two conditions:[3]

1. The time elapsed since the grant of patent is insufficient for the patentee to enable him to work the patented invention on a commercial scale to an adequate extent or to facilitate the patentee to work the patented invention to the fullest extent that is reasonably practicable; and

2. The patent holder has undertaken promptitude, adequate or reasonable steps to initiate the working of the patented invention in India on a commercial scale to an adequate extent.

While granting the compulsory license under Section 84 of the Patents Act, 1970, the Controller shall take into consideration the general purpose of granting compulsory license in India under Section 89 of the Patents Act, 1970, which are as follows:

1. The patented invention is worked commercially in India to the fullest extent without further delay.

2. The interest of the patentee and other persons working on the patented invention in India are not unduly prejudiced.

Thus, after considering the evidence presented and hearing the parties, the Controller may either refuse or grant the compulsory license by a reasoned order. However, when the Controller grants the compulsory license, it must be accompanied with the terms and conditions of the grant per Section 90 of the Patents Act, 1970, which among other things, should provide:[1]

1. Reasonable royalty and other remuneration shall be paid to the patent holder, having regard to the nature of the patented invention and expenditure incurred by the patentee for making and developing the patented invention.

2. The applicant shall work the patented invention to the fullest extent and make a reasonable profit for herself.

3. The patented invention is made available to the public at a reasonably affordable price.

4. The license granted to the applicant would be non-exclusive and non-assignable.

The patent holder may apply under Section 94 (1) of the Patents Act, 1970, read with Rule 102 (1) of the Patent Rules, 2003, for the termination of the compulsory license as per Form 21 of the Patent Rules, 2003. If the patent holder can prove that the circumstances that gave rise to the grant of compulsory license have ceased and are not likely to recur, then the Controller may terminate the compulsory license under Rule 102 (7) of the Patent Rules, 2003.

Therefore, Section 83 of the Patents Act, 1970, is the '*why*' to grant patents, Section 89 of the Patents Act, 1970, is the '*why*' to grant the compulsory license, Section 90 of the Patents Act, 1970, deals with the terms and conditions of the compulsory license granted, Section 93 of the Patents Act, 1970, states that the order of compulsory license shall operate as a deed between the concerned parties and Section 94 of the Patents Act, 1970, is the provision for the termination of the compulsory license.[18]

Finally, it has to be borne in mind that the proceedings before the Controller for the compulsory license are neither against the inventor nor in favour of the applicant of the compulsory license. Instead, these proceedings are in the public interest.

Bayer v *NATCO*

Bayer Corporation v *Union of India*,[1] is one of the most controversial judgments in patent law and the first of its kind in the history of patent law in India. It was the first-ever compulsory licensing case in India (Fig. 1). Bayer Corporation, an American multinational pharmaceutical company, invented a palliative drug, *i.e.*, life-extending drug for advanced stages of kidney and liver cancer, called '*Sorafenib*' (Carboxy Substituted Diphenyl Ureas) in the 1990s.

Bayer developed the palliative drug and launched it in 2005 under the trade name '*Nexavar*' to treat kidney cancer and later got additional approval for the treatment of liver cancer in 2007 in the United States. Similarly, Bayer received regulatory approval for importing and marketing '*Nexavar*' in India and launched it in 2008. In 2011, Indian generic drug

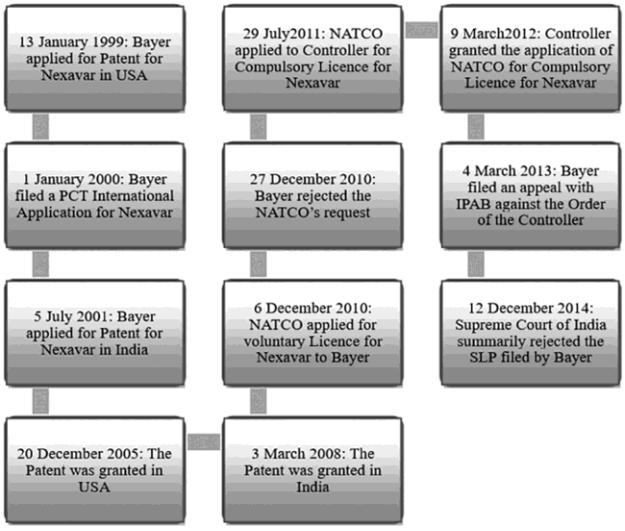

Fig. 1 — Development in *Bayer* v *NATCO*

manufacturer Natco Pharma filled for the compulsory license to the Controller on all three grounds under Section 84 of the Patents Act, 1970. Natco Pharma has fulfilled both the prerequisites for applying for the compulsory license, which are:

1. Natco Pharma (Applicant) applied for the compulsory license (*i.e.,* on 29 July 2011) after completion of three years from the grant of the patent (*i.e.,* on 3 March 2008).

