

# PICKET PATENTS: NON-WORKING AS AN IP ABUSE

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**ABSTRACT:** *Patents picket when the patent holder practices the patent in certain jurisdictions but refuses to work the patent in others. The concept of patent picketing developed as a result of a shift from the representation of the working of an invention physically to the merely describing, effectively, the inventions in patent applications. Patent holders picket with their patents and demand a higher price, thereby not only preventing others from using their invention but also ensuring that the product is not made available in all markets. Such behaviour can be regarded as an intellectual property (IP) abuse when the non-working of a patent leads to deprivation of another patent locally. The issuance of a market-initiated compulsory licence may solve the problems linked with IP abuse arising out of patent picketing.*

## I. INTRODUCTION

The history of patent law notes the metamorphosis of the discipline that supported, though the ages, the nation's quest for self-development. In the early times, the chief aim of the patent system was to encourage industrialization. Patents were granted by nations to develop their natural resources and increase their technical and manufacturing capabilities.<sup>1</sup> In the medieval era, English patent law, the predecessor to the United States', granted privileges with the sole objective of "instructing the English in a new industry."<sup>2</sup> Immigrant weavers, clockmakers, miners, and manufacturers of silk and salt were encouraged to move to England and benefit from the Crown's power to grant privileges for public goods. However, early grant of privileges, in the form of monopoly licences, came with some restrictions. For

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<sup>1</sup> Edith TILTON PENROSE, *THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM* 137 (1951).

<sup>2</sup> E. Wyndham Hulme, *History of the Patent System Under the Prerogative and at Common Law*, 12 L. Q. REV. 141, 142 (1896).

instance, a licence to manufacture white soap not only required the wares to be inspected by the municipal authorities to see if they were as good as those made in Spain, but was also accompanied by a threat of the privilege being rendered void on proof of defective manufacture.<sup>3</sup> In medieval England, there was great emphasis on working the privilege locally and affordably, as is evident from the licence granted to immigrant makers of ovens and furnaces that stipulated that the grant would be void if the patentees failed to practice the grant within two months or proved to be extortionate in their charges.<sup>4</sup> During these years, the grant of patent-like privileges was focused on rewarding creative labour embodied in the subject matter of the manufactured good.<sup>5</sup> Patent specification—the art of technically ‘embodying’ the invention in writing—was yet to appear on the scene.<sup>6</sup>

Things were, however, set to change soon. In the modern era, attention shifted away from the creative labour embodied in the manufactured product or process—the material embodiment—to concentrate more on the description of the creative labour in writing—the textual embodiment. Thus, as a consequence of the implementation of a registration system for patents, mental labour that produced the artifact was sidelined and prominence was given to paper inscriptions that the system produced.<sup>7</sup> By making the patent specification an end in itself, “registration radically changed the nature of the way the law dealt with intellectual property.”<sup>8</sup>

Though the new registration system provided a stable reference point to ascertain the identity of the intangible, it also allowed patentees to secure exclusive rights by the mere demonstration of the invention in writing. This created a practice that focused exclusively on the ways in which documents were drafted, registered and interpreted.<sup>9</sup> Patentees enjoyed exclusivity by

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<sup>3</sup> *Id.* at 145.

<sup>4</sup> Hulme, *supra* note 2, at 146. In 1565, a special mining licence granted to German miners by the Queen of England was challenged by the Earl of Northumberland on the ground that work was within the Royalties granted to his family in the earlier reign. The Earl lost the case on the ground of neglect of the Earl’s family to work the minerals for seventy years. *Id.* at 147.

<sup>5</sup> Hulme, *supra* note 2, at 145 (describing an early grant for the manufacture of saltpeter that required the “secrets of manufacture” to be reduced in writing before payment of the promised reward of £300).

<sup>6</sup> RICHARD MILLER ET AL., *TERRELL ON THE LAW OF PATENTS* 9 (17<sup>th</sup> edn., 2011) (ascribing the emergence of modern specification in England to the Patent Law Amendment Act of 1852).

<sup>7</sup> BRAD SHERMAN & LIONEL BENTLY, *THE MAKING OF MODERN INTELLECTUAL PROPERTY LAW: THE BRITISH EXPERIENCE, 1760-1911*, 181–82 (1999).

<sup>8</sup> *Id.* at 182 (noting that the reduction of intellectual property to a paper inscription helped to overcome the difficulties of space and distance, i.e., those created by the size of buildings occupied by the Registry and those generated by the centralization of the Registers).

<sup>9</sup> *Id.* at 186.

creating documents that complied with the administrative requirements set by the patent office. The harmonization of patent laws of different countries also consolidated the central role of specification.<sup>10</sup> The issue of manufacturing the artifact as it existed earlier and that of working the invention were gradually removed from the newly emerging confines of modern patent law.

The focus on patent specification led to some interesting consequences in the behaviour of patentees. In some cases, patentees could file specifications without any ability or intention to manufacture the product. By doing so, these non-practicing entities (NPEs) used patents as instruments to stop others from doing something which they never did or would do. Though the NPEs restricted others from working the invention, they did not pose an unsolvable problem. They filed infringement suits with the chief objective of seeking higher royalties.<sup>11</sup> The consequence of not working the invention was manageable as these suits were filed against entities that were practicing the artifact covered by the NPE's patent. Non-working of inventions, however, posed a greater problem when patents crossed borders.

Harmonization of patents laws, though modest in its impact, gave an impression that modern universal patent laws did not require patents to be worked locally. The patentees who benefited from harmonization could now secure exclusive rights through which they were free to practice in the countries of their choice. This allowed patentees to use their patents in protest. The practicing entity in one country, for instance the United States, could be a non-practicing entity in another country, thus allowing the patent holder to extract a higher rate of compensation in the country where the patent holder did not practice its patent by refusing to supply or allow others to produce, or by extracting licence terms that benefited its purposes, such as licences allowing production for domestic use and not for export. Patent holders could now picket with their patents, seeking a higher price: a conduct by which they could not only stop others from using their invention, but also, in contrast with the NPE situation, ensure that the invention was not at all available in a given market. The problem of patents that picket emerged as a new situation, where entities that practised their inventions in some jurisdictions refused to practice them in others.

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<sup>10</sup> HAROLD C. WEGNER, *PATENT HARMONIZATION* 23–24 (Sweet & Maxwell, 1993) (describing the creation of a worldwide procedural treaty, the Patent Cooperation Treaty of 1970 as an important tool for patent applicants as it allowed simultaneous filing of applications in multiple locations).

<sup>11</sup> *But cf.* Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 *TEX. L. REV.* 1991 (2006–2007) (reporting that existing patent remedies systematically result in excessive royalties).

Patent picketing is a problem that arises when patents are voluntarily not worked in some jurisdictions (mostly developing countries) while they are worked in others (mostly developed countries). Though picketing by patents is most commonly used in the pharmaceutical industry, there could be instances of picketing in other industries as well. The author shall limit the scope of this paper to only the pharmaceutical industry.

The impact of picketing, in the pharmaceutical industry, was felt when Bayer's patented drug, Nexavar, was not worked locally and consequently became the subject matter of a compulsory licence in 2012. Though the scholarship that emerged highlighted the significance and controversies involved in the issue of the compulsory licence,<sup>12</sup> it failed to note that the resulting response was as unique as the problem that evoked it.

