



## LOCAL WORKING AND COMPUSORY LICENSE UNDER PATENT LAWS: IT'S INTERFACE WITH COMPETITION LAW

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### Abstract

Balancing private intellectual property interests with that of the public is always a difficult task. A general consensus with regard to the local working requirement is that the individual's exclusivity should be subject to public interests especially in cases relating to public health. Since these local working requirements are essential to maintain the balance between monopoly rights *vis-à-vis* public interests, it is essential to develop a comprehensive understanding of the same. Accordingly, the interpretation of local working as a ground for issuing compulsory license has generated a lot of discussion amongst intellectual property stakeholders as well as various political communities. This article primarily analyses the evolutionary interpretation of the local working requirement as a ground for issuing compulsory license under the Paris Convention and the TRIPS agreement. It will also elaborate on the differing political opinion, negotiated prior to the enactment of TRIPS agreement regarding the standards of local working requirement. The analysis will focus on the issue of whether the importation of patented products would satisfy the local working requirement, particularly in light of Paris Convention, TRIPS Agreement and the Patent Act, 1970. Further, the article also tries to analyze the relationship of competition law with that of compulsory license. As per section 4 of the Competition Act 2002, refusal to license is a ground for determining an enterprise's abuse of dominance in the relevant market. Accordingly, the paper looks into the scope of issuance of compulsory license under the provisions of the Competition Act, 2002.

### I. INTRODUCTION

The system of intellectual property rights works upon the utilitarian principle of facilitating the progress of science and useful arts<sup>1</sup>. The world has witnessed notable references to the protection of creative intellect since ancient times even in the absence of a statutory regulation<sup>2</sup>. The right of patent is considered to be the strongest amongst all intellectual properties since patented inventions can protect the ideas themselves.<sup>3</sup> The literal meaning of the term patent is *open* and is derived from the term "*Letters Patent*"<sup>4</sup>, which basically means open letters. Before patents were made the subject of legislation, they were issued by virtue

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<sup>1</sup> E. Hettinger, "Justifying Intellectual Property" 18 (1) *Philosophy and Public Affairs* 31 (1989).

<sup>2</sup> Bruce Willis Bugbee, *The Genesis of American Patent and Copyright Law* (Public Affairs Press, 1967). The author has cited numerous cases relating to intellectual property protection. From chefs being granted year-long monopoly for creating culinary delights to false poets being disgraced for stealing the works of original authors in literary contests and how is ownership related to intellectual work when it is codified differently, intellectual property has been a reason for discourse shortly before first century itself.

<sup>3</sup> Henry C Mitchell, *The intellectual commons: Toward an ecology of intellectual property* 29 (Lexington Books, United States, 2005).

<sup>4</sup> From Latin words "*Litteraepatentes*".

of royal and state prerogatives<sup>5</sup> that granted certain definite privileges, rights, ranks or titles to the holder of the document<sup>6</sup>. The *raison d'être* for promoting and protecting inventions has more or less centered on granting incentives for working the new inventions locally<sup>7</sup>. Patents acted as a tool to attract foreign craftsmen to practice their art in different jurisdictions<sup>8</sup> and thereby promoting technology transfer by the domestic application of foreign inventions in the country granting patent. By the middle of the nineteenth century many industrialized countries had enacted legislations related to patent with the primary objective of bolstering domestic industrialization<sup>9</sup>. Further, the development of technological infrastructure was ascertained specifically by mandating local working of the patent and in case of failure to work in the territory, by the grant of compulsory licensing. Therefore, it can be said that it is the local working requirement that enable patent granting countries to force the foreign patentees to transfer technology in foreign markets.

Under the Indian Patents Act 1970 (hereinafter the Act), compulsory license for a patented invention is issued for disjunctive conditions such as if the reasonable requirement of the public is not met, unaffordable price or if the patented invention has not been worked within the territory of India. The analysis will focus on the issue of whether the importation of patented products would satisfy the local working requirement, particularly in light of Paris Convention for the Protection of Industrial Property, 1883 (Paris Convention), TRIPS and the Act.

## II. "LOCAL WORKING" DEFINED

There is no statutory definition of the term "local working" thereby making it crucial for the government to interpret it as according to the national requirements. Local working is synonymous with national working, requiring the patentee to manufacture or apply the patented product or process, within the country that has granted the patent.<sup>10</sup> It may also be known as commercial working of patent in a country<sup>11</sup>. Historically, the development of local working mandate can be traced back to the Venetian Patent Act of 1474, which provided that a patent would be cancelled if it was not actively exploited within the country<sup>12</sup>. Similarly, the United Kingdom Statute of Monopolies 1623, required the local working condition for retaining the patent. The US and the French statutes also saw regulations for grant of patent

<sup>5</sup> P. Meinhardt, *Inventions, Patents and Monopoly* 43 (Stevens & Sons Ltd., London, 1946).

<sup>6</sup> Paul A. David, "Intellectual Property Institutions and the Panda's Thumb: Patents, Copyright and Trade Secrets in Economic Theory and History, in M.B. Wallerstein, Mary Ellen Mogege, *et.al.*(eds.) *Global Dimensions of IPRs in Science and Technology* (National Academy Press, 1993).

<sup>7</sup> Ulf Anderfelt, *International Patent Legislation and Developing Countries* 3-25 (Springer, Netherlands, 1971).

<sup>8</sup> C. MacLeod, *Inventing the Industrial Revolution: The English Patent System, 1660-1800* 11 (Cambridge University Press, 1988).