2. Natco Pharma (Applicant) made efforts for the voluntary license (*i.e.,* 6 December 2010). However, Bayer (Patent Holder) refused to grant a voluntary license on reasonable terms (*i.e.,* 27 December 2010).

The compulsory license application for '*Nexavar*' was heard and decided by the Controller, the Intellectual Property Appellate Board (*hereinafter*, IPAB) and then finally by the Bombay High Court on all three grounds under Section 84 of the Patents Act, 1970. The ruling of all the three forums with respect to each of the three grounds under Section 84 of the Patents Act, 1970 are as follows:

1. Satisfaction of reasonable requirement of the public under Section 84 (1) (a): The Controller held that the patentee, even after the lapse of three years from the grant of the patent, has failed to satisfy the reasonable requirement of the patented drug in India. As shown in Table 1, the patentee was able to fulfil the requirement of only about 2% of the total kidney and liver cancer patients. The IPAB agreed with the reasoning and ruling of the Controller on the ground that the patent was not worked on a commercial scale as required by Section 84 (7) (e). Additionally, the Controller and the IPAB concurred that any steps taken by the patentee after applying for the compulsory license cannot be considered as per Section 84 (6) of the Patents Act, 1970. Additionally, any supplies of the patented drug made available to the public by an infringer cannot be considered as the infringer's supply is uncertain. The Bombay High Court agreed on the above-discussed points with the Controller and the IPAB and went further to interpret the term '*adequate extent*' under Section 84 (7) with respect to pharmaceutical drugs. The Bombay High Court held that the adequate test for pharmaceutical drugs should be 100%, *i.e.,* to the fullest extent.

2. Availability of patented invention to the public at a reasonably affordable price under Section 84 (1) (b): The Controller held that a reasonably affordable price is to be inferred predominantly with reference to the public in India. The patentee sold the patented drugs at Rs. 2,80,428/- per month of therapy, which according to the Controller, is not affordable by any stretch of the imagination for an average Indian. Therefore, the Controller held that the patentee failed to satisfy the requirement under Section 84 (1) (b) of the Patents Act, 1970. The IPAB concurred with the reasoning and ruling of the Controller in considering the purchasing capacity of the public in India and the evidence of access to less than 2% of patients with liver and kidney cancer to conclude that the patented invention was not reasonably affordable to the public in India. The Bombay High Court clarified that the Controller and the IPAB have no investigative powers. Therefore, they have to depend on the evidence led by the parties to determine the reasonably affordable price of the patented invention. The Bombay High Court interpreted the requirement of availability to the public at a reasonably affordable price under Section 84(1)(b) of the Patents Act, 1970, to mean a reasonably affordable price to any member of the public tendering the price. At the same time, the Bombay High Court also clarified that dual price mechanisms like the Patient Assistance Program adopted by the patentee would not satisfy the requirement of reasonably affordable price under Section 84 (1) (b) of the Patents Act, 1970. Thus, the Bombay High Court also upheld the impugned order of the IPAB.

3. Working of the patented invention in India: The Controller held that the patentee did not work the patented invention in India. The Controller interpreted the '*worked in the territory of India*' to mean '*manufactured to a reasonable extent in India*' as per the principles enumerated under Section 83 of the Patents Act, 1970. However, the IPAB differed with the Controller on interpreting the word '*worked*'. If the patentee can prove through evidence that it is prohibitive to manufacture the invention in India, then

Table 1 — Para 10 of *Natco PharmavBayer Corporation,* Controller of Patents, Mumbai, 2011

	Total patients	Demand for 80% of patients	Bottles per month (required)	Bottles imported in 2008	Bottles imported in 2009	Bottles imported in 2010
Liver cancer	~ 20,000	~ 16,000	~ 16,000	Nil	~ 200 Bottles	Unknown
Kidney cancer	~ 8,900	~ 7,120	~ 7,120			

'*working*' can only be done by import. Although, the IPAB agreed with the Controller that the patentee did not work the patented invention, as the import of the patented drug was done in small quantities, which is insufficient to fulfil the requirement under Section 84 (1) (c) of the Patents Act, 1970. The Bombay High Court concurred with the order of the IPAB. It held that '*working*' could mean local manufacturing entirely and only importation in some cases where the patentee could prove that it is impossible/prohibitive to manufacture the patented drug in India, which is determined from the facts and evidence of each case.

