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# The India Patent System: A Decade in Review

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THE INDIAN PATENT SYSTEM: A DECADE IN REVIEW

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 AND JAY ERSTLING<sup>4</sup>

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## I. INTRODUCTION

Over a decade has passed since India's patent laws were significantly amended to fulfill the country's obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>5</sup> The 2005 amendments to the *Patents Act*<sup>6</sup> were the third in a series of installments to meet India's TRIPS obligations. Earlier, the amendments in 1999 had ushered in a transitional "mail-box" provision and exclusive marketing rights for pharmaceutical products.<sup>7</sup> The 2002 amendments, among others, somewhat controversially expanded the list of statutorily excluded subject matter.<sup>8</sup> The 2005 amendments dispensed with the transitional—and exclusive—marketing-rights provisions of the 1999 amendments along with certain modifications to the excluded subject matter list from the 2002 amendments.<sup>9</sup>

For the most part, the transition of India's patent system post TRIPS has been rather straightforward. However, certain aspects of the *Patents Act, 1970*, as amended in 2005, have attracted considerable attention, particularly the list of exclusions from patentability under Section 3 of the *Patents Act*.<sup>10</sup> Other issues of significance to users of the Indian patent system are the seemingly onerous requirements to disclose details pertaining to related foreign applications; the compulsory licensing regime; and the requirement to annually file working statements after the grant of a patent.

Almost all of the arguably contentious aspects of the Indian Patent Law trace their origin to Justice Ayyangar's *Report on the Revision of the Patents Law* (the *Ayyangar Report*) submitted to the Indian Parliament in September 1959.<sup>11</sup> Accordingly, this review begins with a historical perspective, drawing from the *Ayyangar Report*, of why those provisions came to be incorporated into the Indian Patent Law. The provisions are categorized into three broad categories: compulsory licenses and working of patents; exclusions from patentability; and disclosures related to foreign applications. For each category, we analyze the recommendations of the *Ayyangar Report* that led to the enactment of the *Patents Act, 1970*, as well as the changes brought by the trilogy of amendments at the turn of the millennium leading to the Indian Patent Law as it is in force today. Finally, the evolution of jurisprudence over the past decade is synthesized to shed light on the current state of law with respect to those controversial provisions.

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<sup>5</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, [http://www.wto.org/english/res\\_e/booksp\\_e/analytic\\_index\\_e/trips\\_e.htm](http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_e.htm) [hereinafter TRIPs].

<sup>6</sup> Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India) [hereinafter 2005 Amendments].

<sup>7</sup> Patents (Amendment) Act, 1999, No. 17, Acts of Parliament, 1999 (India) [hereinafter 1999 Amendments].

<sup>8</sup> Patents (Amendment) Act, 2002, No. 38, Acts of Parliament, 2002 (India) [hereinafter 2002 Amendments].

<sup>9</sup> 2005 Amendments, *supra* note 2, at § 3.

<sup>10</sup> *Id.*

<sup>11</sup> Patents Enquiry Committee, N Rajagopala Ayyangar, *Report on the Revision of the Patents Law, 1959* [hereinafter *Ayyangar Report*].

II. EVOLUTION OF THE *PATENTS ACT, 1970*

Shortly after India's independence in 1947, a Patents Enquiry Committee<sup>12</sup> was created in 1948 to review the Patent Laws in India to "ensure that the patent system was more conducive to national interests."<sup>13</sup> Based on the Committee's interim report, the compulsory licensing and working provisions of the *Indian Patents and Designs Act, 1911*<sup>14</sup> were amended to bring them in line with similar provisions in the *UK Patents Act of 1949*. Specifically, sections 22 and 23 of the *Indian Patents and Designs Act, 1911* were amended to expand the grounds for the grant of compulsory licenses, including non-working of patents in India and failure to meet the requirements of the public on reasonable terms.<sup>15</sup> Further amendments were introduced in 1952 to extend the compulsory licensing regime to "food and medicines, insecticide, germicide or fungicide and a process for producing substance or any invention relating to surgical or curative devices."<sup>16</sup> However, the 1952 amendments were repealed in whole in 1957.<sup>17</sup>

The *Patents Bill, 1953*<sup>18</sup> was tabled in Parliament as a separate enactment for dealing with patents in accordance with the final report of the Committee. The *Patents Bill, 1953* generally followed the *U.K. Patents Statute of 1949* with some changes based on the Committee's recommendations. Section 3 of the *Patents Bill, 1953*, for the first time, included an enumerated list of inventions that were not considered patentable. The compulsory licensing provisions were substantially retained; however, revocation of patents for non-working inventions was omitted.<sup>19</sup> The bill also proposed to confer powers on the controller to call for information on the working of patents in India from the patentee or the exclusive licensee.<sup>20</sup> However, the Bill lapsed when the first *Lok Sabha* (the lower house of the Indian Parliament) was dissolved.

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<sup>12</sup> The Patents Enquiry Committee was appointed on October 1, 1948 and included seven members, including Dr. Bakshi Tek Chand and Mr. K Rama Pai, former Controller of Patents as Member-Secretary.

<sup>13</sup> Ayyangar, *supra* note 7, at para. 1.

<sup>14</sup> Indian Patents and Designs Act, 1911, No. 2, Acts of Parliament, 1911(India), at §§ 22–23.

<sup>15</sup> Amendments to sections 22, 23, and 23A to 23G of the *Indian Patents and Designs Act, 1911* (Act 32 of 1950) were based on the interim report of the Committee submitted in August, 1949. The final report of the Committee was submitted in April 1950.