<sup>9</sup> Michael Halewood, "Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law" 35(2) *Osgoode Hall Law Journal* 248 - 252 (1997).

<sup>10</sup> G B Reddy & Harunrashid A. Kadri, "Local Working of Patents- Law and Implementation in India" 18 *Journal of Intellectual Property Rights* 15 - 20 (2013).

<sup>11</sup> The traditional meaning of local working is local manufacture. However, many a times it is being interpreted to include local commercial use, i.e. making available for local sale, a criterion which can be satisfied by importation of the patented invention. See, G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property*, 71 (World Intellectual Property, 1968).

<sup>12</sup> *Supra* note 8, at 9.

on foreign inventions only if the invention was worked locally<sup>13</sup>. A patent got actually revoked in France if the domestic inventor got the same invention patented in any other country<sup>14</sup>. Thus, it can be deduced that, local working requirement had an effect of compelling foreign patentees to situate production facilities within the patent granting country.

### **Local Working under Paris Convention**

The Paris Convention was the first multi-lateral treaty to standardize the regulation as well as the reciprocal treatment of intellectual properties at an international level. Article 5(A)(2) of the Paris Convention allows the Contracting Parties to:

“[...] take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work [emphasis added].”

The member countries have the right to make laws relating to grant of compulsory license to check any monopoly abuse arising from the exercise of the exclusive patent rights. Under this provision, only ‘failure to work’ a patent has been cited as a probable abuse of patent right and has not been expressly defined. It should be noted there was nothing in the provision limiting the freedom of the states to determine what other activities may possibly be suggested to mean abuse of private right. Not only it was reasonable to clarify as to what activities would amount to ‘failure to work’ or ‘insufficient working’, but also required in order to take appropriate action for issuing compulsory license. Further, the power to grant compulsory license is subject to a number of conditions as set out in article 5(A)(4):

“compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license [emphasis added]”

A significant time period of 4 years has been provided to determine the failure of working only after which, an action for the grant of compulsory license can be initiated. No compulsory license shall be granted in case the patentee justifies non-working due to legitimate reasons which may have caused the invention impossible to work or to work more intensively. Further, a for bearing approach on the local working mandate under article 5(A)(1) is noted whereby, a patent was not to be forfeited even if it was being imported in to the patent granting country.<sup>15</sup> By reading article 5(A)(1) in conjunction with article 5(A)(2), there seems to be an intelligent balance between the interests of the patentee *vis-à-vis* that of the community. However, to assess whether only local working requirement can sufficiently address the interests of the community is a nuanced task. The determination of costs and

<sup>13</sup> Supra note 9, at 251.

<sup>14</sup> WIPO, *Introduction to Intellectual Property: Theory and Practice* 19 (1997).

<sup>15</sup> Paris Convention for the Protection of Industrial Property, 1883, art. 5A. (1)- Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

benefits (social and economic) of local working for a community depend upon variety of factors such as the level of economic development of the patent granting country *i.e.* if it's a developed country, developing country or a least developed country, the technology sector involved to name a few. Further, in cases where importation justly satisfies community requirements, imposing local working would be limiting the interests of the patentees. With no precise description of 'failure to work' in Paris Convention, member countries were given freedom to determine its ambit and scope depending on their national requirement. The Convention also recognized the impracticability of requiring immediate working of patent in all the countries and therefore sought to strike a balance between the rights of the patent holder and that of the state<sup>16</sup>. Further, a patent could not be revoked unless the grant of compulsory license was not sufficient to work the patent in the territory.<sup>17</sup> Accordingly, compulsory license became a condition precedent for revocation of patent on the grounds of non-working of a patent.

Paris Convention is seen as one of the most successful treaties, so far, primarily because it did not seek to level out the national laws of the country. It did not even establish the reciprocity principle for national treatment. Rather, it chalked out immense legislative freedom for the member countries to develop laws according to their national requirements. The only restraint was mandated in the form of compulsory equal treatment of nationals as well as foreigners. One of the other commendable features was the rule on priority period to prevent conflict between two or more inventions concerning the same subject-matter.

### **Local Working under TRIPS Agreement**

With TRIPS, the agenda was to create a new kind of international regulatory agreement which introduces a very fine line between international obligations and the freedom of the countries to regulate their own national economies. It contains numerous references to GATT, Berne and Paris Convention. An analysis of the negotiating history of TRIPS reveals that a lot of deliberation took place on interpretation on local working in order to reach a consensus. This part is therefore discussed under two categories: 'local working negotiated before TRIPS' and 'local working under TRIPS'.

#### *'Local working' negotiated before TRIPS*

The negotiating history of TRIPS agreement reveals a lot of deliberations on interpretation and extent of local working of patents in a country. Primarily, three ideas on local working were put forward during the negotiations and the confusions were kept as "bracketed texts" for consideration during future negotiations. The Developing Countries Draft<sup>18</sup> contained a provision regarding the obligations of full disclosure of the invention as well as on the

<sup>16</sup>WIPO Publication No. 489 (E), *Intellectual Property Handbook: Policy, Law, and Use* 241-162, (2<sup>nd</sup>edn., 2004).