When patents picket, countries have an option of issuing a market-initiated compulsory licence, as was done by India in issuing such a licence on Nexavar. Market-initiated compulsory licences are a distinct class of compulsory licences which can be issued at the request of a private party in the absence of a health emergency. Compulsory licences on patents have been regarded as a response to the abuse of a patent right, which amounts to an Intellectual Property (IP) abuse. Though the absence of local working (or non-working) of patents is historically treated as an abuse, it may be difficult to justify the local working in a global economy built on free trade, especially when the final word on international patent law, the TRIPS Agreement, is silent about it. Taking a cue from antitrust law, in part I of this article, I offer a rule-of-reason-like justification for treating the absence of local working as an abuse: not all patents are required to be worked locally but only those, the non-working of which leads to an abuse, i.e., where it leads to the deprivation of benefit locally. Part II of the article looks into the manner in which patent picketing leads to contempt of the patentee's obligation to work his invention, thereby resulting in a shift in focus from the material embodiment of the invention in the product to the textual embodiment of the invention in the specification. This part further discusses in detail the way in which the concept of local working has developed in different countries and the relevance of local working of a patented invention. Part III draws parallels to antitrust law to redefine picketing as an abuse of the patent system and advocating the issuance of compulsory licences by the affected country. The paper finally concludes with an analysis of the benefits of market-initiated compulsory licences as a means to end the abuse of patents due to picketing.

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<sup>12</sup> See, e.g., Betsy Vinolina Rajasingh, *India's First Compulsory Licence over Bayer's Patent*, JIPLP BLOG (May 10, 2012), <http://jiplp.blogspot.com/2012/05/indias-first-compulsory-licence-over.html?m=1>.

## II. PICKET PATENTS: THEY WON'T WORK, THEY WON'T LET OTHERS WORK

Like other Intellectual Property (IP) rights, patents attempt to balance its power of exclusive rights to stimulate the creation of inventions on the one hand and its tendency to curtail widespread public enjoyment of the inventions on the other.<sup>13</sup> This balancing act has affected the way in which a patent is perceived. Is it an absolute right that mysteriously ceases at the end of its term? Or is it a contingent right awaiting a challenge to its validity? Are there any accompanying obligations? Some of these pondering debates pertain to the rights and obligations conferred by a patent. Patents confer a bundle of rights which allow the patentee to exclude others from using, and to permit others to use by way of licence, its invention.<sup>14</sup> They also cast certain obligations on the patentee such as the obligation to make an enabling disclosure.

### A. Patent as a Right

During the Elizabethan era, English patent law regarded the exclusive right of sale as the right subsequent to and derived from the sole right to manufacture.<sup>15</sup> The emphasis on manufacturing can be noticed from the inclusion of 'working clauses' in the grants, which required the patentee to practice the grant on the threat of revocation of the privilege.<sup>16</sup> Most of the early grants of privilege were in the form of manufacturing privileges, though there were few instances of privileges given for facilitating importation as well. The evolution of patent law in England shows that the exclusive right to use or stop others from using emerged from and was dependent on the exclusive right to manufacture. This understanding is, however, at variance with the contemporary exclusivity-centric understanding of patents.

Contemporary legal literature regards patent as a negative exclusionary right, a right that does not require the patentee to do anything but can nevertheless be effectively used to restrain others from doing things covered

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<sup>13</sup> William Fisher, *Theories of Intellectual Property*, in *NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY* 168, 169 (Stephen R. Munzer ed., Cambridge University Press, 2001).

<sup>14</sup> Thomas C. Grey, *The Disintegration of Property*, in *PROPERTY: NOMOS XXII* 69 (John W. Chapman & J. Roland Pennock eds., New York University Press, 1980) (describing patents as a bundle of rights).

<sup>15</sup> Hulme, *supra* note 2, at 153.

<sup>16</sup> Hulme, *supra* note 2, at 153 ("Apart from the frequent insertion of clauses regulating the period within which the new industry was to be introduced, it is obvious that prior to the rise of the patent specification a privilege became void owing to non-working within the reasonable period on the ground of want of consideration.").

by the patent.<sup>17</sup> By this characterization, a patentee is not required to work the patent at all: a patentee can, in fact, receive a patent for the prospect of working the invention in the future.<sup>18</sup> Whether or not the patentee works the invention commercially, manufactures or utilizes the technology covered by the patent is not a concern of patent law.<sup>19</sup> In short, there is no expectation that the invention be worked or practised, though there is a stress on the fact that the invention works.<sup>20</sup>

Patents confer the right to exclude others from making, using, offering for sale or selling the invention throughout the country, or importing the invention into the country.<sup>21</sup> They were considered as property rights due to the characterization of the patent as a right to exclude.<sup>22</sup> The right in a patent mimicked the right in real property in certain ways.<sup>23</sup> There were some benefits in this characterization; it immediately relieved the patentee from the responsibility of working the invention, a boon for technologies which have a long gestation period and for technologies like pharmaceuticals that require regulatory approval before marketing their products. However, there was some harm too. Entities could now patent technologies without any desire to practice or produce them and hold the real manufacturers for a ransom, a conduct that has earned these entities the title of ‘non-practicing

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<sup>17</sup> ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 48–49 (5<sup>th</sup> edn., 2011) (“Unlike other forms of property, however, a patent includes only the right to exclude and nothing else. Patents rights are wholly negative rights — rights to stop other from using — not positive rights to use the invention.”).

<sup>18</sup> *But cf.* Edmund W. Kitch, *The Nature and Function Of The Patent System*, 20 J.L. & ECON. 265, 266–67 (1977) (propounding the “prospect theory”, that patent system performs a hitherto unknown function of awarding exclusive and publicly recorded ownership of a prospect shortly after the discovery, and noticing the grant of many technologically important patents in America long before their commercial exploitation became possible).

<sup>19</sup> But the right to use an invention could become the concern of other laws. *See, e.g., Whistler Corpn. v. Autotronics Inc.*, 1988 US Dist. LEXIS 17302, at 4 (observing that incongruity of asking a court of law through an infringement suit to protect a device (a radar detector) used to circumvent the law (of the states that banned the use of such devices)).

<sup>20</sup> The ‘working’ of an invention refers to the fact that the invention is put to practice or made available to the public. This is different from the fact that the invention works. No patent would be granted for an invention that does not work. The requirement of enablement in patent law is one technique that requires the inventor to describe her invention clearly for a person skilled in the art to make and use it. *See* 35 U.S.C. § 112(1).

<sup>21</sup> *See, e.g.*, 35 U.S.C. § 154(a)(1).

<sup>22</sup> *But cf. Kaiser Aetna v. United States*, 62 L Ed 2d 332: 444 US 164, 176 (1979) (describing the right to exclude as “one of the most essential sticks in the bundle of rights that are commonly characterized as property”).

<sup>23</sup> *But cf. Gilbert H. Montague, Proposed Patent Law Revision*, 26 HARV. L. REV. 128, 133 (1912-1913) (“Owners of unimproved land cannot be compelled to improve their property, nor — except by eminent domain — to allow others to improve it. Similarly, the patent owner cannot be compelled to use his invention, nor — except by eminent domain — to allow others to use it.”).

entities'.<sup>24</sup> The negative characterization also allowed entities to refuse to licence their technology to parties who needed it, as there was no obligation to permit that which came with the right to exclude.<sup>25</sup>

When characterized as an exclusive right to use, the patent exhibits two co-existing characteristics: it confers on the patentee not only the right to exclude but also the right to include others. The right to exclude gives the patentee the right to stop others from using its invention. The right to include allows the patentee to licence its invention to others who, by virtue of such permission, are protected from an infringement action. These two aspects of a patent right are not mutually exclusive as a patentee who grants an exclusive licence can still sue others for infringement.<sup>26</sup>

Sometimes the right or the privilege to use is characterized as a negative obligation. In general, the owner of an IP right does not have an obligation to use the right.<sup>27</sup> In the case of patents, this principle was established by the Supreme Court of United States when it referred to the right to exclude conferred by a patent as “the very essence of the right conferred by the patent, as it is the privilege of any owner of property to use or not to use it, without question of motive.”<sup>28</sup> Concomitant with the absence of an obligation to use is the right to refuse to use or licence the patent.<sup>29</sup> The patentee’s right to refuse to use implies its right to refuse licence to others. However, it need

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<sup>24</sup> See, e.g., Patent Quality Improvement: Hearings Before the Subcomm. on Courts, the Internet and Intellectual Property of the House Comm. on the Judiciary, 198th Cong. 21 (2003) (testimony of David Simon, Chief Patent Counsel, Intel Corporation) (coining the term ‘patent trolls’ for non-practicing entities and describing their practices).