<sup>16</sup> CONTROLLER GENERAL OF PATENTS DESIGNS AND TRADEMARKS, HISTORY OF INDIAN PATENT SYSTEM, at ¶ 7, <http://www.ipindia.nic.in/history-of-indian-patent-system.htm> (last visited March 13, 2016).

<sup>17</sup> Indian Patents and Designs [Amendments] Act, 1952, No. 70, Acts of Parliament, 1952 (India) (repealed in whole by The Repealing and Amending Act, 1957, No. 36, Acts of Parliament, 1957 (India)).

<sup>18</sup> The Patents Bill, 1953 (was not proceeded with and lapsed by Lok Sabha, 1953) [hereinafter Patents Bill, 1953].

<sup>19</sup> Indian Patents and Designs Act, 1911, No. 2, Acts of Parliament, 1911 (India), at §§ 22–23 (providing grounds for revocation). However, the *Ayyangar Report* notes that these were omitted in the 1950 amendments as well as the *Patents Bill, 1953*; see Ayyangar, *supra* note 6, at ¶ 611.

<sup>20</sup> Patents Bill, 1953, *supra* note 14, at cl. 105.

In 1957, the Indian Government entrusted Justice N Rajagopala Ayyangar, an eminent Indian jurist, with the task of advising on revisions to the patent and design laws. Justice Ayyangar was highly critical of the then current Indian patent system. He felt that it “ha[d] failed in its main purpose, namely to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public.”<sup>21</sup> Justice Ayyangar’s final report consequently contained a comprehensive set of recommendations for revisions to the patent laws,<sup>22</sup> which laid the foundations for the first major reforms in the patent laws of independent India in 1970.<sup>23</sup>

The *Patents Act, 1970*,<sup>24</sup> adopted almost all the recommendations of Justice Ayyangar. Of specific interest is Justice Ayyangar’s views on the scope of statutory provisions for compulsory licensing and working of patents; exclusions from patentability; and disclosure of details pertaining to related foreign applications, each of which is discussed in this article. In addition, the *Patents Act, 1970* introduced restrictions on product patents and allowed only methods or processes of manufacture to be patentable for food, medicines, and chemicals based on the recommendations of Justice Ayyangar.<sup>25</sup> These restrictions were included as Section 5 of the *Patents Act 1970*.<sup>26</sup> Inventions relating to atomic energy were also excluded from patent protection.<sup>27</sup>

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<sup>21</sup> See N. Rajagopala Ayyangar, REPORT ON THE REVISION OF THE PATENTS LAW 1959 (Government of India 1959), quoted in INTELLECTUAL PROPERTY IN ASIA 59 (Paul Goldstein & Joseph Strauss eds., 2009).

<sup>22</sup> Ayyangar, *supra* note 7.

<sup>23</sup> An earlier attempt in 1965 via *The Patents Bill, 1965* based on the *Ayyangar Report* died with the dissolution of the third Lok Sabha in 1967.

<sup>24</sup> The *Patents Act, 1970*, No. 39, Acts of Parliament, 1970 (India) [hereinafter *Patents Act, 1970*].

<sup>25</sup> Ayyangar, *supra* note 7, at ¶ 327.

<sup>26</sup> *Patents Act, supra* note 20, at § 5.

<sup>27</sup> *Id.* at § 4.

### III. COMPULSORY LICENSES AND WORKING OF PATENTS

“A compulsory license is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state.”<sup>28</sup> The compulsory licensing of patents is one of the most contentious issue in patent law internationally. Various countries support the practice as necessary to ensure access to socially beneficial technologies. Other countries disfavor compulsory licensing because of the harm it inflicts on the incentive to invent and the creation of the very technology at issue. Compulsory licensing has long been recognized internationally in accordance with the Paris Convention of 1883<sup>29</sup> and has been a fixture in patent systems around the world, especially those of developing countries. Nevertheless, the legitimacy of compulsory licensing has remained a persistent topic of controversy.

Justice Ayyangar in his *Report*, termed non-working of patents an “evil” and sought to provide remedies “from foreign owned patents which are not worked in the country, but which are held either to block the industries of the country or to secure a monopoly of importation.”<sup>30</sup> The *Ayyangar Report* provides a detailed account of the use of compulsory licensing and revocation for non-working in various countries, with specific emphasis on the United Kingdom. The *Ayyangar Report* states, “[i]f a country with the industrial progress of the U.K. is unwilling to drop the provision as to revocation for non-working in her law, the need for such provision in the circumstances of our country requires no elaborate argument.”<sup>31</sup> Justice Ayyangar went on not only to recommend retaining the compulsory licensing and revocation for non-working provisions from the *Patents Bill 1953*, but also to expand the grounds for awarding compulsory licenses and revocations.<sup>32</sup> The recommendations of the *Ayyangar Report* were substantially adopted as Chapter XVI in the *Patents Act, 1970*.<sup>33</sup> The compulsory licensing provisions continue to exist even after the trilogy of amendments to bring India’s Patent Laws to be in compliance with TRIPS.<sup>34</sup>

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<sup>28</sup> Gorecki, P.K., REGULATING THE PRICE OF PRESCRIPTION DRUGS IN CANADA: COMPULSORY LICENSING, PRODUCT SELECTION, AND GOVERNMENT REIMBURSEMENT PROGRAMS, (Economic Council of Canada 1981).

<sup>29</sup> Paris Convention for the Protection of Industrial Property, art. 5A, ¶ 4, Mar. 20, 1883; “A 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.”

<sup>30</sup> Ayyangar, *supra* note 7 at ¶ 45(3).

<sup>31</sup> *Id.* at § 1.V, cl. 142.

<sup>32</sup> *Id.* at § 1.V, cl. 143.

<sup>33</sup> *Patents Act 1970, supra* note 20, at ch. XVI §§ 82–98.