<sup>17</sup>Paris Convention for the Protection of Industrial Property, 1883, art. 5A (3)- Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

<sup>18</sup>The countries of Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay and Pakistan had this view. Part II, chap. II, art. 5, ¶ 2, GATT Doc. MTN.GNG/NG11/W/71 (May 14, 1990) [hereinafter Developing Countries' Draft]. It is published in Carlos M. Correa and Abdulqawi A. Yusuf, *Intellectual Property and International Trade: The Trips Agreement*, 441 (Kluwer Law International, 1998).

information regarding the foreign applications and grant to be met by the patent applicant. The developing nations never wanted local working to be an optional clause for a patentee. Local working requirement was intended to be the primary and mandatory obligation for conferral of exclusive rights as opposed to an exception to patent rule. In the context of local working of patents, the provision had a further obligation for the patent applicants *viz*:

“to work the patented invention in the territory of the Party granting it within the time limits fixed by national legislation and subject to the sanctions provided for in chapter VI.”<sup>19</sup>

The developing countries distinctly required the patent holders to work the patent locally within a fixed time period in return for receiving patent protection in the patent granting country. This mandate on local working requirement stayed put throughout the negotiations for developing countries. The provision specifying the obligations eventually paved its way to the TRIPS agreement as article 29<sup>20</sup> titled as ‘Conditions on Patent Applicants’. The countries also emphasized on patent holders to not to engage in any abusive or anti-restrictive practices which might hinder technology transfer as evident from the following clause:

“in respect of license contracts and contracts assigning patents, to refrain from engaging in abusive or anti-competitive practices adversely affecting the transfer of technology subject to the sanctions provided for in chapters VI and VII.”

Clearly, for the developing countries, the primary goal of effecting technology transfer was to be met with the local working requirement in the patent granting country. Conversely, the United States was completely on the other end of the spectrum with barring local working obligation on the patentees. The U.S. Draft<sup>21</sup> not only sought to prohibit local working requirement but also any other responsibility for the patentee in case of failure to work the patent. It further tightened the knot by totally negating the grant of compulsory license as a remedy for a patentee’s failure to work the invention locally. The proposal offered very limited grounds for evoking compulsory licensing *viz.* antitrust violations and declared national emergencies;

“Contracting parties may limit the patent owner’s exclusive rights solely through compulsory licenses and only to remedy an adjudicated violation of competition laws or to address, only during its existence, a declared national emergency.”

<sup>19</sup>*Id.* atch II, art. 5 (2).

<sup>20</sup> TRIPS Agreement, art. 29: Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.

<sup>21</sup>Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights, Communication from the United States, art. 27, GATT Doc. MTN.GNG/NG11/W/70 (May 11, 1990) [hereinafter U.S. Draft], stating that the U.S. proposal restricted compulsory licensing to national emergencies and anti-competitive abuses; available at <https://docs.wto.org/gattdocs/q/UR/GNGNG11/W70.PDF> (last visited on Mar. 12, 2021).

In effect, the US draft suggested a relaxed mode of regulation under which a patentee's exclusivity on patents would always be free from any kind of adverse impacts even in case of failure to locally work a patent.

Amidst these extremities, the European Countries' Draft<sup>22</sup> proposed a middle ground by suggesting that local working requirements should not be a patentee's obligation, but a rather permissible exception to the patent rights. Clause (4) of the proposed provision for compulsory license<sup>23</sup> dealt with the requirement of local working of patents. As compared to the draft by the developing nations, the EC Draft was more lenient and ideal in approach as it didn't grant compulsory license simply for want of local working and instead permitted national laws to excuse local working in situations where it was justifiable with legitimate reasons. It also differed from the US Draft as it did not see to limit the grounds available for issuing a compulsory license and rather stipulated the conditions for such issuance.

These ideological differences received fair share of attention amongst the negotiating group. The developing and the European countries were fairly skeptical about the highly restrictive approach of the US for the grounds related to compulsory licensing<sup>24</sup>. Subsequently, a reconciliation of the prevailing different views was attempted with Chairman's Draft<sup>25</sup> as per which compulsory license was permitted in case of failure to work, dependent patents<sup>26</sup>, and overriding public interests<sup>27</sup>. This draft had more resemblance with the conditions stipulated under the Developing Countries' draft and the EC draft rather than the US draft. It was clearly stated that working of the patented invention in the country of grant was one of the primary obligations of a patentee. Such working was seen as an essential element of the patent system and it created balance between the interests of patent owners and that of the country undertaking to protect inventions.<sup>28</sup>

<sup>22</sup>Draft Agreement on Trade-Related Aspects of Intellectual Property, Communication from the European Communities, art. 26, GATT Doc. MTN.GNG/NG11/W/68 (Mar. 29, 1990) [hereinafter EC Draft], available at <https://docs.wto.org/gattdocs/q/UR/GNGNG11/W68.PDF> (last visited on Mar. 12, 2021).

<sup>23</sup>EC Draft, art. 26: Compulsory Licences- Where the law of a contracting party allows for the grant of compulsory licences, such licences shall not be granted in a manner which distorts trade, and the following provisions shall be respected..... (4) Compulsory licenses may not be issued for non-working or insufficiency of working on the territory of the granting authority if the right holder can show that the lack or insufficiency of local working is justified by the existence of legal, technical or commercial reasons.

<sup>24</sup>Negotiating Group on TRIPS, Meeting of Negotiating Group of 14-16 May 1990, GATT Doc. MTN.GNG/NG11/21, ¶ 13 (June 22, 1990), available at <https://docs.wto.org/gattdocs/q/UR/GNGNG11/21.PDF> (last visited on March 10, 2021).

<sup>25</sup>Gatt-Uruguay Round (referring to the Chairman's Report to the GNG on the Status of Work in the Negotiating Group, GATT Doc. MTN.GNG/NG11/W/76 (July 23, 1990) [hereinafter Chairman's Draft], available at <https://docs.wto.org/gattdocs/q/UR/GNGNG11/W76.PDF> (last visited on March 10, 2021).