<sup>25</sup> See, e.g., *In re, Independent Service Organizations Antitrust Litigation*, 203 F 3d 1322, 1328 (Fed Cir 2000) (holding that a refusal to licence would not amount to exclusionary conduct in the absence of “any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws.”).

<sup>26</sup> *But cf.* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1092 (1971–1972) (“An entitlement is protected by a property rule to the extent that someone who wishes to remove the entitlement from its holder must buy it from him in a voluntary transaction in which the value of the entitlement is agreed upon by the seller.”).

<sup>27</sup> Herbert Hovenkamp et al., *Unilateral Refusals to Licence*, 2 J. COMPETITION L. & ECON.1, 2–3 (2006).

<sup>28</sup> *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 52 L Ed 1122: 210 US 405, 429 (1908). Eastern owned a patent for a machine for making self-opening square paper bags which it never used or licensed to others. Eastern sued Continental for patent infringement. Continental raised a plea that it would be inequitable to enforce a patent as Easter was not using the patented machine and was using the patent to suppress competition. The district court found that Continental infringed the patent, the Court of Appeals, First Circuit and the Supreme Court affirmed the decision.

<sup>29</sup> 35 U.S.C. § 271(d)(4) (stating that a patent owner cannot be deemed guilty of misuse by virtue of its refusal to licence or use any rights to the patent). Though this provision refers

not necessarily imply that the patentee's right to enforce is independent of its right to use.<sup>30</sup> Despite the stress on the characterization of the patent as a *right*, modern patent statutes cast some requirements on the patentee that view the patent as an *obligation*.

One such obligation is the duty to disclose information to the patent office, which if the applicant violates through bad faith or intentional misconduct, can jeopardize the grant of a patent on the application.<sup>31</sup> Courts regard the obligation to disclose information, which in some cases is imposed judicially, as one of the conditions for enforcing the issued patent.<sup>32</sup> The right to exclude, which materializes upon the grant of a patent is, thus, dependent on the obligation to disclose.<sup>33</sup>

## B. Patent as an Obligation

Patent law has historically imposed an obligation on the patent holder to practice the patent. Patents evolved as rights with a strong component on working, a positive act that the patentee did to put his invention to practice within a specified time.<sup>34</sup> In the early days, patent-like privileges were tied to manufacture and were focused on bringing foreign technology to local markets.<sup>35</sup> Patentees were required to compulsorily work the invention as such privileges would become void if not worked within the stipulated time, on the ground of want of consideration.<sup>36</sup> Since most countries held the view that patents were granted in order to promote technical progress and as an indemnity to the inventor for making the invention public, they perceived

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to patent misuse and not directly to antitrust violations, the policy it expresses remains relevant in antitrust law. See Hovenkamp et al., *supra* note 27, at 3.

<sup>30</sup> In some cases the right of the patentee to injunctive relief is dependent on the use of the invention. See, e.g., *Foster v. American Machine & Foundry Co.*, 492 F.2d 1317 (2nd Cir. 1974) (where the court refused to grant permanent injunctive relief to the patentee which did not practice the invention either directly or through licensees).

<sup>31</sup> 37 C.F.R. § 1.56(a) & (b); Patents depart from other forms of intellectual property in its disclosure obligations. While copyright (protection of unpublished works) and trade secret laws condone non-use and non-disclosure of the rights, patent laws confine its scope of protection to nonuse alone. See Hovenkamp et al., *supra* note 27, at 3.

<sup>32</sup> MERGES & DUFFY, *supra* note 17, at 1111.

<sup>33</sup> *J.E.M. Ag Supply Inc. v. Pioneer Hi-Bred International Inc.*, 51 L Ed 2d 508; 534 US 124, 142 (2001) ("The disclosure required by the Patent Act is the *quid pro quo* of the right to exclude.").

<sup>34</sup> PENROSE, *supra* note 1, at 2–3 (noting the practices in 15th and 16th century Europe that made working the invention an important consideration for the grant of a special privilege).

<sup>35</sup> See, e.g., Statute of Monopolies, 1623, 21 Jac.1, c.3, § 6 (Eng.). The Statute of Monopolies is regarded as the 'direct ancestor' of the United States patent law. PENROSE, *supra* note 1, at 43.

<sup>36</sup> Hulme, *supra* note 2, at 154.



that this aim would not be achieved if the patentee was allowed to prevent others from exploiting the invention without being, simultaneously, put under an obligation to make the invention available to the public through his own efforts.<sup>37</sup> Until the early 20th century, countries were almost unanimous in requiring patents to be compulsorily worked within a specified time.<sup>38</sup> One of the early commentators of the Paris Convention emphasized the importance of local working by holding the view that the member states were free to define what they understood by ‘failure to work’.<sup>39</sup>

This unanimity diminished gradually as countries scaled the ladder of development. Opposition to the compulsory working requirement came in the latter part of the 19th century, when countries like Belgium, Great Britain, Russia, Turkey, Italy and the United States insisted that working in one country, the country of origin, should suffice as working in all the others.<sup>40</sup> Developed countries, the ones where patents were more likely to be filed and practiced, relaxed the compulsory working requirement as most of the patents were aimed at the markets in those countries. Moreover, by making similar arrangements among other developed countries, the requirement for working diminished as, given the purchasing power of the consumers in these countries, the invention would be practiced anyway to be commercially viable. In keeping with the times, scholars soon developed a dislike for local working and regarded the requirement of local working as redundant and discriminatory.<sup>41</sup> Non-working, thus, was not a problem which the developed countries perceived. This was because they were the markets for the new inventions and there was very little possibility of the inventions not being worked or practised in those countries.<sup>42</sup>

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<sup>37</sup> JAN VOJÁČEK, *A SURVEY OF THE PRINCIPAL NATIONAL PATENT SYSTEMS* 59 (Prentice-Hall 1936).

<sup>38</sup> PENROSE, *supra* note 1, at 137.

<sup>39</sup> G.H.C. BODENHAUSEN, *GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY, AS REVISED AT STOCKHOLM IN 1967*, 71 (World Intellectual Property Organization 1968).

<sup>40</sup> PENROSE, *supra* note 1, at 79–81.

<sup>41</sup> The discussions on non-working, though relevant in history, did not have a place in modern times. The early works on international patent law devoted a few pages of commentary on non-working or the absence of local working. *See, e.g.*, VOJÁČEK, *supra* note 37, at 59–63. As times changed, the newer works did not have any discussion on non-working of patents. Scholars proclaimed that there is no place for compulsory licensing or working in a conservative understanding of intellectual property laws. *See, e.g.*, Hovenkamp et al., *supra* note 27, at 4.