<sup>34</sup> *Patents Act, supra* note 5, at ch. XVI, §§ 84-94.

Indeed, TRIPS addresses the concept of compulsory licensing, although the phrase “compulsory license” never appears in the patent part of the agreement. TRIPS allows the grant of compulsory licenses as an exception to the agreement’s minimum requirement that all Member States must afford a patentee the right of exclusivity during the complete patent term under specific circumstances.<sup>35</sup> In addition, the World Trade Organization’s 2003 Implementation Decision of the Doha Ministerial on TRIPS and Public Health permits compulsory licenses to be obtained to manufacture and export patented medicines to other countries not having local manufacturing capacity.<sup>36</sup>

With this background, we now review the developments in the compulsory licensing practice in India over the past decade.

#### A. *Statutory Provisions*

Section 84<sup>37</sup> of the *Patents Act* provides the broadest grounds for seeking a compulsory license. A compulsory license seeker under Section 84 cannot file an application until after the targeted patent has been in force for a minimum of three years, and must make out a *prima facie* case in order to be granted the license. The patent owner may initiate an opposition proceeding against the grant of this type of compulsory license. Additionally, under this procedure, the compulsory license may be granted for supply of the patented product only in the domestic market.

<sup>35</sup> TRIPS, *supra* note 1, at arts. 30 and 31.

<sup>36</sup> DOHA, DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, WTO Ministerial (2001).

<sup>37</sup> *Patents Act* 1970, *supra* note 20, at § 84.

(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—

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

(2) An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be estopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.

(5) Where the Controller directs the patentee to grant a licence he may, as incidental thereto, exercise the powers set out in section 88.

(6) In considering the application filed under this section, the Controller shall take into account,—  
(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

Section 84<sup>38</sup> of the *Patents Act* is a more limited provision for the grant of compulsory licenses on notification of the Indian government in circumstances of national emergency such as a public health crisis.

Section 92A<sup>39</sup> of the *Patents Act*, added by the 2005 Amendments, permits manufacture and export of patented medicines to other countries not having local manufacturing capacity in accordance with the WTO's Doha Declaration on TRIPS and Public Health.<sup>40</sup>

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(ii) the ability of the applicant to work the invention to the public advantage;  
 (iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;  
 (iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.

Explanation.—For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—

- (a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,—
- (i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or
  - (ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or
  - (iii) a market for export of the patented article manufactured in India is not being supplied or developed; or
  - (iv) the establishment or development of commercial activities in India is prejudiced; or
- (b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or
- (c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing; or
- (d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or
- (e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by—
- (i) the patentee or persons claiming under him; or
  - (ii) persons directly or indirectly purchasing from him; or
  - (iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

<sup>38</sup> *Patents Act*, *supra* note 5, at § 92.

<sup>39</sup> *Id.* at § 92A.

*Compulsory license for export of patented pharmaceutical products in certain exceptional circumstances*

- (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing

Section 91<sup>41</sup> of the *Patents Act* provides for compulsory licenses to remove blocking patents by brokering a cross-license.

All applications for the grant of compulsory licenses are made to the Controller General of Patents (Controller), who is the head of the Indian Patents Office, and appeals from the Controller's decisions are heard first by the Intellectual Property Appellate Board (IPAB), an administrative tribunal similar to the PTAB, and ultimately by the Indian Supreme Court.

#### *B. Compulsory Licensing: 2007 to 2011*

The first ever compulsory license application following the 2005 amendments was filed under Section 92A by Natco Pharma Ltd. (Natco) in September 2007. The application sought a compulsory license for the manufacture and thereafter exportation to Nepal of F Hoffman La Roche Ltd.'s (Roche) patented anti-cancer drug, Erlonitib (Patent No. 196774), sold under the brand name Tarceva, and Pfizer's anti-cancer drug Sunitinib (Patent No. 209251), sold under the brand name Sutent. While the application was still under consideration, Natco filed an interlocutory petition before the Controller asserting that Section 92A did not provide an opportunity for patentees whose patents were the subject of compulsory license applications to be heard, and therefore neither Roche nor Pfizer should have a right to respond to Natco's application.<sup>42</sup> Natco possibly raised this contention owing to the fact that, unlike the scheme of compulsory license provided under Section 84 of the *Patents Act*, which expressly allows the patentee an opportunity to be heard,<sup>43</sup> the compulsory license scheme provided under Section 92A of the *Patents Act* does not specifically provide for any such opportunity. However, Natco subsequently withdrew the compulsory license application before any pronouncements could be made on the merits of Natco's position, thus, leaving the issue of a patentee's opportunity to be heard undecided.

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capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

- (2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.
- (3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.

Explanation: For the purposes of this section, 'pharmaceutical products' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.

<sup>40</sup> DOHA, in Fourth Session of Ministerial Conference (November 2001).

<sup>41</sup> *Id.* at § 91.

<sup>42</sup> Swarup Kumar, "Compulsory Licensing Provision Under TRIPS: a Study of Roche vs. Natco Case in India vis-à-vis The Applicability of the Principle of Audi Alteram Partem", SCRIPTed Vol. 7, No.1 (March 15, 2010).