<sup>26</sup>The patents which require the use of another patented product or process.

<sup>27</sup>Terence P. Stewart, *The Gatt-Uruguay Round: A Negotiating History (1986-1992)*, 2274 (Kluwer Law International, 1993)[Hereinafter Gatt-Uruguay Round].

<sup>28</sup>Daniel Gervais, *The Trips Agreement: Drafting, History and Analysis*, (Sweet & Maxwell Ltd, UK 2012).

In the late 1990, the TRIPS negotiating group reached to a consensus and submitted the Brussels Draft<sup>29</sup> which reflected the observations under the Chairman's Draft. It reflected the determination of the developing countries as they could successfully persuade other states to maintain a balance between the rights and obligations for patentees. Technological and economic development remained as a yardstick for defining the principles of intellectual property and consequently many obligations were placed upon the patentee. Even though the parties never reached upon a consensus on making local working a mandatory obligation (as it was retained in brackets), it still appeared in the Brussel text:

PARTIES may provide that a patent owner shall have the following obligations:

(a) To ensure the [working] [exploitation] of the patented invention in order to satisfy the reasonable requirements of the public. [For the purposes of the Agreement the term "working" may be deemed by PARTIES normally to mean manufacture of a patented product or industrial application of a patented process and to exclude importation.

Local working as a ground for compulsory license was independently dealt and it was stated that the authorization shall not be granted in case of failure to work, [where importation is adequate to supply the local market] or if the right holder can justify failure to work or insufficiency of working by legitimate reasons. The provision read as follows:

Authorisation by a PARTY of such use (i.e. compulsory licensing) on grounds of failure to work or insufficiency of working of the patented product or process shall not be applied for before the expiration of a period of four years from the date of filing of the patent application or three years from the date of grant of the patent, whichever period expires last. Such authorisation shall not be granted [where importation is adequate to supply the local market or] if the right holder can justify failure to work or insufficiency of working by legitimate reasons, including legal, technical or economic reasons.

Without the bracketed text, the provision functionally resembled article 5A (4) of the Paris Convention on permitting a grace period of three-four years before issuing compulsory license. However, incorporation of the bracketed text is significant to the ground of issuing compulsory license in the sense that the failure to work a patent locally (manufacture it locally) would not trigger compulsory license if by importation, local market needs are taken care of. In effect, a substantial change in consequences was noticed from the Paris Convention in the event of failure to work. To summarize the Brussels draft, 'working' was understood as local manufacture of the patented invention and it was imposed upon the patentee as an obligation for conferring the exclusive patent rights. Yet, compulsory license may not be issued in case where importation of a patented product/process could satisfy the local market requirements. In effect, two different standards of interpretations were suggested

<sup>29</sup>Supra note 27 at 2275 (noting the submission of the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN.TNC/W/35/Rev.1 (Dec. 3, 1990) [hereinafter Brussels Draft].

for working/non-working of patents. This issue remained unsettled and in brackets as the negotiating groups failed to reach a consensus even during the following Uruguay rounds.

With pressure to conclude TRIPS agreement and no finality on issues, Arther Dunkel, the Director-General of the GATT and the Chairman of the Trade Negotiating Committee, in his paper suggested that the parties should not determine the availability of patent on the basis of whether the product is locally manufactured or imported.<sup>30</sup>This suggestion led to the complete elimination of the discussion with respect to local working requirement in context of granting of patent and introduced the 'non-discriminatory clause' which is now seen in TRIPS.<sup>31</sup>The introduction of non-discrimination clause for patented inventions failed to properly address the negotiating groups' actual issue: whether importation can be seen to satisfy local working in lieu of local manufacturing. It also failed to represent the negotiated consensus between the countries on rights and obligations of the patentee in any way. As it turned out, the arbitrated draft at the end that had nothing to do with disputed interpretation on local working and rather obliged the member countries from not discriminating between locally produced and imported patents while granting patents. A hard-hitting inference is ultimately that the developing countries couldn't succeed in making local manufacturing a necessary obligation for the patentee and what constitutes local working still remains a puzzle.

#### *'Local working' under TRIPS agreement*

As previously stated, as per TRIPS agreement, no member country can insist local manufacturing to confer patent rights<sup>32</sup>. It has been argued by many countries that article 27 (1) of the TRIPS precludes any member country from making any laws mandating the local working of the patents. In order to understand the objectives of the TRIPS agreement, article 27 (1) should be read in conjunction with other provisions which not only lay down the objectives but also emphasize upon the social and economic significance of intellectual property rights. Article 7 of the agreement states that promotion of technological innovation and technology transfer should be the result of protection and enforcement of intellectual property rights.<sup>33</sup> Such technology transfers while creating a balance of rights and obligations should be for the mutual advantage of the private interest of the patent holder and the society in a manner which is beneficial to the social and economic welfare. Article 8(1) allows member countries to take necessary measures to advance the public interest in sectors of vital

<sup>30</sup> *Supra* note 25 at 2279.

<sup>31</sup> TRIPS Agreement, art. 27(1): Patentable Subject Matter- patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

<sup>32</sup> TRIPS Agreement, art. 27(1) Patentable Subject Matter

Subject to the provisions of paras 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to para 4 of art.65, para. 8 of art. 70 and para. 3 of this article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

<sup>33</sup> TRIPS Agreement, art. 7 Objectives: The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.



importance to their socio-economic and technological development.<sup>34</sup> Correspondingly, article 8 (2) provides the member countries to assume measures to prevent the abuse of intellectual property rights by right holders or the resort to unreasonable practices which may restrain trade or adversely affect the international transfer of technology.<sup>35</sup> To balance out the exclusivity of the patent rights conferred, the agreement also provides for limited exceptions under article 30.<sup>36</sup> It has also been provided that these exceptions while taking account of the legitimate interests of third parties should not unreasonably conflict with a normal exploitation of the patent and unduly prejudice the legitimate interests of the patent owner.