<sup>42</sup> *But cf.* ASHISH ARORA ET AL., *MARKETS FOR TECHNOLOGY: THE ECONOMICS OF INNOVATION AND CORPORATE STRATEGY* 200 (MIT Press 2001) (countering the prevailing thought that integration of countries increase growth as the fixed cost of producing ideas spread over a larger market and observing that integration, though beneficial to the follower countries, does not increase the number of Specialized Engineering Firms (SEFs) in the First World, as most of the SEFs which arose to serve the First World market remain

This change is also attributed to the manner in which patent law developed. History witnessed a shift from the material embodiment of the invention in the product—the fact that the invention worked when practiced—to the textual embodiment of the invention in the specification—the fact that the invention worked as disclosed. Thus, around the 18th century, the obligation to work the invention was replaced by the obligation to disclose the invention, as both had in common the object of “making the new art known and training others in the practice of it.”<sup>43</sup> Spectacularly, the obligation to disclose relieved the burden of putting the invention to practice from the patentee as he was only required to disclose the invention in a manner that enabled a skilled person to make and use the invention. This move was accentuated by the understanding that not all patents are granted for the introduction of new industries.<sup>44</sup> As the doctrine of enabling disclosure evolved, the requirement of working the invention increasingly became confined to what the patentee said in the specification and what the skilled person could do with it.<sup>45</sup>

The story unfolded in a different way in developing countries. These countries saw local working as a means to promote technical progress that assisted them in capacity building and insisted, in their patent laws, for the requirement of local working. Scholarship, too, recognized the importance of local production and manufacture.<sup>46</sup> These countries hoped that by granting patent protection the technology covered by the patent would be made available locally.<sup>47</sup> These countries geared their patent laws to make an allowance for working the technology locally; some of them made the grant of a patent upon the condition of working them locally.<sup>48</sup> Some countries even imposed an obligation on every patentee with the responsibility of filing working statements annually indicating whether the inventions were

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faithful to history and as their investments were not motivated by the hope of serving developing country markets that did not yet exist).

<sup>43</sup> PENROSE, *supra* note 1, at 138.

<sup>44</sup> E. Wyndham Hulme, *On the Consideration of the Patent Grant Past and Present*, 13 L. Q. REV. 314, 317–18 (1897) (noting that the doctrine of instruction of the public by means of the personal efforts of the patentee was finally abandoned in favour of the novel theory that this function belonged to the patent specification).

<sup>45</sup> MERGES & DUFFY, *supra* note 17, at 265 (noting that the enablement requirement requires the inventor to describe her invention clearly enough so that one skilled in her art can understand it well enough to make and use it).

<sup>46</sup> See, e.g., U.N. Conf. on Trade & Dev., *Investment in Pharmaceutical Production in the Least Developed Countries: A Guide for Policymakers and Investment Promoting Agencies*, [http://unctad.org/en/docs/diaepcb2011d5\\_en.pdf](http://unctad.org/en/docs/diaepcb2011d5_en.pdf) [hereinafter *Pharmaceutical Production*](describing the impact of local production of pharmaceuticals in Least Developed Countries).

<sup>47</sup> VOJÁČEK, *supra* note 37, at 59.

<sup>48</sup> See The Patents Act, No. 39, § 83(a) (India).

being worked locally.<sup>49</sup> The emphasis on working took stronger ground as developing countries saw a peculiar problem which did not happen in the developed countries, especially in the case of pharmaceutical patents.<sup>50</sup> Some of the pharmaceutical patents were not worked locally and they were not made available to the local market at an affordable price given the disparities in the purchasing power of the masses compared to their counterparts in developed countries.<sup>51</sup> Consequently, these developing countries had to deal with the problems that arise when patents picket.

### C. When Patents Picket

Patents picket when they are not worked locally. These patents are not worked locally on a commercial scale and because of their exclusionary nature, others are not allowed to work the invention covered by the patent.<sup>52</sup> By doing so, these patents picket.<sup>53</sup> In other words, patents picket when they do not work at all or are worked insufficiently. Like a labour strike which involves a concerted stoppage of work for an enhancement of wage, picketing patents too result in a stoppage of working of the patent in expectation of a monopoly price. Sometimes the price set by the patentee is too high for most of the population to afford, as it often happens in the case of patented pharmaceutical drugs sold in developing countries where only a small percent of the population can afford the drug.

What amounts to working is not clearly defined in any of the international conventions on patents.<sup>54</sup> Scholars, however, are in agreement that this gives the countries room to define what working means.<sup>55</sup> The term has

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<sup>49</sup> *Id.* § 146.

<sup>50</sup> Of all fields of technologies, patents play the most significant role in the pharmaceutical industry. *See*, JAMES BESSEN & MICHAEL JAMES MEURER, *PATENT FAILURE : HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK* 14, 89 (Princeton University Press 2008).

<sup>51</sup> *But cf.* Patricia M. Danzon, *The Economics of Parallel Trade*, 13 *PHARMACOECONOMICS* 293 (1998) (suggesting that exempting on-patent products from parallel trade could preserve price differentials for pharmaceutical products).

<sup>52</sup> *See, e.g.*, Khomba Singh, *No interim stay on Cipla's Nexavar clone*, *ECON. TIMES*, Mar. 1, 2009, [http://articles.economictimes.indiatimes.com/2010-03-01/news/28487477\\_1\\_nexavar-patent-linkage-prathiba-singh](http://articles.economictimes.indiatimes.com/2010-03-01/news/28487477_1_nexavar-patent-linkage-prathiba-singh) (describing Bayer's infringement suit against Cipla, a company that was manufacturing generic version of Bayer's patented drug, Nexavar).

<sup>53</sup> A picket refers to a person, either on strike or supporting that strike, who seeks to prevent other persons from gaining access to a place of work during the course of an industrial dispute. *Picket Definition*, *CREDOREFERENCE.COM*, <http://www.credoreference.com/entry/collinsecon/picket> (last visited Feb. 14, 2013).

<sup>54</sup> *But cf.* PENROSE, *supra* note 1, at 3 (referring to the phrase "working a patent" as an unfortunate piece of technical jargon which meant "producing with the use of the patented invention").

<sup>55</sup> BODENHAUSEN, *supra* note 39, at 71.

been interpreted “to mean working it industrially, namely, by manufacturing the patented product or industrial application of a patented process” while excluding importation or sale of the patented article or of the article manufactured by a patented process.<sup>56</sup>

A peek into history shows that the compulsory working requirement was an integral part of patent law in the United States, the United Kingdom and many other countries.<sup>57</sup> The reason for its absence from the modern patent system can be explained by the economic conditions prevalent today in these nations. Patent laws were intricately linked to the stage of development of a country and every time there was an issue related to development, patent law was flexed to suit the local developmental needs.<sup>58</sup> Scholars have noted that there was little that has been said either for or against the patent system in the 20th century that has not been said in the 19th century.<sup>59</sup> Both United States and United Kingdom have gone through cycles where they had to adjust the terms of IP protection to suit their stage of economic development.<sup>60</sup>

Local working or failure to work in the local market is one of the original grounds on which compulsory licences were granted.<sup>61</sup> The premise was that a compulsory licence could be granted if the patent holder did not manufacture the patented invention locally. Patents evolved historically with the expectation that the patent holder would make the patented invention locally.<sup>62</sup> Countries held a view that apart from being beneficial to the industry,

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<sup>56</sup> *Id.*

<sup>57</sup> PENROSE, *supra* note 1, at 137–43 (noting that the United States was the first country to remove this requirement from its laws).

<sup>58</sup> See, e.g., B. ZORINA KHAN, *THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, 1790-1920* 289 (2005) (noting that the intellectual property institutions stimulated early American economic growth because of their flexible responses to economic and social circumstances).

<sup>59</sup> See Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 10, 28 (1950).