<sup>43</sup> *Patents Act* 1970, *supra* note 20, at § 87

Procedure for dealing with applications under §§ 84 and 85.-

The Department of Industrial Policy and Promotion (DIPP), situated within the Ministry of Commerce and Industry, is responsible for the administration of the Patent system in India. In August 2010, it released a discussion paper to address concerns regarding market-availability of low-price life-saving drug.<sup>44</sup> The objective was to facilitate development of a predictable environment for the use of compulsory licensing in the pharmaceutical sector, thereby balancing the rights of the patent holder and the governmental obligation to ensure availability of products, especially life-saving drugs, at reasonable prices. In the paper, different stakeholders' views were sought on the scope of compulsory licensing provisions to gauge the need for new guidelines. The DIPP received a diverse set of responses from academics, domestic industry bodies, foreign industry groups, and of course public health NGOs.<sup>45</sup> The generic drug industry supported the general view of the DIPP in its paper while the innovator companies strongly opposed any move to dilute their existing patent rights through the issuance of compulsory licenses.

On April 11, 2011, the DIPP issued a press release stating that the existing legal provisions were sufficient and that there was no need for any further guidelines for the issuance of compulsory licenses<sup>46</sup>. Significantly, the DIPP also advised the Controller not to delegate the power to any subordinate authority so that compulsory license matters could be decided promptly and the power to grant licenses was exercised with due care and caution.<sup>47</sup>

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(1) Where the Controller is satisfied, upon consideration of an application under section 84, or section 85, that a prima facie case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and 175 [shall publish the application in the official journal].

(2) The patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition.

(3) Any such notice of opposition shall contain a statement setting out the grounds on which the application is opposed.

(4) Where any such notice of opposition is duly given, the Controller shall notify the applicant, and shall give to the applicant and the opponent an opportunity to be heard before deciding the case.

<sup>44</sup> *Government starts review of Compulsory Licensing Norms*, BUSINESS STANDARD, Aug 25, 2010; [http://www.business-standard.com/article/economy-policy/government-starts-review-of-compulsory-licensing-norms-110082500080\\_1.html](http://www.business-standard.com/article/economy-policy/government-starts-review-of-compulsory-licensing-norms-110082500080_1.html).

<sup>45</sup> Press Release, DIPP (April 11, 2011), [http://dipp.nic.in/English/acts\\_rules/Press\\_Release/pr11042011.pdf](http://dipp.nic.in/English/acts_rules/Press_Release/pr11042011.pdf).

<sup>46</sup> *Supra* note 38.

<sup>47</sup> *Supra* note 41.

### C. Compulsory Licensing: 2011 Onwards

The first post-TRIPS compulsory license was granted in 2012 to Natco for Bayer Corporation's (Bayer) anti-cancer drug sorafenib tosylate (Indian Patent No. 215758), sold under the brand name Nexavar. Bayer appealed against the grant of the compulsory license all the way to the Supreme Court of India, but in vain. All the appellate judicial forums upheld that grant of the compulsory license, albeit differing on the interpretations of certain provisions governing compulsory licenses under the *Patents Act*.

#### 1. Brief Background of the Controller General and IPAB Orders

Natco applied to the Controller for grant of a compulsory license to manufacture and sell Nexavar in India after Bayer refused to grant a voluntary license.<sup>48</sup> The application was made under Section 84(1) of the *Patents Act*<sup>49</sup> and allowed Bayer to oppose the application.<sup>50</sup> The Controller allowed<sup>51</sup> Natco's application on the grounds that the reasonable requirement of the public in India was not met<sup>52</sup> and that the patented invention was not available to the public.<sup>53</sup> With regard to whether the patented invention was not worked in the territory of India,<sup>54</sup> the Controller interpreted "worked in the territory of India" to mean "manufactured to a reasonable extent in India."<sup>55</sup>

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<sup>48</sup> Compulsory License Application No. 1 of 2011 (Controller General of Patents, Mar. 9, 2012), [http://www.ipindia.nic.in/iponew/compulsory\\_license\\_12032012.pdf](http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf).

<sup>49</sup> *Patents Act*, § 84(1) (1970), [http://www.liiofindia.org/in/legis/cen/num\\_act/pa1970109/](http://www.liiofindia.org/in/legis/cen/num_act/pa1970109/).

<sup>50</sup> *Patents (Amendment) Act*, § 87 (2002), [http://www.liiofindia.org/in/legis/cen/num\\_act/pa2002189/](http://www.liiofindia.org/in/legis/cen/num_act/pa2002189/) (states the procedure for consideration of applications under Section 84 and 85 of the *Patents Act*).

Section 87 : Procedure for dealing with applications under sections 84 and 85-

(1) Where the Controller is satisfied, upon consideration of an application under section 84, or section 85, that a prima facie case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the patentee and any other person appearing from the register to be interested in the patent in respect of which the application is made, and shall publish the application in the official journal.

(2) The patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition.

(3) Any such notice of opposition shall contain a statement setting out the grounds on which the application is opposed.

(4) Where any such notice of opposition is duly given, the Controller shall notify the applicant, and shall give to the applicant and the opponent an opportunity to be heard before deciding the case.

<sup>51</sup> Controller General of Patents, *supra* note 48 at 60.

<sup>52</sup> *Patents (Amendment) Act*, § 84(1)(a) (2002) (amended 2005), [http://www.liiofindia.org/in/legis/cen/num\\_act/pa2002189/](http://www.liiofindia.org/in/legis/cen/num_act/pa2002189/).

<sup>53</sup> *Patents (Amendment) Act*, § 84(1)(b) (2002) (amended 2005), [http://www.liiofindia.org/in/legis/cen/num\\_act/pa2002189/](http://www.liiofindia.org/in/legis/cen/num_act/pa2002189/).

<sup>54</sup> *Patents (Amendment) Act*, § 84(1)(c) (2002) (amended 2005), [http://www.liiofindia.org/in/legis/cen/num\\_act/pa2002189/](http://www.liiofindia.org/in/legis/cen/num_act/pa2002189/).

<sup>55</sup> Controller General of Patents, *supra* note 46, at 43.