It is clear that article 27(1) is not an independent clause. The assertion that article 27 is a general principle and hence free from the exceptions stipulated under articles 30 or 31 would be negating the legal principles of construction on the face of it.<sup>37</sup> In spite of numerous debates, it is obvious that articles 7, 8 and 30 of the TRIPS guide the operation of article 27 (1) of the TRIPS. In case it had to be interpreted otherwise, the objectives of the agreement will hold no significance. The intent and the objectives have a sweeping effect over the entire provisions of the agreement. Moreover, to clear any ambiguity towards the interpretation of article 27 (1) of the TRIPS, a reference to article 2 of the TRIPS becomes imperative since it makes Paris convention a part of TRIPS and compliance to it mandatory.<sup>38</sup> Thus, the interpretations of articles in the Paris Convention should be used to put an end to any ambiguity that exist in TRIPS articles regarding similar issues. Accordingly, in the context of interpreting local working requirements, it is important to look into the meaning implied by the Paris Convention as well as the *travaux preparatoires* of the TRIPS agreement as discussed previously.

### III. LOCAL WORKING AND COMPULSORY LICENSING UNDER PATENT ACT, 1970

Chapter XVI of the Patent Act deals extensively with the concept of working of patents, compulsory license as well as revocation of patents. Section 83 is the guiding principle regarding the interpretation of local working requirement under the Act. The two-fold objectives stipulated in TRIPS agreement are reinstated as it states that the patent laws should

<sup>34</sup> TRIPS Agreement, art. 8(1) Principles: 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

<sup>35</sup> TRIPS Agreement, art. 8(2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

<sup>36</sup> TRIPS Agreement, art. 30 Exceptions to Rights Conferred: Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

<sup>37</sup> The rule of legal construction *lex specialis derogate legi generali* establishes that where a general legal provision conflicts with specific provision, the specific legal provision takes place. In the present context, the generality of art. 27 is over-ridden by arts. 30, 31 in any contravening scenario.

<sup>38</sup> TRIPS Agreement, art. 2 (1) Intellectual Property Conventions  
In respect of Parts II, III and IV of this Agreement, Members shall comply with art. 1 through 12, and art. 19 of the Paris Convention (1967).

encourage invention along with securing commercial working of the patented invention within the country to the extent reasonably practicable.<sup>39</sup> The provision also emphasizes on the patent law's purpose for the promotion of technology innovation, technology transfer and prevention of abuse of patent rights which unreasonably restrain international transfer of technology.<sup>40</sup> It has also been categorically stated that the patent exclusivity granted to the right holders should not be limited to the importation of the patented article in the country.<sup>41</sup> This provision paves way for requiring the patentees to ensure local working of the patented invention within the country.

The grant of compulsory license has been dealt under section 84 as per which, a person may make an application to the Controller after expiration of 3 years from grant of patent for the following grounds:

- a) reasonable requirements of the public with respect to the patented invention have not been satisfied,
- b) patented invention is not available to the public at a reasonably affordable price, or
- c) patented invention is not worked in the territory of India.<sup>42</sup>

It is clear that not working of a patented invention within the territory is a specific ground for issuing compulsory license. Clause (7) of section 84 elaborates the different circumstances as per which it shall be comprehended that the reasonable requirements of the public are not met. Amongst them, the condition having bearing with local working is the one whereby which, unless the patent has been worked in India on a commercial scale to a reasonably possible adequate extent, it shall be understood that the reasonable requirements of the public are not met.<sup>43</sup> Further, it is stated that reasonable requirement of the public will also be deemed to have been not met in case commercial working of the patented invention within the territory is hindered solely by way of importation of the patented article. It is pertinent to note that importation of patented article to India has not been expressly barred and to such extent, this provision is in line with the 'non-discrimination' requirement under TRIPS. It is only when such importation results in the prevention or hindering of working of the product within India that it would be deemed that reasonable requirement of public is not met.

Section 84(6) stipulates different conditions to be considered by the Controller while examining applications for compulsory license. Amongst other things the Controller shall

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<sup>39</sup>Patents Act, 1970, s. 83(a) General principles applicable to working of patented inventions. -Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely; -(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay.

<sup>40</sup>Patents Act, 1970, s. 83(c)& (f).

<sup>41</sup>Patents Act, 1970, s. 83 - Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely; - (a).....; (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

<sup>42</sup>Patents Act, 1970, s. 84(1).

<sup>43</sup>Patents Act, 1970, s. 84(7)(d).

look into the nature of invention; measures taken by patentee/ licensee to make full use of the invention; applicant's ability to work the invention to the public advantage *etc.* The Controller shall also consider on merits the efforts taken by the applicant to obtain a license from the patentee on reasonable terms and conditions. However, this requirement may be done away with during contingencies such as that of national emergency, extreme urgency, public non-commercial use or establishment of anti-competitive practices by the patentee.<sup>44</sup> In such circumstances, an applicant will not be required to establish the efforts taken to receive a license from the patentee. Further, even after the grant of compulsory license, a patent can be revoked on the grounds of non-working, not meeting the reasonable requirements of the public or non-availability of the patented invention on a reasonably affordable price.<sup>45</sup> The Controller has also the power to adjourn the hearing of application for compulsory license on the ground of non-working or as per section 84(7)(d), if he is satisfied that the time elapsed after sealing of patent was by any reason insufficient to work the invention on a reasonable possible commercial extent.<sup>46</sup> As per section 89, the Controller shall exercise his powers while dealing with an application on compulsory license to secure the commercial working of an invention to the fullest extent which is reasonable possible. Additionally, one of the primary conditions for compulsory license under section 90 is that the person to whom such license is granted shall work the invention to the fullest extent practically possible. An understanding of all these provisions make it clear that patent law requires the patented article to penetrate into the commercial setup of the country to the extent as far as possible. Theoretically, all these provisions *in toto* depict the seriousness of the Act regarding the local working requirement of patented invention.

