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INTERNATIONAL JOURNAL OF MULTIDISCIPLINARY EDUCATIONAL RESEARCH
ISSN:2277-7881(Print); IMPACT FACTOR :9.014(2025); IC VALUE:5.16; ISI VALUE:2.286
PEER REVIEWED AND REFEREED INTERNATIONAL JOURNAL
(Fulfilled Suggests Parameters of UGC by IJMER)
Volume:14, Issue:11(2), November, 2025
Scopus Review ID: A2B96D3ACF3FEA2A
Article Received: Reviewed: Accepted
Publisher: Sucharitha Publication, India
Online Copy of Article Publication Available: www.ijmer.in

COMPULSORY LICENCE OF PATENTS UNDER WTO-TRIPS REGIME

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I Introduction

The compulsory licence is one mechanism through which state limits private power that resides in the grant of patents. However, after the conclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) compulsory licensing has been a controversial issue. Even though all World Trade Organization (WTO) members provide for the possibility of granting compulsory licences through their national laws, the grant of compulsory licences remains a rare exception especially in developing countries. The paper, in general, analyses compulsory licensing regime before and after the TRIPS Agreement.

II Pre-TRIPS Compulsory Licensing

Compulsory licenses are generally defined as "authorizations permitting a third party to make, use, or sell a patented invention without the patent owner's consent."[1] The WTO states that compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner.[2] The practice of granting compulsory licenses was in existence in the local laws of different countries for a very long time. The *English Statue of Monopolies 1623* is among some of the earliest legislations in which compulsory licensing was provided for.[3] The concept was discussed in United States (US) Senate in 1790; it was popular in United Kingdom (UK) since 1850s and in Germany in 1853.[4] Thus, prior to TRIPS different countries of the world already had legislation granting compulsory licenses but these legislations varied on different aspects. With its adoption in the Paris Convention in 1883 compulsory licensing became a fixture in almost all patent systems.[5] The Article 5A (2) of the Paris Convention, expressly mentions that countries of the Union shall have right to grant compulsory licenses to prevent abuse of exclusive rights granted by patent. In the late 1970s and early 1980s, developing countries demands for a New International Economic Order (NIEO) included greater access to technology.[6] These demands were manifest in negotiations on revision of the Paris Convention.[7] These negotiations broke down in 1982, in significant part because of competing demands concerning compulsory licensing.[8] The failure of these negotiations convinced industry interests that they would not succeed in solving what they viewed as the "intellectual property problem" at World Intellectual Property Organization (WIPO).[9] This led to a refocusing of Intellectual Property Rights (IPR) efforts towards the General Agreement on Tariffs and Trade (GATT). GATT was signed in 1948 and had close to 30 member countries. Its primary objective was to see that impediments to international trade - mainly in the form of tariffs - were reduced or removed in order to facilitate the movement of goods across borders.[10] However, over time, the nature and character of global trade started to get very complex.[11] Countries began to realise that

[1] Colleen Chien, "Cheap Drugs at What Price to Innovation:Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?"18.1 *BTLJ* 6 (2006).
[2] Compulsory Licensing Of Pharmaceuticals & TRIPS, *available at*: www.wto.org/english/tratoop_e/trips_e/public_health_faq_e.htm (Visited on January 28,2014).
[3] See *Supra* note.
[4] *Id.* at 7.
[5] *Ibid* .
[6] UNCTAD-ICTSD, Resource Book On TRIPS and Development 463(UNCTAD-ICTSD, New York,2005).
[7] *Ibid*.
[8] *Ibid*.
[9] *Ibid*.
[10] Brief History of WTO, *available at* : http://infochangeindia.org/agenda/cost-of-liberalisation/a-brief-history-of-the-wto.html (Visited on January 28,2014).
[11] *Ibid*.