Bayer appealed the order of the Controller before the Intellectual Property Appellate Board (IPAB). However, the IPAB upheld the Controller's order granting the compulsory license.<sup>56</sup> It is pertinent to note that the IPAB differed with the Controller's order on the interpretation of the term "worked in the territory of India."<sup>57</sup> The IPAB was of the opinion that the requirement of working on the patented drug in India did not necessarily mean that the drug ought to be manufactured in India; the requirement could also be fulfilled by importing the patented drug to India.<sup>58</sup>

## 2. Order of the Division Bench of the Bombay High Court

Aggrieved, Bayer moved on to the Bombay High Court with a writ of certiorari seeking to quash the order from IPAB into which the order of the Controller had been merged. The Division Bench of the Bombay High Court upheld the order of the IPAB, thus maintaining Natco's compulsory license.<sup>59</sup>

The following are some of the important issues framed by the Division Bench of the Bombay High Court in order to decide the writ filed by Bayer:

- a. Whether Bayer has satisfied the reasonable requirements of the public under Section 84(1)(b) of the Act?<sup>60</sup>
- b. Whether the patented drug is available to the public at a reasonably affordable price?<sup>61</sup>
- c. Whether the patented drug has been worked in the territory of India?<sup>62</sup>
- d. Whether the terms and conditions for grant of compulsory license were proper under Section 90 of the Act?<sup>63</sup>

## 3. Bombay High Court's Reasoning and Judgment

### a. Reasonable Requirement of the Public

#### i. Burden of Proof

Bayer argued that the initial burden to make out a *prima facie* case for the grant of a compulsory license was on Natco and that Natco had failed to do so.<sup>64</sup> The Division Bench agreed that the initial burden is on the applicant who makes an application for a compulsory license to establish a *prima facie*, but it held that Natco was able to make such a showing to the satisfaction of the Controller General.<sup>65</sup>

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<sup>56</sup> Bayer Corporation v. Union of India, No. 45 of 2013 (IPAB Mar. 4, 2013), <http://www.ipabindia.in/Pdfs/Order-45-2013.pdf>.

<sup>57</sup> *Id.* at ¶ 23.

<sup>58</sup> *Id.* at ¶ 52.

<sup>59</sup> Bayer Corporation vs. Union of India, (2014) 60 PTC 277 (Bombay HC).

<sup>60</sup> *Id.* at ¶ 13.

<sup>61</sup> *Id.* at ¶ 14.

<sup>62</sup> *Id.* at ¶ 15.

<sup>63</sup> *Id.* at ¶ 17.

<sup>64</sup> *Id.* at ¶ 13.

<sup>65</sup> *Id.*

*ii. Quantum of Drug Required by the Public*

The Division Bench observed that it was not possible to determine the reasonable requirement of the public without ascertaining the exact quantum of the patented drug required by the public.<sup>66</sup> The Division Bench held that such an exercise cannot be carried out on a mathematical basis but has to be determined based on the evidence provided by the parties.<sup>67</sup> The parties had, before the IPAB and the Controller, relied upon the Globocan 2008 data<sup>68</sup> to determine the incidence of patients suffering from cancer in India. The Division Bench held that the reasonable requirements of the public ought to be determined based on this data.<sup>69</sup> The Division Bench also took into consideration Bayer's country medical director's affidavit that illustrated that the quantum of drugs sold was not in consonance with the quantum of patients requiring the drug.<sup>70</sup> Thus, the Division Bench upheld the determination by the Controller General and the IPAB that the reasonable requirement of the public was not satisfied by Bayer.

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<sup>66</sup> *Id.*

<sup>67</sup> *Id.* at ¶ 12.

<sup>68</sup> INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, *GLOBOCAN 2008: Cancer Incidence and Mortality Worldwide* (May 1, 2010), <https://www.iarc.fr/en/media-centre/iarcnews/2010/globocan2008.php> (a project undertaken by the International Agency for Research on Cancer under the aegis of the World Health organization aimed at providing contemporary estimates of the incidence of mortality and prevalence of major types of cancer at the national level for 184 countries of the world).

<sup>69</sup> Bayer Corporation vs. Union of India, (2014) 60 PTC 277 (Bombay HC) at ¶13.

<sup>70</sup> *Id.*

*iii. Infringer's Supply*

The Division Bench rejected Bayer's argument that supplies of the anti-cancer drug by other infringers, including Cipla, a major Indian multinational pharmaceutical company, should also be considered to determine the satisfaction of the reasonable requirement test.<sup>71</sup> Bayer contended that in order to determine whether the reasonable requirement of public was met with respect to the patented invention, supplies of the patent drug undertaken by other infringers such as Cipla also need to be taken into account.<sup>72</sup> The Bench held that the obligation to meet the reasonable requirement of the public rests upon the patentee, either alone or through its licensees. Section 146 of the Indian *Patents Act* and Rule 131 of the Indian Patents Rules require patentees to report annually<sup>73</sup> on the extent to which “the patented invention has been commercially worked in India.”<sup>74</sup> IPAB had reasoned that since Bayer had not included Cipla’s sale of the patented drug in Bayer’s reporting, the extent to which Cipla supplied the market should not be taken into account.<sup>75</sup> The Division Bench essentially agreed with this reasoning and therefore concluded that Bayer had not satisfied the reasonable requirement test<sup>76</sup>.

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<sup>71</sup> *Id.* at ¶13(d).

<sup>72</sup> *Id.*

<sup>73</sup> Patentees fulfill the annual reporting obligation by completing and submitting to the Controller of Patents Form 27, “Statement Regarding the Working of the Patented Invention on Commercial Scale in India.”