As regards the procedural aspect of implementing local working provisions', section 146 (1) is the enabling provision as per which the Controller can ask for information or periodical statement from the patentee or licensee (exclusive or otherwise) regarding the commercial working of the patent in India and the same has to be furnished within 2 months.<sup>47</sup> Further, Rule 131(2) of the Patent Rules 2003 (hereinafter Rules) requires the statements under section 146(2) to be furnished within 3 months of the end of every calendar year. Rule 131(1) prescribes that the information on the commercial working should be filed under Form 27. Even though the Form deals with the critical issue of determining commercial working of a patent, the lack of clarity in the approach and ambiguities has led to serious confusions. It

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<sup>44</sup>Patents Act, 1970, s. 84(6).

<sup>45</sup>Patents Act, 1970, s. 85.

<sup>46</sup>Patents Act, 1970, s. 86(1).

<sup>47</sup>Patents Act, 1970, s. 146: Power of Controller to call for information from patentees - (1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.

(2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.

(3) The Controller may publish the information received by him under sub-section (1) or sub-section (2) in such manner as may be prescribed.

was after filing of a public interest litigation<sup>48</sup> by Prof. Shamnad Basheer, that the Office of the Controller General of Patents, Designs & Trademarks (Controller) invited comments and conducted stakeholder meetings for procedurally overhauling Form 27. In 2019, a revised Form 27 was published by the Department for Promotion of Industry and Internal Trade (DIPP). The proposed revisions sought to address some of the existing ambiguities with respect to the details which are required to be filed in the Form 27. After a series of backlashes/scrutiny by people from all fields including academicians, Form 27 has been revised and officially notified by the Patent (Amendment) Rules 2020<sup>49</sup> (Amendment).

Prior to the recent notification, Form 27 mandated disclosure of the following information:

- i. whether the invention has been worked;
- ii. if not worked, the reasons for not working the invention, and the steps being taken to work the invention;
- iii. if worked, quantum and value (in rupees) of the patented product:
  - manufactured in India,
  - imported from other countries, giving details of the countries concerned;
- iv. licenses and sub-licenses granted during the year;
- v. whether the public requirement has been met, at a reasonable price either partly, adequately or to the fullest extent.

As per the previous Form 27, a patentee or the patent licensee had to explain the reasons for not working of the patent along with the steps taken to make that invention work in the territory, even if the patent is not commercially worked in India. Additionally, in case of importation of patented products, country-wise information regarding the details from where it is being imported is sought in the Form. Legal sanctions have also been specified in the event of failure/refusal to file or providing false information in the form. A patentee may in such case be subject to either paying a fine extending to INR 10 lakhs or imprisonment upto six months or both.<sup>50</sup> The information received by the Controller under Form-27 is to be published as per section 146(3) read with Rule 131(3). The publication of such information assumes significant importance as it relates to different aspects of patent which is granted ranging from the quantum and value of the patented product, country of import, number of licensees, etc. and therefore it has been contended by the patentees that such information should remain confidential. However, this disclosure of information related to commercial working is with the purpose of keeping the Controller abreast about the commercial status of a patent within the country especially because non-working of a patent is one of the principal

<sup>48</sup>W.P.(C) 5590/2015, CM No. 10090/2018

<sup>49</sup>Ministry of Commerce & Industry, Department for Promotion of Industry and Internal Trade, G.S.R. 652(E), (19<sup>th</sup> October 2020).

<sup>50</sup> Patents Act, 1970, s. 122(1): Refusal or failure to supply information -If any person refuses or fails to furnish- (a) to the Central Government any information which he is required to furnish under sub-section (5) of sec. 100; (b) to the Controller any information or statement which he is required to furnish by or under s. 146, he shall be punishable with fine which may extend to [ten lakh rupees]; s. 122 (2) - If any person, being required to furnish any such information as is referred to in sub-section (1), furnishes information or statement which is false, and which he either knows or has reason to believe to be false or does not believe to be true, he shall be punishable with imprisonment which may extend to six months, or with fine, or with both.

grounds for seeking the grant of a compulsory license under patent law. The availability of such data can eventually open up opportunities for involved parties which may seek the grant of compulsory licenses on account of non-working of patents. This is especially important in the areas of public health or national emergency. However, it should be understood that a complete non-disclosure shall not encourage the mechanisms related to the grant of compulsory licensing in the event of failure of local working.