<sup>60</sup> See, e.g. CHRISTOPHER MAY & SUSAN K. SELL, *INTELLECTUAL PROPERTY RIGHTS* 109 (Boulder, Colo., Lynne Rienner Publishers, 2006) (“The diversity of intellectual property policies between countries was, and remains, in part a function of their different stages of development.”). The 19th century also saw the House of Lords passing a bill for “a reduction of patent protection to seven years, strictest examination of patent applications, forfeit of patents not worked after two years, and compulsory licensing of all patents.” Machlup & Penrose, *supra* note 59, at 4. In the United Kingdom, the working of a patent was introduced by the Patent Law Amendment Act of 1902, which compelled people to work, or to allow others to work, their patents, instead of allowing them to use the patent to stop others from working it. See THOMAS HENRY O’DELL, *INVENTIONS AND OFFICIAL SECRECY: A HISTORY OF SECRET PATENTS IN THE UNITED KINGDOM* 66 (1994).

<sup>61</sup> See PENROSE, *supra* note 1, at 78.

<sup>62</sup> See Paul Champ & Amir Attaran, *Patent Rights and Local Working under WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT’L L. 365, 370–71 (2002).

“patents should also be *used for working the patented invention in the country where the patent is granted*, and not merely as an exclusive right to prevent others from doing so or to control importation.”<sup>63</sup> Failure to work the patented invention, which included insufficient working, was regarded as an abuse which could not be alleviated by importation.<sup>64</sup> The echoes of local working from the past can still be heard today.<sup>65</sup> In the modern context, the TRIPS Agreement allows Member States to take appropriate measures to prevent the abuse of intellectual property rights by right holders.<sup>66</sup> It implicitly recognizes the right of the Member States to define abuse of Intellectual Property rights.<sup>67</sup> In modern economies, the governments decide the rules of the game as they define fair competition, anticompetitive conduct and other behaviour that amounts to an abuse.<sup>68</sup> Thus, the provision of local working in the domestic patent law may not be in contravention of the TRIPS Agreement.<sup>69</sup>

What could be the relevance of local working in a global economy? Local working is tied to the concept of local manufacture and local production. It is expected to bring in the benefit of ‘learning by doing’ to the domestic market and thereby result in the transfer of technology.<sup>70</sup> Local working of

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<sup>63</sup> BODENHAUSEN, *supra* note 39, at 70 (emphasis in original).

<sup>64</sup> BODENHAUSEN, *supra* note 39, at 71; *See also*, CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 131 (2011).

<sup>65</sup> When Indonesia threatened originator pharmaceutical companies with compulsory licence, it also indicated that it would expel those companies from the market unless they were willing to invest in local production of pharmaceuticals. *See* Sinfah Tunsarawuth, *Indonesia Mulls Compulsory Licences On Three More HIV/AIDS Drugs*, INTEL. PROP. WATCH, Nov. 26, 2007, <http://www.ip-watch.org/2007/11/26/indonesia-mulls-compulsory-licences-on-three-more-hiv-aids-drugs/>. Brazil was taken to the WTO for making local working a requirement under their law. India had provisions for local working built into its law which required submission of timely information to the patent office on whether the invention was being worked. *See generally* Champ & Attaran, *supra* note 62, at 365.

<sup>66</sup> *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, art. 8(2), Apr. 15, 1994, Annex 1C, 33 I.L.M. 1197 (1994) (hereinafter TRIPS Agreement),

<sup>67</sup> *See* Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as last revised at Stockholm, July 14, 1967, 25 Stat. 1372, 828 U.N.T.S. 305 (hereinafter Paris Convention). The TRIPS Agreement states that the provision of the Paris Convention shall be complied with by the member states implying that the Paris Convention is to be read as a part of TRIPS Agreement. *Id.* Art. 2(1); Article 5(A)(2) of the Paris Convention states that each member shall have the right to take legislative measures providing for the grant of compulsory licences in order to prevent any abuse of patent rights, such as failure to work.

<sup>68</sup> JOSEPH E. STIGLITZ, THE PRICE OF INEQUALITY 30 (New York, W.W. Norton & Co. 1st edn., 2012).

<sup>69</sup> Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law*, 35 OSGOODE HALL L. J. 244, 260 (1997).

<sup>70</sup> *But cf.* Gabriel Szulanski, *The Process of Knowledge Transfer: A Diachronic Analysis of Stickiness*, 82(1) ORG. BEHAV. & HUM. DECISION PROCESSES 12 (2000) (acknowledging

patents is an important cog in developing capacity, as capacity building is seen as the long-term solution by developing countries for the problem of access to affordable medicines and in handling health crises where drugs are needed in large quantities.<sup>71</sup> While local working could result in the availability of higher quantities in the local market, it does not necessarily translate into cheaper prices, especially for patented drugs.

There appears to be no consensus on whether local production will have an effect on the local availability of the drug. Patent holders on the one hand hold that local production need not necessarily mean that the drug is made available in sufficient quantity for local consumption, as the demand of the market is subject to various conditions. Given that pharmaceutical companies are in the businesses of efficient production, a patent holder can be expected to only make available such quantities that the local market can afford.<sup>72</sup> Since patented drugs would be covered by monopoly prices, the number of individuals who can afford them in a developing country will be few in number. As a result, importation of the invention would suffice to meet the small demand. Developing countries on the other hand, which insist on local working, cite the transfer of technology, availability of drug in large quantities, and developing local capacity for manufacturing in times of crises as the significant reasons for their insistence.<sup>73</sup> That local working could have an impact on the pricing of the drug is a matter which both the patent holders who charge monopoly prices and prefer importation and the developing countries which have the regulatory authority to control prices of drugs tend to ignore.<sup>74</sup>

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that learning by doing entails resolution of unexpected problems that arise when new knowledge is put to use by the recipient in an intra-firm context).

<sup>71</sup> FREDERICK M. ABBOTT, WTOTRIPS AGREEMENT AND ITS IMPLICATIONS FOR ACCESS TO MEDICINES IN DEVELOPING COUNTRIES 13-14 (2000) [hereinafter, ABBOTT, ACCESS TO MEDICINES] (U.K. Commission on Intellectual Property Rights (CIRP) Study Paper 2a), available at [http://www.iprcommission.org/papers/pdfs/study\\_papers/sp2a\\_abbott\\_study.pdf](http://www.iprcommission.org/papers/pdfs/study_papers/sp2a_abbott_study.pdf).

<sup>72</sup> See *Natco Pharma Ltd. v. Bayer Corpn.*, CLA No. 1 of 2011, 9-3-2012 (Controller of Patents, Mumbai), 38-39, [hereinafter Nexavar licence] available at [http://www.ipindia.nic.in/ipoNew/compulsory\\_License\\_12032012.pdf](http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf) (India.) (citing Bayer's argument that the quantities required in India do not economically justify setting up a manufacturing facility in India).

<sup>73</sup> See, e.g., The Patents Act, 1970, No. 39, § 83 (India) (detailing the reasons for the grant of compulsory licences).

<sup>74</sup> Not many countries have linked the local working requirement to the issue of compulsory licences. India, for one, has a provision in the patent law which calls for revocation of patents that are not worked. See *id.* § 85.