<sup>74</sup> *Patents Act*, § 146(1) (1970), [http://www.liiofindia.org/in/legis/cen/num\\_act/pa1970109/](http://www.liiofindia.org/in/legis/cen/num_act/pa1970109/).

<sup>75</sup> *Bayer Corp. v. Union of India*, No. 45 of 2013 (IPAB Mar. 4, 2013), <http://www.ipabindia.in/Pdfs/Order-45-2013.pdf> at ¶ 13(d), *supra* note 44.

<sup>76</sup> *Id.*

iv. *Interpretation of "Adequate Extent"*

As mentioned above, Section 84(1)(a) of the *Patents Act* provides that any interested party may apply for a compulsory license if “the reasonable requirements of the public with respect to the patented invention have not been satisfied.”<sup>77</sup> Section 84(7)(a)(ii) specifies that the reasonable requirements are deemed not to have been satisfied if “the demand for the patented article has not been met *to an adequate extent . . .*” (emphasis added). The Division Bench was thus faced for the first time with having to interpret the term “adequate extent.”<sup>78</sup> It held that with regard to medicines, the adequate extent test has to be 100%, i.e. to the fullest extent.<sup>79</sup> Referring to the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), adopted on November 14, 2001,<sup>80</sup> the Bench held that adequate extent for medicines had to be interpreted as medicines being made available to every patient.<sup>81</sup> Thus, the Bench held that in the instant case, Bayer did not meet the requirements of all the patients.<sup>82</sup>

b. *Reasonably Affordable Price*

i. *Controller's Obligation under Section 90(1)(iii)*

The Division Bench upheld the order of the IPAB and the Controller that the patented drug was not made available to the public at a reasonably affordable price.<sup>83</sup> Bayer contended that under Section 90(1)(iii) of the *Patents Act*,<sup>84</sup> there exists an obligation on the Controller to determine the reasonably affordable price of the patented drug.<sup>85</sup> The Division Bench however, rejected the contention and held that the *Patents Act* does not bestow any such powers of investigation on the authorities to determine the reasonably affordable price of a patented drug.<sup>86</sup> The Division Bench held that the evidence as introduced by the parties would form the basis of determining reasonably affordable prices.<sup>87</sup> The Division Bench also held that the reasonably affordable price has to be determined on the basis of the relative price being offered by the patent holder and the applicant after hearing other interested parties opposing the application.<sup>88</sup> Applying this principle, the Division Bench compared the prices<sup>89</sup> at which Bayer and Natco sold Nexavar and held that Bayer did not sell the drug at a reasonably affordable price.<sup>90</sup>

<sup>77</sup> *Patents (Amendment) Act*, § 84(1)(a) (2002) (amended 2005), [http://www.liiofindia.org/in/legis/cen/num\\_act/pa2002189/](http://www.liiofindia.org/in/legis/cen/num_act/pa2002189/).

<sup>78</sup> *Bayer Corp. v. Union of India*, No. 45 of 2013 (IPAB Mar. 4, 2013), <http://www.ipabindia.in/Pdfs/Order-45-2013.pdf> at ¶ 13(f).

<sup>79</sup> *Id.*

<sup>80</sup> WORLD TRADE ORGANIZATION, *Declaration on the TRIPS Agreement and Public Health* (Nov. 11, 2001), [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>81</sup> *Bayer Corp. v. Union of India*, No. 45 of 2013 (IPAB Mar. 4, 2013), <http://www.ipabindia.in/Pdfs/Order-45-2013.pdf> at ¶ 13(f).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* at ¶14

<sup>84</sup> *Patents (Amendment) Act*, § 90(1) (2002) (amended 2005), [http://www.liiofindia.org/in/legis/cen/num\\_act/pa2002189/](http://www.liiofindia.org/in/legis/cen/num_act/pa2002189/).

Terms and conditions of compulsory licences. –

(1) In settling the terms and conditions of a licence under section 84, the Controller shall endeavour to secure-

*ii. R&D Costs in Developing Drug*

The Bench held that under Section 90(1) of the *Patents Act*, in determining whether the patented drug was available to the public at a reasonable price, only the expenditure incurred for research and development on the patented drug should be taken into account and not costs incurred in respect of research and development on failed drugs.<sup>91</sup> Bayer had asserted that in determining whether the patented drug was available to the public at a reasonable price, the price of the patented drug should be such that the costs incurred in respect of research and development on failed drugs were also reflected.<sup>92</sup>

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- (i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;
  - (ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him;
  - (iii) that the patented articles are made available to the public at reasonably affordable prices;
  - (iv) that the licence granted is a non-exclusive licence;
  - (v) that the right of the licensee is non-assignable;
  - (vi) that the licence is for the balance term of the patent unless a shorter term is consistent with public interest;
  - (vii) that the licence is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product, if need be in accordance with the provisions of sub-clause (iii) of clause (a) of sub-section (7) of section 84;
  - (viii) that in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use;
  - (ix) that in case the licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, the licensee shall be permitted to export the patented product, if need be.

<sup>85</sup> *Bayer Corp. v. Union of India*, No. 45 of 2013 (IPAB Mar. 4, 2013), <http://www.ipabindia.in/Pdfs/Order-45-2013.pdf>, at ¶ 14.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> Bayer sold the drug at about 4260 USD (2,84,000 INR) for a month's therapy as opposed to Natco's price of 132 USD (8,800 INR) for a month's therapy.