In contrast with the old form, the Amendment distinguishes between the disclosure requirements for both product and process patent. It removes the assessment required on 'quantum of patented product' and instead focuses on the value (INR) accrued from both manufacturing and importation into India. The Amendment also does away with submission of country details from where the product has been imported or the process carried out. In cases where the product is covered with multiple patents and the value accrued from a particular patent is not deducible separately, the patentee can provide combined value accrued from all the related patents. The Amendment also eliminates the requirement of showing the steps being taken by the patentee in case of failure to work. Finally, the patentee need not provide any statement on 'whether the public requirement has been met partly/adequately/to the fullest possible extent at reasonable price' which may be best assessed in a judicial proceeding rather than by the patentee himself. These alongwith few other amendments in the Form 27 indicate the serious approach of the Indian government on assessing more properly the commercial working of a patent. Even prior to this amendment of Form 27, the Controller in 2009 had issued a notification directing the disclosure of all relevant information regarding commercial working of the patent mandatory for all the patentees or patent licensees. Any failure to comply with this order attracts punitive provisions as stated under section 122. A similar notification was again issued in 2014 appealing to the patentees to comply with the directions under section 146 of the Act. It is clear that the repeated notifications by the Patent Office as well as the amendment to Form 27 emphasize the patentees to strictly comply with the procedure of submitting necessary information regarding commercial working of patent in India. Such information has a dynamic utility for determining the applications for issuing compulsory license or even for approaching the patentee for a license/assignment over the said patented article. It will also be surely relied upon during litigation process to assess whether or not a patent has been commercially worked in the country or not. For instance, in India's first ever grant of compulsory license in the decision of *Bayer v. Natco*<sup>51</sup>, both the Patent Office as well as the Intellectual Property Appellate Board (IPAB) relied heavily on the information provided by the patentee (Bayer) on the commercial working of its drug- Nexavar. It was held that the product, locally failed to work because of low affordability, accessibility and availability. The Hon'ble Supreme Court went beyond the requirement of manufacturing in India and empirically determined the availability of the drug based upon its price, dose and usage per patient. It was observed that the grant of compulsory licenses due to failure to work accrued specifically because of lesser affordability considering the quantum of requirement of the drug.

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<sup>51</sup>*Bayer Corporation v. NatcoPharma Ltd.*, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai).

#### IV. LOCAL WORKING MANDATE IN FOREIGN JURISDICTIONS

The Brazilian patent law was challenged by the US as being discriminatory against the US owners of Brazilian patents whose products were imported into but not locally produced within Brazil.<sup>52</sup> Article 68 of Brazil's Industrial Property Law authorizes the government to grant compulsory license if the patent owner does not manufacture the product in the territory of Brazil within three years of the patent grant.<sup>53</sup> A plain reading of article 68 does imply violation of TRIPS agreement, yet the question to be determined was whether the law is permissible under any of the exceptions under articles 30 & 31 of the agreement. The invention on which license was granted were two anti-retro virals Efavirenz and Nelfinavir needed for treating HIV-AIDS. Brazil took a stand that either they should be allowed to grant the license or the medicines should be made available in the country at 50% discount. The case was however dropped with the claim that the United States sought to protect their intellectual property without sabotaging the measures to combat HIV-AIDS.

#### V. COMPETITION LAW'S NEXUS WITH COMPULSORY LICENSING

Extending the realm of competition law to intellectual property is still an area that requires major attention. As an overly simplistic view, it is understood that there is an inherent conflict between these two branches of law. While intellectual property laws such as that of patents grant exclusivity, competition law policies seek to ensure a competitive market place, conducive to the consumer's interests. The exclusivity granted to a holder of intellectual property has the potential to cause competition concerns by creating entry barriers, refusing to deal agreements and abuse of market power all of which are explicitly prohibited by competition law. This interpretation however is short-sighted as the common objective of encouraging innovation and enhancing consumer welfare runs through both these set of laws. In fact, there is plethora of academic literature recognising the complementary nexus between all sorts of intellectual properties and competition law.<sup>54</sup> In an economic sense, intellectual property rights may not be necessarily be monopolistic in nature as there may be similar competitive products in the market. Accordingly, the realm of competition law policies does not *per se* concern itself with prohibiting exclusivity; it only aims to prevent the misuse or the abuse arising out of such exclusivity. Therefore, these two set of laws are invariably complementary to each other.

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<sup>52</sup>Chia Ling Lee, "The legality of local patent working requirements under the TRIPS agreement" 2 (1), *NTUT Journal of Intellectual Property Law & Management* 39-48 (2013).

<sup>53</sup>Brazil Industrial Property Law 1996, art. 68: para. 5 - A compulsory license under para. 1 may only be requested if 3 (three) yearshave elapsed since the patent was granted (emphasis supplied).

<sup>54</sup>Micheal A Carrier, "Innovation for the 21<sup>st</sup> Century: Harnessing the Power of Intellectual Property and Antitrust law", (Oxford University Press, New York 2010); J Newberg and T Willard, "Antitrust and Intellectual Property: From Separate Spheres to Unified Fields" 66 *Antitrust LJ* 167 (1997); Tom and Newberg, "Antitrust and Intellectual Property: From Separate Spheres to Unified Field" 66 *Antitrust LJ* 167 (1997-98); Jacob, "Competition Authorities Support Grasshoppers: Competition Law as a Threat to Innovation" 9 *Competition Policy International* 15 (2013).