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GATT did not have all the answers to the questions posed by the increasingly complicated nature of global trade.[12] This led member countries to launch a new round of more detailed negotiations, from 1986-1994, known as the Uruguay Round.[13] The US played a major role in the inclusion of the TRIPS negotiations in the Uruguay Round. The first US proposal was for a GATT-based intellectual property agreement aimed at a general prohibition of compulsory licences whereas the second approach provided for compulsory licences solely to address a declared national emergency or to remedy an adjudicated violation of antitrust laws and included the European Commission (EC) proposal for judicial review.[14] Whereas the first proposal required "full compensation", if a compulsory licence is granted by way of exception, the second proposal provides for "compensation commensurate with the market value" and includes government use of patents.[15] Both US proposals claimed the non-exclusivity of compulsory licences.[16] By contrast, India held the view that each country must be free to specify the grounds on which compulsory licences can be granted under its law as well as the conditions for such grant, and provided for an extensive concept of compulsory licences.[17] Moreover, India proposed a so-called "licence of rights", which is the automatic grant of non-voluntary licences in sectors of critical importance.[18] Similarly, Japan intended that compulsory licences "shall be conducted in accordance with the present Paris Convention and in a way that the interests of all the parties concerned are taken into account in a balanced manner."[19] During the meetings of the TRIPS Negotiation Group that followed in September and December 1989 and January 1990, the subject of compulsory licensing was discussed extensively, particularly in relation to the issue of non-working of patents and further grounds upon which to grant compulsory licences (in particular the public interest), without a conclusion being reached.[20] This disagreement is accurately reflected in the subsequent Draft Agreements by the EC, the US and a group of developing countries.[21] Eventually, an Indian proposal that combined both categories—"government use" and "compulsory licences" - under a single set of conditions was accepted.[22] The Anell draft contained two basic approaches to the negotiations on TRIPS, approach A and B.[23] Approach A provides a single TRIPS agreement, encompassing all the areas of negotiation and dealing with all seven categories of intellectual property on which proposals have been made; this agreement would be implemented as an integral part of the General Agreement.[24] Approach B provides for two parts, one on trade in counterfeit and pirated goods (reflected in Part IX of the attached text) and the other on standards and principles concerning the availability, scope and use of IPR (reflected in Parts I-VIII).[25] The "A" text contained clause on compulsory licensing in section 5.[26] Section 5A.2 provided the purposes for which a compulsory license may be granted and the purposes were an adjudicated violation of competition laws, a [declared] national emergency, public interest concerning national security, or critical peril to life of the general public or body thereof and also where the exploitation of the patented invention is required by reason of an overriding public interest, the possibility of exploitation of the patented invention by the government, or by third persons authorized by it.[27] Section 5A.2.4 provided that if there is failure to exploit the patented invention or that its exploitation *i.e.* acts of manufacturing, selling or importing did not satisfy the [basic] needs of the local market, compulsory license could not be granted before the expiration of a period of four years from the date of the patent application, or three years from the date

[12] *Ibid.*
[13] *Ibid*.
[14] Peter Tobias Stoll, Jan Burche, *et.al*. , *WTO Trade Related Aspects of Intellectual Property Rights* 560 (Martinus Nijhoff Publishers, Leiden, 2009).
[15] *Ibid* .
[16] *Ibid* .
[17] *Id.* at 561.
[18] *Ibid.*
[19] *Ibid.*
[20] *Ibid.*
[21] *Ibid* .
[22] *Ibid* .
[23] See document MTN.GNG/NG11/W/76 at page 1.
[24] *Ibid* .
[25] *Ibid* .
[26] *Id.* at 3.
[27] See *Supra* note 15.

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of the grant of the patent, whichever period expires last, unless there existed legitimate reasons.[28] In the Anell Draft, the only compulsory licensing text in "B" was that the agreement would not prevent taking of necessary action for the working or use of a patent for governmental purposes; or (ii) where invention patented was capable of being used for the preparation or production of food or medicine, for granting to any person a licence limited to the use of the invention for the purposes of the preparation or production and distribution of food and medicines.[29] The Anell Draft however, indicated that the endeavour to restrict the concept of compulsory licences remained unsuccessful, as there was no formal definition of the terms, including "public interest."[30] The Brussels Draft revealed a more liberal approach to the circumstances justifying the grant of compulsory licences and contained wording very similar to that of the current provisions.[31] Still, the grounds for granting compulsory licences were left to the individual Members to determine.[32] However, the term "public interest" was no longer applied, but a provision on "public [non-commercial] use" was included instead.[33] Additionally, the draft contained specific reference to the "working issue."[34] The final draft (Dunkel Draft) did not include a specific regulation on the "working issue" but incorporated the notion of "public non-commercial use."[35]

III Compulsory Licensing in the TRIPS Agreement

TRIPS came into effect on January 1, 1995 with the primary objective of minimizing the distortions and impediments to global trade by giving due importance to protection of IPR.[36] It provided for minimum standards to harmonize divergent domestic laws of the WTO member countries and provided mandatory rights for right holders.[37] It required all WTO member states to adopt regulations relating to IPR as laid down in the TRIPS.[38] TRIPS incorporated the Paris Convention under its Article 2(1)6 and both apply on equal footing.[39] TRIPS, however, provided for higher standards of IPR.[40] Article 27(1)7 of the TRIPS provides that patent shall be available in both products and processes in any field of technology if they are new, involve inventive step and are capable of industrial application.[41] The agreement also provides that there shall be no discrimination as to the place of invention, the field of technology and whether products are imported or locally produced subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of Article 27.[42] Article 28 provides those minimum rights that are conferred on the patent holder with respect to the thing patented and Article 28.2 states, *inter alia,* that patent holder shall also have right to assign, to conclude licensing of contracts.[43] However, Article 30 provides the members with authority to provide limited exceptions to this rights provided these exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the owner of the patent, taking into account legitimate interests of third parties.[44] Article 31 provides provision relating to other use without authorisation of the right holder and it is within this article that compulsory licensing is impliedly included as the TRIPS