The relationship between local working and the price of the drug has not been explored in detail.<sup>75</sup> Patentees could argue that since the prices are high, only few units need to be made available to the local market based on the ability to afford. The contrary argument would be that it is the high price that makes the drug unaffordable to much of the population in the developing country though they have a need for it. Though the patents create monopolies, there appears to be no effective way of eliminating the associated deadweight loss.<sup>76</sup>

The question that, then, arises is that why drugs are not differentially priced in the developing countries? There are at least four theories that explain why companies do not practice differential pricing: the first theory states that since patents grant monopoly control over prices there is no incentive to price-discriminate in the absence of any competition; the second theory postulates that pharmaceutical companies do not practice differential pricing due to the fear of reference pricing, the apprehension that prices marked in developing countries could be used as benchmarks in developed countries; the third theory looks at the profitability of selling medicines and holds that selling medicines at high prices to the rich in the developing countries is more profitable than selling at lower prices to the masses;<sup>77</sup> and the fourth theory offers a defense against parallel importation, the practice of low-priced medicines eating into the market of higher priced medicines when they are imported into developed countries.<sup>78</sup> These theories indicate that the concept of price is intricately tied to the availability of the drug in the local market. The availability of the drug, both in times of normalcy and crisis, is dependent on the capacity of local production, which in turn is dependent on the local working for a patented drug.

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<sup>75</sup> Few studies exist on the effect of local production on access to drugs. See, e.g., Pharmaceutical Production, *supra* note 46.

<sup>76</sup> Pankaj Tandon, *Optimal Patents with Compulsory Licensing*, 90 J. POL. ECON. 470, 470-71 (1982) (suggesting compulsory licences as a way to reduce deadweight loss).

<sup>77</sup> In the primary market of pharmaceutical companies, the United States, of the 12 drugs approved by the Food and Drug Administration, 11 were priced above \$100,000 per patient per year. See *The Real Cancer Killer: Rip-off Prices for Drugs Set by "Profiteering" Big Pharma Giants*, THE INDEPENDENT, Apr. 29, 2013, <http://www.independent.co.uk/news/uk/home-news/the-real-cancer-killer-ripoff-prices-for-drugs-set-by-profiteering-big-pharma-giants-8591825.html>.

<sup>78</sup> Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 971(2007) [hereinafter Abbott & Reichman, *Doha Round's Legacy*].

Countries have addressed the issue of non-working of both home-grown and foreign patents with their compulsory licensing regimes.<sup>79</sup> Compulsory licences are liability rule entitlements where the state sets the rates of compensation to be paid to the patent holder based on the submissions of the parties.<sup>80</sup> Countries have addressed this not just by their compulsory licensing regimes but also by having an effective working requirement built into their patent laws.<sup>81</sup> Though the compulsory licensing regime relieved the patentee from the danger of forfeiture of its patent, it did create an obligation to work the invention locally.

### III. REDEFINING NON-WORKING AS ABUSE

Improper exploitation of patents falls into two categories. A patent may be improperly exploited by, first, violating the antitrust laws or, second, extending the patent beyond its lawful scope.<sup>82</sup> The doctrine of patent abuse or misuse refers to an equitable concept designed to prevent a patent owner from using the patent in a manner contrary to public policy. The doctrine applies to practices by the patentee which appears to extend its patent grant beyond its statutory limits.<sup>83</sup> The doctrine of patent misuse was first expounded by the Supreme Court of United States in the *Morton Salt* case.<sup>84</sup> Since patent misuse is traditionally defined as an enforcement of a non-statutory patent right i.e., a right which is not conferred on the patentee by the grant of the patent, the demarcation of the limits of the statutory right conferred by a patent can have a bearing on determining and defining patent misuse.

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<sup>79</sup> PENROSE, *supra* note 1, at 162–87 (making a separate case for compulsory licensing of foreign patents).

<sup>80</sup> *But cf.* Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL L. REV. 1293, 1296 (1996).

<sup>81</sup> For instance, in India, a patent is granted subject to certain condition, one of which is an expectation that the patent would be worked; The Patents Act, 1970, No. 39, § 83(a) (India).

<sup>82</sup> See 6 DONALD CHISUM, PATENTS §19.04[1] (1990). See also Dan L. Burke & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1662-63 (2003).

<sup>83</sup> See Burke & Lemley at 1664 (“More generally, the courts could use patent misuse to enforce a conception of the proper scope of a patent in a given industry in the face of efforts by patentees in different industries to change that scope.”). See *USM Corpn. v. SPS Technologies Inc.*, 694 F 2d 505 (7th Cir 1982). The instances of misuse include resale price maintenance (fixing the price at which the purchaser of the patented item could resell it).

<sup>84</sup> *Morton Salt Co. v. G.S. Suppiger Co.*, 86 L Ed 363; 314 US 488 (1942). The case involved the patentee making use of its patent monopoly to restrain competition in the marketing of unpatented articles, the salt tablets, for use with their patented machines. The trial court, without getting into the merits of validity and infringement, summarily dismissed the complaint for infringement. On appeal by the patentee, the Court of Appeals reversed the decision. The Supreme Court found the conduct of the patentee as one amounting to a patent misuse.



Traditionally, abuse of patent meant more than just the failure to work.<sup>85</sup> Non-availability and non-affordability of a patented drug in the local market were instances of abuse as well. Since these two grounds have traditionally been regarded as public interest grounds, and more importantly are not the chief grounds for initiating a market-initiated compulsory licence, the relevance of these two grounds is not discussed here. In contrast, the ground of non-working has been more contentious and its affiliation to abuse of patent right has been controversial. The following discussion is confined to an analysis of non-working as an abuse of patent right.

### A. Compulsory Working and Compulsory Licensing

Historically, abuse of patents has been addressed by two broad approaches: (1) by compulsory working and (2) by compulsory licensing.<sup>86</sup> Compulsory working of patents had its origin in the belief that foreign patents would protect the market for their exports by retarding domestic industrial development.<sup>87</sup> Compulsory working came with a strong penalty: failure to use the invention in countries that had compulsory working requirement led to its forfeiture.<sup>88</sup> Some countries who had strong export potential saw these provisions as harsh and bargained for restricting the compulsory working requirement to the country of origin, i.e., they introduced the principle that working in one country can be regarded as working in others.<sup>89</sup> Other countries continued to retain compulsory working in their laws. In the Madrid Conference of 1890, the compromise that was suggested was that compulsory licensing should be substituted for compulsory working as a way to reconcile the conflicting interests.<sup>90</sup> Thus, compulsory licensing emerged as an alternative to compulsory working.<sup>91</sup> While non-working would have

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<sup>85</sup> When the concept of abuse was first introduced in United Kingdom, it encompassed 6 types of abuses, namely, (1) failure to work, (2) prevention of production in Britain by importation, (3) failure to meet the demand to an adequate extent on reasonable terms, (4) refusal to grant licences on reasonable terms to the prejudice of trade or industry in the United Kingdom when it is in the public interest that a licence be granted, (5) the imposition of conditions on sales, leases or licences which are prejudicial to trade or industry, and (6) the use of a patent which covers a process involving the use of unpatented materials in order to control the materials in such a way as unfairly to prejudice their manufacture, use or sale in the United Kingdom. PENROSE, *supra* note 1, at 178-79.

<sup>86</sup> Paris Convention, Arts. 5(A)(2) and (3); *See also* PENROSE, *supra* note 1, at 78.

<sup>87</sup> PENROSE, *supra* note 1, at 137.

<sup>88</sup> PENROSE, *supra* note 1, at 137.

<sup>89</sup> PENROSE, *supra* note 1, at 79-81.

<sup>90</sup> PENROSE, *supra* note 1, at 81.

<sup>91</sup> VOJÁČEK, *supra* note 37, at 60. (“The best method seems to be to put an obligation on the patentee to grant licences on reasonable terms, and to reserve the penalty of forfeiture of patent only for cases of flagrant misuse of the monopoly rights, particularly wilful neglect or fraudulent dealing.”).

resulted in forfeiture of the invention in a regime that mandated compulsory working, the option of compulsory licensing saved the patentee from the danger of forfeiture of his patent. Local working as it exists in modern legislations is different in this sense from the compulsory working requirement. Local working is mostly used as a trigger for initiating a compulsory licence rather than as a tool for forfeiture.