<sup>90</sup> *Bayer Corp. v. Union of India*, No. 45 of 2013 (IPAB Mar. 4, 2013), <http://www.ipabindia.in/Pdfs/Order-45-2013.pdf>, at ¶ 14.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

*iii. Adverse Inference against Bayer*

The Division Bench noted Bayer's omission of audited accounts establishing the amount spent on research and development of the patented drug.<sup>93</sup> It concluded that Bayer had failed to produce the best evidence before the authorities and thus held that an adverse inference had to be drawn against Bayer.<sup>94</sup> On the issue of the expenditure incurred for research and development, Natco asserted that about fifty percent of Bayer's expenditure incurred for research and development of the patented drug qualified for reimbursement either by tax credit or otherwise due to the drug's classification as an orphan drug<sup>95</sup> in the U.S.<sup>96</sup>

*iv. Importance of Patient Assistant Program (PAP) Schemes*

The role of PAP schemes that subsidize costs to certain patients was considered and rejected by the Division Bench. Bayer argued that under its PAP scheme, if a patient buys three dosages (12 tablets) of Nexavar, the remaining tablets (108 tablets) for the month were provided free of cost, and suggested that the patented drug was available to the public at a reasonably affordable price. Natco responded that the special price under PAP was only given to particular patients on the recommendation of the doctor and at the discretion of Bayer. The Division Bench concurred with Natco and held that the patented drug ought to be available to any member of the public at a reasonably affordable price. Thus, the Division Bench held that the price under PAP was an exceptional price and not the price at which the patented drug was available to the public in the ordinary course.

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<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> Orphan Drug Act § 316.3(b)(10) & (11), 21 CFR Part 316 (2016)

("(10) Orphan drug means a drug intended for use in a rare disease or condition as defined in section 526 of the act.

(11) Orphan-drug designation means FDA's act of granting a request for designation under section 526 of the act.").

<sup>96</sup> *Bayer Corp. v. Union of India*, No. 45 of 2013 (IPAB Mar. 4, 2013),

<http://www.ipabindia.in/Pdfs/Order-45-2013.pdf> at ¶ 14.

c. *Worked in the territory of India*

The Bench held that when a patent holder is faced with an application for a compulsory license, it is for the patent holder to show that the patented invention is worked in the territory of India by manufacture or import. The Bench also clarified that manufacture in all cases may not be necessary to establish working in India. However, the Bench held that given the mandate under Section 83 of the Act, which is directed to “General principles applicable to working of patented invention,”<sup>97</sup> the patent holder would have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India. Bayer argued that in light of Article 27 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which states that there can be no discrimination in respect of a patented product whether locally manufactured or imported,<sup>98</sup> the patented drug Nexavar has been worked in India. Further, Bayer referred to the reporting requirement (Form 27) prescribed in Section 146 of the Act and Section 131 of the Rules, wherein the patent holder while giving details of the patented drug in India, has to make a declaration of working in India of the patented product. Bayer asserted that the information to be submitted in the form is divided into two classifications, namely, “manufacture in India” and “imported from other countries,” and thus working the patent product in the territory of India does not exclusively mean manufacture of the patented product in India. In light of the above, Bayer contended that imported supply of goods within the territory would amount to working of the patent in India. The Respondents, the Union [Government] of India, opposed Bayer's contention on the ground that for the purposes of working in India, the patented drug has to be manufactured in India. It is pertinent to note that this contention of the Union of India, although accepted by the Controller General, was rejected by the IPAB.

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<sup>97</sup>See *Intellectual Property India*,

“Section 83. *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;
- (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- (c) that the protection and enforcement of patent rights 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;
- (d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
- (e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
- (f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
- (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.”

<sup>98</sup> See *Agreement on Trade-Related Aspects of Intellectual Property Rights*,  
[https://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](https://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

The Bench, referring to Section 83 of the Act, held that some efforts to manufacture in India should be made by the patent holder. Further, referring to Form 27, the Bench agreed with the interpretation by the IPAB that whether a patent has been worked in the territory of India has to be determined on a case-to-case basis.

*d. Terms and Conditions for the Grant of a Compulsory License*

Section 90 of the Act states among other terms that the Controller has to ensure that the royalty and other remuneration paid to the patent holder should reasonably cover the expenses incurred by the patent holder in making or developing the patented invention.<sup>99</sup> In this regard it is pertinent to note that the Controller General fixed the royalty rate to be paid by Natco to Bayer at 6% of the net sales made by Natco. This figure was arrived at by the Controller General on the basis of the United Nations Development Programme Report, which recommends that the normal rate of royalty should be at 4% of the net sales. The IPAB however, increased the royalty rate to 7% of the net sales. It was this determination of the royalty rate that Bayer averred to be insufficient and contrary to Section 90 of the Act.

The Bench held that Bayer failed to adduce any evidence to show in what manner the royalty rate of 7% of the net sales was inadequate. Further, the Bench observed that Bayer failed to introduce any evidence on the cost incurred by Bayer to develop Nexavar. Hence, in light of the fact that Bayer failed to adduce evidence to show that the terms of the compulsory license were contrary to Section 90 of the Act, the Bench upheld the royalty rate fixed by IPAB at 7% of the net sales.

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*Article 27 Patentable Subject Matter*

1. *Subject to the provisions of paragraphs 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. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 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.*

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.”)

<sup>99</sup> *Supra* note, 48 at 90(1)(i).

*e. Supreme Court on the Nexavar Compulsory License*

Bayer filed a Special Leave Petition to the Supreme Court India<sup>100</sup> to appeal against the order of the Division Bench of the Bombay High Court. However, the Supreme Court dismissed the petition, thereby upholding the grant of the compulsory license.

The compulsory license application for Nexavar is the only case which has been examined at all judicial levels, from the Controller to the IPAB, the High Court and the Supreme Court of India. The Division Bench of the Bombay High Court elaborated and clarified several provisions pertaining to the compulsory license regime in India. The Division Bench also emphasized that the proceedings under Section 84 of the Act are in public interest, and that public interest is fundamental in deciding a matter of compulsory licensing with respect to medicines or drugs.

