



# A Critical Analysis Of The Concept Of Compulsory License In Indian Patent Law For The Pandemic Situation

N. Umamaheswari

Assistant Professor

Department of Intellectual Property Law  
Tamil Nadu dr. Ambedkar Law University

## ABSTRACT

Compulsory licensing is a check-out mechanism by the government on the monopoly right granted to the patent holder. Compulsory licensing is granted generally when the patent holder abuses his exclusive rights, and it is proved on the concept of non-availability and non-affordability. Doha declaration paved a way for exploring the concept of compulsory licensing in the TRIPS Agreement in 2005. During the Era of the pandemic COVID-19 the concept of compulsory licensing in the Indian patent regime falls into the perspective of balancing of economic and public health disaster in an extreme emergency. This paper discusses the concept of compulsory licensing in Indian patent its evolution, conditions and drawbacks during the Pandemic.

**Keywords:** Patent, Compulsory License, TRIPS, Article 31bis, Conventions, Doha Declaration, The Patents Act, 1970, COVID-19

## INTRODUCTION

Intellectual property rights is the statutory rights given to the contribution of human creative labour as an incentive and reward to their mental labour. IP protection is one of the forms of balancing public and private interest, one way it excludes others from its commercial exploitation as a negative right and on the other it gives the right to the owner to exploit it commercially, as a positive right. The major aim of granting statutory protection to IP goods to promote innovation and technology transfer as in case of patent law. IP generally manifests itself in different forms one of such important form is Patent, which is a protection given to the inventors for his invention, the statutory protection given here is exclusive rights for limited a period of time . Under patent law the eligible criteria to obtain patent rights are the invention should be new or novel , involves an inventive step and capable of industrial application.

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 invention a trade secret. Such disclosure will ensure the effective dissemination of such technology and facilitate further research and innovation.<sup>1</sup> It will also induce capital investment in research and development to produce new technologies, products and processes

<sup>1</sup> History of Indian Patent System, IP India; <https://ipindia.gov.in/history-of-indian-patent-system.html>

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.<sup>2</sup>

The concept of licencing can be divided into two forms – voluntary licensing, which promotes commercial exploitation by granting licensing by the patent holder to third party and Non-voluntary or compulsory licensing which is granted by government on the reason of non-availability, non-affordability, national emergency, extreme urgency or in case of public non-commercial use.

## COMPULSORY LICENSING

Compulsory licensing is the key process of granting the license to the third party by the government in order to utilize the patent and other form of intellectual property without the consent of patent holder, which allows regulators to break a patent holder's monopoly in situations where the monopoly is abused to deny access to innovation to a very large number of people specially in case of necessary emergencies.<sup>3</sup>

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.<sup>4</sup> 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 31bis of the TRIPS Agreement.<sup>5</sup>

## COMPULSORY LICENSING UNDER TRIPS AND SUBSEQUENT DEVELOPMENTS

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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup>

Article 27 of TRIPS provides that patents shall be available for any inventions, whether products or processes, in all fields of technology. However, Article 27(2) allows members to exclude inventions from patentability to protect public order or morality, including to protect health. TRIPS attempts to strike a balance between the short-term objective of providing access to life saving medicines and the long-term objective of providing incentives to the pharmaceutical industry for the development of new medicines. Hence, it also imposes certain restriction on the rights of the patent holder, including compulsory licensing.<sup>9</sup>

Article 8 of TRIPS allows member countries to adopt measures, consistent with the TRIPS Agreement, necessary to protect public health and nutrition. It also allows states to take measures to prevent the abuse of

<sup>2</sup> Patent law and Compulsory Licensing : Indian Perspective

<sup>3</sup> Lalitha N. Doha Declaration and Public Health Issues. *Journal of Intellectual Property Rights* 2008 September; 13:401-13

<sup>4</sup> 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: Communication from India and South Africa; <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

<sup>5</sup> 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: Communication from India and South Africa; <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

<sup>6</sup> *Natco Pharma v Bayer Corporation*, Controller of Patents, Mumbai, 2011; <https://patentdocs.typepad.com/files/compulsory-license-application.pdf>