In spite of the possible co-existence of these laws, a lot is being deliberated on the extent to which an intellectual property owner can be compelled to grant a license to third party. A generally acceptable proposition is that such an owner is entitled to determine the nature and extent of exploitation of the intellectual property and imposition of compulsory license should be limited to exceptional circumstances. Even under the TRIPS agreement, the member countries are allowed to enact legislations restricting such licensing practices of intellectual property rights that may possibly restrain trade or affect competition negatively.<sup>55</sup>

As already stated, in India, the provision relating to the compulsory license under the Act was first applied in the case of *Natco v Bayer*<sup>56</sup> in relation to Bayer's patented anti-cancer drug Nexavar (*sorafenib tosylate*). The Controller observed that all the three grounds of stipulated under section 84 were satisfied under this case. Accordingly, a compulsory license was granted to Natco for the manufacture and sale of Nexavar for the remaining term of the patent. With respect to the grounds (i) and (ii) of section 84, it was understood that the drug Nexavar due to its high price, was affordable to only roughly 2% of the total potential patients. However, a lot of furore was created due to this decision in the intellectual property community in respect of application of ground (iii) *i.e.* 'the patented invention is not worked in the territory of India' in the instant matter. The implication of such an interpretation by the Controller is that the patented invention must be manufactured in India to reasonable extent or that the license must be granted by the patent holder to third parties to manufacture the patented invention in India. In other words, even if solely by means of importation, a patented invention satisfies the reasonable requirements of the public at affordable price, it may still be subjected to compulsory license.

Other than the decision of *Natco v Bayer*, which was dealt categorically under the Act, the Competition Commission of India (CCI) also dealt with the issue of refusal to license intellectual property rights in the decision rendered in *MCX Stock Exchange Ltd. & Ors vs National Stock Exchange Of India*<sup>57</sup> and *HT Media v. Super Cassettes Industries Ltd*<sup>58</sup>. Even though these cases did not pertain specifically to the pharmaceutical sector, the common thread of a potential competitor's voluntary request being denied by the intellectual property right holder runs through all of these cases.

It is pertinent to note that there is no express provision regarding grant of access of intellectual property as a remedy for abuse of dominance through refusal to license, under the Competition Act 2002 (Competition Act). Having stated that, there are some provisions indicating the possibility of permitting access to intellectual property rights within the existing framework of the competition statute. As per section 4(2)(c), denial of market access by dominant enterprise may constitute abuse of dominance. Accordingly, as a general interpretation, the market access in relation to products protected under the intellectual

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<sup>55</sup>TRIPS Agreement, art. 40.

<sup>56</sup>Supra note at 51.

<sup>57</sup>CCI, Case No. 13/2009.

<sup>58</sup>CCI, Case No. 40 of 2011.

property regime and its licensing may be included in this provision. Further, under the section 27 of the Competition Act, CCI has the power of inquiry into agreements or abuse of dominant position and pass orders. Accordingly, CCI can direct enterprises and person involved in abuse of dominance to discontinue and desist from such activities in the future. Further, under section 27 (g) of the Competition Act, CCI has very wide power to pass an order of any nature as it may deem fit. This can be the power which may be used by CCI to provide access to IPRs to avoid abuse of dominance in exceptional cases.

In recent cases, it has also been observed by the courts that the issuing compulsory license under the Act and preventing anticompetitive practices under the Competition Act are not entirely in exclusion of each other, and rather they have to be read in conjunction with each other. In *Telefonaktiebolaget LM Ericsson v. CCI*<sup>59</sup>, the Delhi High Court observed that in cases where CCI has found a patentee's conduct to be anticompetitive and its decision has reached finality, the Controller can also proceed on the said basis and the patentee can be estopped from contending otherwise. However, even though there is no irreconcilable repugnancy between the two legislations, it cannot be necessarily stated that the provisions under Competition Act, explicitly guarantee access to the patented products, which otherwise fall under the purview of the Act. In other words, a remedy to address abuse of dominance may not include access to patented products. In such circumstances, it becomes imperative to establish boundaries for determining abuse of dominance by an enterprise due to refusal to license. While in such cases, where competition law comes to an aid, CCI has to tread cautiously as it may lead to different ramifications in various cases as the remedy of issuing compulsory license falls squarely under the Act.

## VI. CONCLUSION

For developing countries like India, signing up international agreements for the protection of intellectual property rights is not just limited to the goal of safeguarding monopoly rights. These also provide an opportunity to maximise technology transfer. In health sector, the local firms are also encouraged to compete and improve innovations. Further, encouraging patent laws just to enable foreign companies to import in a particular jurisdiction but not use it for fostering technological development seems to fall short on the very objectives of the law. India has accordingly made use of the flexibility under the TRIPS agreement in the context of local working requirement as a ground for compulsory licensing. Both the substantive and procedural conditions on local working clearly indicate that it has been regarded as a fundamental obligation for patent holders. Even though some countries<sup>60</sup> diluted this concept to include importation, ensuring a patented article's local manufacture or application has significant impact on the long- term growth of the economy of the patent granting country. National working of a patented invention has the potential to hit to the socio-economic goals of the particular country such as industrial and technological development, creation of job

<sup>59</sup>W.P.(C) 464/2014 & CM Nos.911/2014 & 915/2014; Also see,*Koninklijke Philips Electronics v. Rajesh Bansal*(12.07.2018 – DELHC): MANU/DE/2436/2018.

<sup>60</sup> The countries such as Australia, Hungary, South Korea and Mexico treated importation to satisfy local working requirement.



opportunities, production of more and more competitive goods, economic sovereignty, and thereby promoting general welfare. Though importation of patented product would satisfy the local working requirement both under the TRIPS as well as the Indian Patent Act, 1970, it serves only as an exception and not as a general rule. Further, in relation to competition intervention, it should be limited to cases where the dominance of an enterprise is undisputable and no other remedy is available to harmonise the interests of the stakeholders. This is all the more important in the cases of where access to healthcare is in question. Unwarranted intrusions under the Competition Act may lead to curbing of social inequality rather than protecting and promoting a competitive economic environment which otherwise is the primary goal of the legislation.