[28] *Ibid.*
[29] See *Supra* note 7 at 465.
[30] See *Supra* note 15.
[31] *Ibid* .
[32] *Ibid* .
[33] *Id*.at 562.
[34] *Ibid* .
[35] *Ibid.*
[36] Muhammad Zaheer Abbas, Shamreeza Riaz, "Evolution of The Concept of Compulsory Licensing : A Critical Analysis of Key Developments Before and After TRIPS," 4 *ARI* 5 (2013).
[37] *Ibid.*
[38] *Ibid.*
[39] *Ibid.*
[40] *Ibid.*
[41] Article 27 (1) of the TRIPS Agreement.
[42] See *Supra* note 37.
[43] Article 28 of The TRIPS Agreement.
[44] Article 30 of the TRIPS Agreement.

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does not use the term "compulsory licensing" in relation to patents anywhere.[45] Therefore, a compulsory licence in the meaning of Article 31, is an authorization for a third party, against or regardless of the patent owner's will, to perform acts that would legally require authorization from the patentee.[46] Article 31 contains all those exceptions to the use of patented subject matter that are not already covered by Article 30.[47] Article 31 sets out specific conditions for the grant of a compulsory licence.[48] With regard to the grounds for compulsory licensing, the list in Article 31 is not exhaustive (with the exception of semi-conductor technology).[49] As explicitly recognized by the *Doha Declaration on the TRIPS Agreement and Public Health, "*each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."[50] The fixed set of conditions laid down by Article 31 provides for legal security and serves the interests of patentees in their exclusive rights, at the same time, Members remain flexible and can respond to urgent national needs and emergency situations because the provision is open with regard to the purposes of or grounds upon which to grant a licence.[51] Article 31(f) which states that compulsory licensing should be predominantly for supply to the domestic market of the Member authorising such use and this was subject to a lot of criticism from the governments and heath activists as this would leave behind those countries which do not have adequate manufacturing facilities or know-how to produce drug under compulsory license.[52] In Doha Ministerial Conference in November 2001 these doubts were settled and the members stressed on the importance of interpreting the TRIPS in such a way that it supports the public health and adopted a separate declaration on TRIPS and Public Health.[53] The Declaration has immense importance in the context of compulsory licensing as it affirmed the sovereign right of countries to take measures, particularly through compulsory licensing and parallel imports, to protect public health and give it priority over intellectual property.[54] Specifically, the declaration stated that the TRIPS agreement 'does not and should not prevent members from taking measures to protect public health... (and it) should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and in particular, to promote access to medicines for all'.[55] Of particular interest was the interpretation of Article 31(f) of the TRIPS agreement, which stated that compulsory licensing shall be 'predominantly for the supply of domestic markets'.[56] To this end, governments can issue a license to a local manufacturer, whilst offering a lower level of compensation to the originator. In effect, compulsory licensing essentially lowers prices to consumers by creating competition in the market for the patented product.[57] As many developing countries lack the domestic capacity or technical expertise to manufacture patented pharmaceuticals, the WTO further agreed to modify the TRIPS provisions relating to compulsory licensing.[58] In August 2003, a temporary waiver was established to permit countries with local manufacturing the ability to issue compulsory licenses and export drugs to countries unable to produce pharmaceuticals domestically.[59] In December 2005, the provision was confirmed as an amendment to the TRIPS agreement.[60]

IV Conclusion

The recent development in the field of compulsory licensing is going to open up new avenues for the developing countries to utilize the patents for the public interest. It can be used to strike a balance between interests of patent holder and public

[45] See *Supra* note 15 at 556.
[46] *Ibid*.
[47] *Id* .at 564.
[48] *Ibid.*
[49] *Ibid.*
[50] *Id.* at 565.
[51] *Ibid*.
[52] Editorial, "Balancing Intellectual Property Privileges and Need For Essential Medicines" *Globalization and Health,* June 12, 2007.
[53] *Ibid.*
[54]*Ibid*.
[55] *Ibid.*
[56] *Ibid.*
[57] *Ibid.*
[58] *Ibid.*
[59] *Ibid.*
[60] *Ibid.*

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and to mitigate the restrictive effects of patent holder's monopoly rights. However, there is also chance that if the compulsory licensing tool is not used with caution than it might discourage innovation. But at the same time if used properly this will go a long way in benefitting the public which is one of the goals for encouraging patent protection.