While granting the compulsory licence to Natco Pharma to manufacture and sell the patented drug, the Controller directed Natco Pharma to pay Bayer royalty at 6% of its net sales of the patented drug, which Natco Pharma would sell at Rs. 8800 for 120 tablets for a month of treatment. However, IPAB increased the royalty rate payable by Natco Pharma to Bayer from 6% to 7% of the sales of the patented drug. The Bombay High Court did not interfere with the order of the IPAB. Subsequently, Bayer filed a Special Leave Petition (*hereinafter*, SLP) in the Supreme Court of India. However, the Supreme Court summarily dismissed Bayer's SLP.[21]

Although *Bayer Corporation* v *Union of India*,[1] attracted much attention, a few more compulsory licences were expected to be granted in India. However, the applications for compulsory licences that followed were rejected on procedural grounds.

In March 2013, BDR Pharmaceuticals applied for the compulsory license for an anti-cancer drug '*Dasatinib*', which Bristol-Myers Squibb patented in India. The Controller rejected the application for the compulsory license because the applicant did not make reasonable efforts to obtain a voluntary license from the patent holder on reasonable terms and conditions as required by Section 84(6)(iv) of the Patents Act, 1970. The applicant failed to respond to the queries raised by the patent holder and, thereby, was unable to comply with the statutory requirement of mutual deliberation between the applicant and the patent holder.[19]

In June 2015, Lee Pharma applied for the compulsory licensing for '*Saxagliptin*', which is used to treat type-II diabetes mellitus. '*Saxagliptin*' was patented by Bristol Myers Squibb and marketed by AstraZeneca AB in India. The compulsory license application was rejected because, based on the evidence presented before the Controller, the applicant failed to satisfy any of the three grounds of compulsory license under Section 84 of the Patents Act, 1970.[22]

Conclusion

The idea of protecting the rights of inventors of the patented invention is to encourage research, innovation, and development of modern technologies and, at the same time, promote social well-being. As a result, the patent law in India protects the inventor's rights for 20 years under Section 53 of the Patents Act, 1970. Still, such protection is subject to the responsibilities, duties and liabilities imposed on the patent holder as provided under Section 83 of the Patents Act, 1970. However, if the patent holder refuses to fulfil her obligation under the patent law, she will be denied her rights and shall be subject to compulsory licensing under Section 84, Section 92, and Section 92-A of the Patents Act, 1970. The paper discussed various concepts relating to compulsory licensing, like a reasonable requirement, affordable prices, and the working of patents, and the first compulsory licensing case in India. However, after the *Bayer* case, there was a strong push from international pharmaceutical companies, directly and indirectly, to discourage compulsory licensing in India. The big multinational companies lobbied against India to force the Government to check the grant of compulsory licensing in India, which might have affected the cases of generic drug companies from making a successful case for the grant of compulsory licenses. Besides, India is still on the 'Priority Watch List' of the '*2022 Special 301 Report*', prepared annually by the Office of the US Trade Representative.[23] Therefore, putting pressure on India to have a more robust regulatory framework and practices for protecting intellectual property in India.

However, Objective 3 of the National Intellectual Property Rights Policy, 2016 encourages '*to have strong and effective IPR Laws in India to balance the interest of rights owners with the larger public interest*'.[24] Thus, a robust regulatory framework shall not impact the interest of the public and the welfare of society in India. India is one of the few TRIPS+ compliant member-nation of WTO and shall not mould its policies, practices or regulatory framework under international pressure. Under its compulsory license regime, India must fulfil its obligation under the Doha Declaration towards its citizens to promote access to medicines for all.[8] At the same time, it also meets the commitment towards the

global community under the Sustainable Development 'Goal 3: *Good Health and Well Being*'[25] towards poor and least developed countries and take steps to check the abuse of patent rights by the inventor without being influenced by international pressure. The successful efforts undertaken by India and South Africa at WTO to waive the patent for COVID-19 vaccines under exceptional circumstances for an effective response to prevent and contain COVID-19 infection, while complying with the Marrakesh Agreement, the Doha Declaration, and the Sustainable Development Goal 3. India could also have considered enforcement of provisions under the Patents Act, 1970, like Section 66, Section 92 or Section 102 for revocation, compulsory license, or acquisition, respectively. However, lack of raw materials, technical know-how and adequate research capabilities forced India to approach WTO in the interest of humanity. The approach adopted by the Government of India has several considerations, including geostrategic, political, economic, and social concerns. In hindsight, further research can be undertaken to determine the best course of action for similar circumstances based on the cost-benefit analysis considering various concerns to choose between '*economic and political disaster*' versus '*public health disaster*'.

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