<sup>7</sup> Raza A, Theoretical underpinnings of Patent Law: Decisions of the Supreme Court of India, *Journal of Intellectual Property Rights*, 27 (4) (2022)

<sup>8</sup> Raza A, Theoretical underpinnings of Patent Law: Decisions of the Supreme Court of India, *Journal of Intellectual Property Rights*, 27 (4) (2022)

<sup>9</sup> Ipshta Khatri, Compulsory Licencing under Patents Law in India, 5 *INDIAN J.L. & LEGAL RSCH.* 1 (2023).

intellectual property rights or resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.<sup>10</sup>

Article 30 is a broad provision which allows the member countries to provide limited exceptions to patent rights. When TRIPS was originally negotiated, Article 30 was seen as a mechanism similar to 'fair use' of copyrighted materials.<sup>3</sup> It allows limited exceptions provided that they do not unreasonably conflict with normal exploitation of the patent nor prejudice the legitimate interests of the patent owner; taking account of the legitimate interests of third parties.

Article 31 of the TRIPS Agreement deals with compulsory licensing in case of patents, although TRIPS phrases it as 'other use without authorization of the right holder'. Provisions of compulsory licensing are there in the Article-31 of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement. Compulsory license can be granted on certain conditions stipulated in the Agreement.

The noteworthy conditions to be followed in granting a compulsory license are

- (1) Such use shall be non-exclusive;
- (2) Such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (3) Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (4) Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (5) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. So, compulsory licensing of patents is provided in the TRIPS Agreement ab initio.

### **DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH;**

The Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO (World Trade Organization) Ministerial Conference of 2001 in Doha on November 14, 2001. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines.<sup>11</sup> This Doha declaration broadens and enlightens the compulsory licensing phenomenon and facilitates the launch of generic drugs of the patent pharmaceutical to satisfy the public health desires. It highlighted in para 4 and 6 not to prevent the WTO members to take measures in the case of public health crisis and granting of compulsory licences and the freedom on grounds of granting compulsory licences.<sup>12</sup>

### **AMENDMENT TO ART 31 OF THE TRIPS AGREEMENT**

Article 31 of the TRIPs Agreement had been amended in light of Paragraph 6, i.e., the mechanism that enables compulsory licences for the production and export of generic medicines for the benefit of countries with insufficient or no manufacturing capacities in the pharmaceutical sector, of the Doha WTO Ministerial conference of November 14, 2001. Limitations imposed under of clauses (f) and (h) of Article 31 have been waived.<sup>13</sup>

<sup>10</sup> TRIPS Agreement 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C (1994); [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](https://www.wto.org/english/docs_e/legal_e/27-trips.pdf)

<sup>11</sup> TRIPS Agreement 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1(1994); [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](https://www.wto.org/english/docs_e/legal_e/27-trips.pdf)

<sup>12</sup> WTO General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health; [https://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)

<sup>13</sup> [https://www.wto.org/english/res\\_e/publications\\_e/ai17\\_e/trips\\_art31\\_bis\\_oth.pdf](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf)

Article 31bis provides as follows: Obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement. Eligible importing member under the system has to notify its needs to the TRIPS Council. The eligible importing Member, other than a least developed country Member, requires establishing that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Article. Eligible importing member requires confirming that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Articles 31 and 31bis<sup>14</sup> of this Agreement and the provisions.<sup>15</sup>

## COMPULSORY LICENCE UNDER INDIAN PATENT ACT, 1970

The Indian Patent Act 1970, was amended first in 1999, the second in 2002 and the third in 2005. The Amendment in the year go for the phenomenon of compulsory licensing and make possible for the grant of compulsory license that are contained in the section 84 to 92 of the Indian Patents Act 1970. Grounds For Compulsory Licensing Under the Indian Patent 1970, can be sub-divided into the following categories:

- (1) Abuse of patent rights, dealt with broadly under sec 84.
- (2) 'Public Interest', dealt with broadly under sec 92.
- (3) New Grounds introduced by the 2005 amendments. under section 92A.<sup>16</sup>

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,<sup>17</sup> 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 under Section 92 (Special provision for compulsory licenses on notifications by Central Government), if the Central Government is satisfied that compulsory licenses must be granted at any time after the sealing of patent to work the invention, it may make a declaration to that effect, by notification in the Official Gazette. The compulsory license under this section is granted under following circumstances:
  1. National emergency; or
  2. In circumstances of extreme urgency; or
  3. In case of public non-commercial use.