Thus, it is not difficult to justify local working in modern patent legislations. First, they are used as a trigger, the absence of which can lead to the issue of a compulsory licence. Second, if the working requirement is inbuilt into the patent law such that the patentee is required to furnish working statements to the patent office or if the patent law requires all inventions to be worked locally, the provision by itself may not be regarded as harsh and unfair.

When the compulsory working requirement was relaxed, countries began to argue that importation of the invention should suffice as working. The concept of working encompasses two things: use of the patent by the patentee and licensing of the patent to a third party. Whether importation of a drug would amount to working or not remains unsettled.

## B. Importation as Working

One of the most serious objections that have been raised against the concept of working is that importation amounts to working.<sup>92</sup> As noticed, Bayer's contention that importation satisfies the requirements of working was rejected by the Controller.<sup>93</sup> In doing so, the Controller relied on Section 83(c) of the Patents Act, a provision which explicitly states that importation would not satisfy the requirements of working.<sup>94</sup> The Controller drew an analogy between working by the compulsory licensee and working by the patentee. Section 90(3) provides that no licence granted by the Controller shall authorize the licensee to import the patented article from abroad. By citing this provision, the Controller concluded that what is good for the compulsory licensee holds good for the patentee. This interpretation has

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<sup>92</sup> The confusion on the issue of importation is justifiable. Article 5(A)(1) of the Paris Convention provided the importation of patented articles by the patentee shall not entail forfeiture of the patent. This was done to move on-working patents from the greater threat of revocation to the lesser threat of non-voluntary licence. JEROME H. REICHMAN & CATHERINE HAZENZAHL, ICTSD-UNCTAD PROJECT ON IPRS & SUST. DEV., NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS 10 (2003). The TRIPS Agreement is however silent over this issue.

<sup>93</sup> *Nexavar licence*, *supra* note 72, at 39. However, the IPAB reversed this finding to hold that in some cases importation can amount to working provided the same is proved.

<sup>94</sup> *Nexavar licence*, *supra* note 72, at 43.

been criticized for equating the rights of the patentee with that of a licensee.<sup>95</sup> The key to the puzzle lies in Form 27 of the Indian Patent Rules, which are statements of working that patentees are required to file annually at the Indian Patent Office. Those critical of the working requirement have argued that if importation did not amount to working, there would have been no need to mention importation under the heading of ‘working the invention’ in Form 27.<sup>96</sup> Since importation is regarded as one of the elements of working, the critics conclude that importation alone would satisfy the working requirement. What they overlook is the fact that Form 27 mentions importation conjointly with local manufacture. Keeping in line with the statutory mandate in Section 83(c) that importation does not amount to working of the invention, a more reasonable reading of Form 27 would be to regard importation as a relevant factor when the drug is locally manufactured. In such cases, importation could show the extent to which the drug is made available in the market, either by manufacturing or by import.

### C. Economic Efficiency of Local Working

Some of the objections for local working come from the fact that it is often economically inefficient.<sup>97</sup> Local working, it is argued, would prevent a patentee from choosing to exploit only one of the many lines of its products it has developed much to the detriment of specialization. There is also the question as to who will determine whether the patentee is satisfying the working requirement.<sup>98</sup> Some hold a view that it is “physically impossible and economically absurd” for a patentee to work his patent in every country or even in most of the industrial countries of the world.<sup>99</sup>

Much ink has flown from the pens of scholars arguing for and against local working.<sup>100</sup> But local working is not the only reason for the grant of the licence though it may be touted as the most vociferous of the grounds. As mentioned earlier, market-initiated compulsory licences become infeasible when granted on multiple grounds combining local working grounds with public interest grounds. Thus, even if non-working were to amount to

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<sup>95</sup> Ritushka Negi & Vineet Rohilla, *Compulsory licensing: Is the working requirement legitimate?*, MANAGING INTELL. PROP. (2012), <http://www.managingip.com/Article/3084083/Compulsory-licensing-Is-the-working-requirement-legitimate.html>.

<sup>96</sup> The Patents Rules, 2003, Form 27, Gazette of India, part II section III(2) (May 2, 2003).

<sup>97</sup> PENROSE, *supra* note 1, at 156–58.

<sup>98</sup> Hovenkamp et al., *supra* note 27, at 7. In India, that question is answered by the working statement which patentees are required to file every year. FERAZ ALI KHADER, *THE LAW OF PATENTS: WITH A SPECIAL FOCUS ON PHARMACEUTICALS IN INDIA* 319 (2007).

<sup>99</sup> PENROSE, *supra* note 1, at 158.

<sup>100</sup> HO, *supra* note 64, at 131 (discussing the diverging views of scholars on the permissibility of local working).

discrimination under Article 27 of the TRIPS Agreement, it would not be a ground to cancel a compulsory licence if it is also granted, as would most likely be the case, on the grounds of public interest. Further, the non-discrimination clause appears to affirm the patent owner's rights to enjoy the patent to the exclusion of others and is silent as to whether it suggests that the patent owner would lose his right to exclude others if he failed to make the product locally.<sup>101</sup> Here again, by the grant of a compulsory licence, the patent owner's right to exclude others remains largely intact except for the compulsory licensee who alone would be able to make the product now.<sup>102</sup> Hence, there would not be a total taking away of the right to exclude either. Since TRIPS is built upon the foundation of the Paris Convention, it could throw some light on how the provision is to be interpreted.<sup>103</sup> The Convention expressly considers lack of local working as an abuse of patent right that is a ground for the issuance of compulsory licensing.<sup>104</sup> Since there is no clear indication in the TRIPS Agreement on repealing local working, the default position that was carried over from the Paris Convention should continue.

It is true that local working may not work for all countries.<sup>105</sup> Increasing the local production of pharmaceuticals by developing countries may not reflect a wise use of available scarce resources except for a few developing countries which possess a comparative advantage in this field.<sup>106</sup> India is one country which has a comparative advantage in the development of cheap and cost-effective drugs. But recent evidence shows that local production could benefit the developing countries, more particularly, the LDCs.<sup>107</sup>

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<sup>101</sup> HO, *supra* note 64, at 132.

<sup>102</sup> *Nexavar licence*, *supra* note 72, at 62 (stating that the residual rights of the patentee remain intact).

<sup>103</sup> Bryan Mercurio & Mitali Tyagi, *Treaty Interpretation in WTO Dispute Settlement*, 19 MINN. J. INT'L L. 275, 296–325 (2010) (arguing that the non-discrimination clause in the TRIPS should be interpreted so as not to nullify the requirement of non-working inherited from the Paris Convention).

<sup>104</sup> Paris Convention, Art.5(A); TRIPS Agreement, Art.2(1).

<sup>105</sup> FREDERICK M. ABBOTT & GRAHAM DUKES, *GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW'S WORLD* 136-140 (2009).

<sup>106</sup> See generally Roger Bate, *Local Pharmaceutical Production in Developing Countries: How Economic Protectionism undermines Access to Quality Medicines*, INT'L POL'Y NETWORK (2008) (Campaign for Fighting Diseases discussion paper no. 1); Warren Kaplan & Richard Lang, *Local Production of Pharmaceuticals Industrial Policy and Access to Medicines*, WHO REPORT (2003) (Paper prepared for World Bank Meeting on the Role of Generics and Local Industry in Attaining the Millennium Development Goals (MDGs) in Pharmaceuticals and Vaccines Conference Washington, D.C., June 24, 2003).

<sup>107</sup> See *Pharmaceutical Production*, *supra* note 46.

### D. The ‘Rule of Reason’ Justification

The right to refrain from using one’s Intellectual Property is not an absolute right.<sup>108</sup> Working requirement would be enforced when the right to refrain from using and refusing others from using becomes abusive. This view does not change the settled understanding of intellectual property rights as a negative right. This only qualifies the right in circumstances where the exercise or non-exercise of the right amounts to an abuse. Working is required, not in all cases, but at least in cases where non-working would lead to an abuse. Like the ‘rule of reason’ in antitrust law which limits the prohibition of restraint of trade,<sup>109</sup> courts interpreting the working requirement in patent law could evolve a similar rule that limits the local working to instances where the absence of working amounts to an abuse.

Thus, the duty to interpret the term “worked in the territory of India” would require a reasonable meaning which would not destroy the patentee’s right to exploit the patent. Patents are applied for at an early stage in the life of an invention, and in many cases inventors will require time to further develop and commercialize their inventions for financial, regulatory and business reasons.<sup>110</sup> Indeed, a rule that required all patents to be offered for licence would be wasteful and burdensome. Thus, working requirement should be applied only in cases where non-working or inadequate working amounts to an abuse such as non-availability of the drug, non-affordability of drug or in cases where there is a need to build capacity locally. Such an understanding will distinguish the local non-working of patents from the broader concept of a patent abuse. The remedy for local non-working could be the local working of the patent, which could be satisfied by ‘sham’ working without any real benefit, whereas the remedy for an abuse would be to address the situation caused by the abuse, where local working will not necessarily address the abuse.<sup>111</sup>

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<sup>108</sup> A reasonable fetter on the patent rights in the form of compulsory licence is within the purview of the Paris Convention and TRIPS Agreement, when there is an abuse of patent rights. *Nexavar licence*, *supra* note 72, at 42.

<sup>109</sup> Lee Loevinger, *The Rule of Reason in Antitrust Law*, 19 A.B.A. ANTITRUST SECTION 245, 246 (1961) (stating the Supreme Court’s decision in *Standard Oil* case that the rule of reason was not that acts which the statute prohibited could be removed from its prohibitions by a showing that they were reasonable, but that the duty to interpret the term restraint of trade required a reasonable meaning which would not destroy the individual right to contract and carry on trade).

<sup>110</sup> Feroz Ali Khader, *Making Patents Work*, SPICY IP BLOG (Mar. 11, 2010, 12:41 AM), <http://spicyipindia.blogspot.com/2010/03/guest-post-by-feroz-ali-making-patents.html>.

<sup>111</sup> PENROSE, *supra* note 1, at 170–71.

#### IV. CONCLUSION

Unexpectedly, the grant of market-initiated compulsory licences allowed originator pharmaceutical companies to practice price differentiation without the fear of parallel import as the terms of the grant restricted the sale locally. Moreover, since it is the government of the developing country that sets the price of the licensed product, such instances may not be used for reference pricing of products in the primary market. The grant of such licence protected the inventions made in the developed countries by removing the threat of forfeiture of patents, which would have opened the invention to all domestic firms by limiting third-party use to one entity.<sup>112</sup> In countries where generic companies that engage in proactive infringement and do not face the threat of treble damages, a market-initiated compulsory licence restricts the entry of generics to a single entity and operates as a disincentive for generics to compete on lower prices.<sup>113</sup> The terms of the grant strictly imposed restrictions on the licensee allowing the patentee to hold the patent and exploit the residual rights. Market-initiated compulsory licences also allow originator companies to profit from newer, untapped and highly differentiated markets like India, where the market is segmented with the originator companies catering to the rich, high-income consumers and generics to the poorer, middle and low income consumers.<sup>114</sup>

The Nexavar licence episode is a testimony to the resilience of the compulsory licensing regime which has grown stronger with every effort to constrain it.<sup>115</sup> The emergence of market-initiated compulsory licences as an alternative to government use-licences, to some extent, democratizes a regime that was seen as arbitrary. Different from those issued in times of a health emergency, market-initiated compulsory licences are responses to

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<sup>112</sup> PENROSE, *supra* note 1, at 159. When a compulsory licence is issued, the monopoly becomes a duopoly.

<sup>113</sup> It is unlikely that another generic company will enter the market after the grant of a compulsory licence. Cipla's case in the Nexavar episode was exceptional as it had entered the market before the grant of the licence. Cipla's profit margins after the grant of licence plummeted when the price was set at Rs. 8800. Cipla had to reduce its prices to survive in the market. See Priyanka Golikeri, *Natco's Compulsory Licence has had the Intended Effect*, DAILY NEWS & ANALYSIS, May 22, 2012, [http://www.dnaindia.com/money/report\\_natcos-compulsory-licence-has-had-the-intended-effect\\_1691978](http://www.dnaindia.com/money/report_natcos-compulsory-licence-has-had-the-intended-effect_1691978).

<sup>114</sup> See Interview by V. Venkatesan with Shamnad Basheer, Chair Professor Intellectual Property Law, National University of Juridical Sciences, Kolkata (Apr. 21, 2012), <http://www.frontlineonnet.com/fl2908/stories/20120504290802600.htm>

<sup>115</sup> Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions*, 37 J.L. MED. & ETHICS 247, 248 (2009) (noting that while international minimum standards of patent protection have gradually and progressively risen over time, every attempt to limit or constrain a state's power to issue compulsory licences has invariably resulted in a strengthening of that power at the international level).

a special situation caused when patents picket—a condition identified as a refusal to work the patent locally, either by the patentee on its own, or by a third-party licensee. Like any compulsory licence, market-initiated compulsory licences are exceptions which need to be used exceptionally.<sup>116</sup> And their assertion is not without accompanying costs: it takes a special legal regime, vibrant local talent, political will and economic incentives to work the system. Not all countries, given the disparities in development even amongst developing countries, may have the ability to work a market-initiated licensing regime. And, more significantly, not all countries with the capability will take it lightly to issue such licences. For when such licences are issued, they significantly affect the redistribution of entitlements.

Given the history of development of compulsory licences, countries will continue to use them and justify their use. Since market-initiated compulsory licences are triggered by an abuse of patent, countries have to declare what amounts to an abuse to avoid uncertainty in the market and to balance the policy implications, both for the patentee and for the consumers, in granting such licences. The responsibility is, however, not one-sided. Patentees of life-saving drugs who operate in markets where the majority cannot afford their products should devise ways in which they can address the issues of consumers who pay a heavy price for their inability to pay the price of a life-saving drug. While harmonization of international laws enabled these giants to cross borders with ease, these companies need to adapt to meet the local needs in the developing markets, which are different from those in advanced markets, and may through ingenious adaptations even profit from these markets.

If there is one lesson that the Nexavar licence tells us, it is this: the world is not fully ready for complete harmonization. The world, as some see it, is at best partially globalized or semi-globalized.<sup>117</sup> A semi-globalized world is still a divided world. The Nexavar licence, strangely, tells us that there could be some benefits that flow from the disparities in development between countries, as strictly enforced compulsory licensing regimes will offer protection for the originator company from the dangers of parallel importation and reference pricing and encourage them to practise price differentiation.

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<sup>116</sup> *But cf.* Robert P. Merges, *Of Property Rules, Coase and Intellectual Property*, 94 COLUM. L. REV. 2655, 2656 (1994).

<sup>117</sup> *See generally* PANKAJ GHEMAWAT, *REDEFINING GLOBAL STRATEGY: CROSSING BORDERS IN A WORLD WHERE DIFFERENCES STILL MATTER* (2007) (noting that while the world's market and economies are becoming increasingly integrated, the process is far from complete).