<sup>14</sup> WTO, Annex and Appendix to the TRIPS Agreement

[https://www.wto.org/english/docs\\_e/legal\\_e/31bis\\_trips\\_annex\\_e.htm](https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm)

<sup>15</sup> [https://www.wto.org/english/tratop\\_e/trips\\_e/par6laws\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm)

<sup>16</sup> Department of Industrial Policy & Promotion, National Intellectual Property Rights Policy 2016;

[https://dpiit.gov.in/sites/default/files/National\\_IPR\\_Policy\\_English.pdf](https://dpiit.gov.in/sites/default/files/National_IPR_Policy_English.pdf)

<sup>17</sup> 9F. Hoffmann-La Roche V. Cipla Ltd. 2009 (40) PTC125 (Del) pg152; V.K.Ahuja, Law Relating To Intellectual Property Rights, ( LexisNexis, Third edition 2017) , p.570.

The Controller shall grant to the applicant a license under such circumstances on the terms and conditions as he thinks fit. He shall settle the terms and conditions of a license and try to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights. The public health crises may be related to Acquired Immuno Deficiency Syndrome (AIDS), Human Immuno Deficiency Virus (HIV), tuberculosis, malaria or other epidemics for the export of patented pharmaceutical products.

Compulsory Licensing for the export of patented pharmaceutical products under Section 92 A: Section 92-A was inserted by the Patent (Amendment) Act, 2005<sup>18</sup>, to comply with Article 31bis 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,<sup>19</sup> 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)<sup>20</sup>, 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 31bis 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 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)<sup>21</sup> are fulfilled. Thus, it balances the patentee's rights and the rights of society (third party).

<sup>18</sup> The Patents Act, 1970, as amended by Act No. 15 of 2005

<sup>19</sup> The Patents Act, 1970, as amended by Act No. 15 of 2005

<sup>20</sup> The Patents Act, 1970, as amended by Act No. 15 of 2005

<sup>21</sup> Lee Pharma v AstraZeneca AB, Controller of Patents, Mumbai, 2016 [https://ipindia.gov.in/writereaddata/Portal/News/33\\_1\\_2-compulsory-license-application-20jan2016.pdf](https://ipindia.gov.in/writereaddata/Portal/News/33_1_2-compulsory-license-application-20jan2016.pdf)

## OTHER PROVISIONS UNDER THE PATENTS ACT, 1970 THAT DEALS WITH PANDEMIC SITUATION

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).<sup>22</sup>
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 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<sup>23</sup>.
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.<sup>24</sup> 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. 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.<sup>25</sup>

## CONCLUSION

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. At the same time, it also meets the commitment towards the global community under the Sustainable Development Goal 3: Good Health and Well Being 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

<sup>22</sup> Doha WTO Ministerial 2001: TRIPS, Declaration on the TRIPS Agreement and Public Health; [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

<sup>23</sup> The Patents Act, 1970, as amended by Act No. 15 of 2005

<sup>24</sup> United Nations, Sustainable Development Goals 3: Ensure healthy lives and promote well-being for all at all ages; <https://sdgs.un.org/goals/goal3>

<sup>25</sup> United Nations, Sustainable Development Goals 3: Ensure healthy lives and promote well-being for all at all ages; <https://sdgs.un.org/goals/goal3>

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. Bearing in mind the financial conditions of India, compulsory licensing as an obligatory regulation is unquestionably a major necessity. Thus compulsory licenses enables access to these medicines creating a balance of trading patent technologies in a fair manner for equitable distribution and access to medicines. The provision of compulsory licensing must be used judiciously as it is an exception and flexibility to the general rule of patent. The provision falls mid-way; neither full patent protection is granted, nor is it denied altogether it directly affects innovation funding and unfettered use of this provision may result in global pharmaceutical companies being hesitant to introduce new medicines in other countries