*D. Other Recent Compulsory License Attempts*

Following the Nexavar case, India's tryst with compulsory license has continued. In March 2013, BDR Pharmaceuticals International Pvt. Ltd. (BDR) filed an application for a compulsory license for Bristol-Myers Squibb's (BMS) anti-cancer drug Dasatinib (Indian Patent No. 203937), sold under the brand name Sprycel. However, on October 29, 2013, the Controller rejected<sup>101</sup> the application, mainly on the ground that BDR did not undertake enough effort to obtain a voluntary license on reasonable terms and conditions from BMS for the drug. The Controller's decision made clear that it is a statutory mandate under Section 84(6)(iv) of the Act for an applicant to make efforts to obtain a voluntary license before seeking a compulsory license.

The latest compulsory license episode recently unfolded with the Controller of Patents rejecting a compulsory license application filed by Lee Pharma Ltd. ("Lee Pharma"), a Hyderabad-based pharmaceutical manufacturer, for AstraZeneca AB's ("Astrazeneca") anti-diabetic drug Saxagliptin (Indian Patent No. 206543), sold under the brand name Onglyza, by order dated January 19, 2016.

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<sup>100</sup> A Special Leave Petition is roughly analogous to a petition for a writ of certiorari filed with the U.S. Supreme Court.

<sup>101</sup> Compulsory License Application No. 1 of 2013; Controller General of Patents, Order Dated October 29th, 2013.

Lee Pharma sought a compulsory license on the grounds that the reasonable requirements of the public with respect to Saxagliptin were not being satisfied; that Saxagliptin was not available to the public at a reasonably affordable price; and that Saxagliptin was not being worked in India. The Controller, in a detailed order<sup>102</sup> analyzed each ground and held that Lee Pharma failed to establish a *prima facie* case under any of them. Essentially, the Controller held there existed other DPP-IV inhibitors, such as Linagliptin, Vildagliptin and Sitagliptin, which were being concurrently prescribed by Indian doctors. Moreover, the Controller took into consideration the submission that 90% of patients were prescribed DPP-IV inhibitors other than Saxagliptin. The Controller also noted that the other DPP-IV inhibitors, despite their greater volume of sales, were priced the same as that of Saxagliptin. The Controller thus held that if the other similarly-priced DPP-IV inhibitors were arguably affordable, then, without any evidence to the contrary, it could not be held that Saxagliptin was being sold at an excessively high price in India.

Further, the Controller also reiterated the ruling of the Bombay High Court in the Nexavar case that manufacturing in India is not a necessary precondition to show working in India; however, the patentee is required to establish reasons that prevent the patentee from manufacturing in India. Accordingly, the Controller held that Lee Pharma failed to show any report, evidence or study that established the number of patients requiring Saxagliptin and therefore whether there existed any shortage in supply of the drug. The lack of such data from Lee Pharma was held by the Controller insufficient to establish necessity of manufacture in India.

#### *E. Conclusion*

It appears that the jurisprudence on the compulsory licensing regime is now settled in India. The analysis by the IPAB and the Bombay High Court in the Nexavar application has provided clarity on the scope of the grounds for granting a compulsory license under Section 84 of the *Patents Act*. Essentially the grounds for seeking a compulsory license under Section 84 are that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or that the patented invention is not available to the public at a reasonably affordable price, or that the patented invention has not been worked in the territory of India. While there may be due process concerns owing to unclear wording regarding the Patent Act's other compulsory licensing provisions (such as Section 92A), the Indian Judiciary has established specific conditions for issuing compulsory licenses under Section 84 of the *Act*, and it thereby seems to have allayed fears that compulsory licensing will be used as a tool to undermine patent rights.

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<sup>102</sup> Compulsory License Application No.1 of 2015; Controller General of Patents, Order Dated January 19th, 2016.

Clause 105 of the *Patents Bill 1953*<sup>103</sup> empowered the Controller of Patents to seek, from patentees or exclusive licensees, information pertaining to the commercial working of their patented inventions in India. Justice Ayyangar embraced this provision in his recommendations and called for “setting up of a unit in the Commerce Ministry for [obtaining information as regards the working of patents].”<sup>104</sup> Justice Ayyangar dismissed concerns that such a provision would be “burden rather than an advantage” and that “compliance with the provisions of this clause would compel manufacturers to disclose their trade secrets.”<sup>105</sup> Instead, he opined that “particulars as to working of the invention would be useful for statistical purposes as at present no estimate can be made of the extent to which patents are being worked.”<sup>106</sup> Further, Justice Ayyangar sought to expand the powers of the controller to seek the requisite working information from not just the patentees or exclusive licensees, but also from non-exclusive licensees.<sup>107</sup>

The recommendations of Justice Ayyangar with respect to working statements were incorporated as Section 146 of the *Patents Act 1970*.<sup>108</sup> In addition, the *Patents Act 1970* imposed a statutory requirement on patentees and their licensees (exclusive or otherwise) to “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.”<sup>109</sup> Section 146(2) of the *Patents Act 1970*, read in conjunction with section 131 of the *Patent Rules 2003*,<sup>110</sup> currently mandates that patentees and their licensees provide information on the working of patented inventions in India for the preceding calendar year on or before March 31 of the subsequent year in a format as prescribed by Form 27.

As discussed earlier, non-working of a patented invention is not only a ground for the grant of a compulsory license, but for the revocation of the patent itself.<sup>111</sup> Consequently, the submission of working statements under Section 146(2) of the *Patents Act 1970* and section 131 of the *Patent Rules 2003* is critical to maintain a patent in force in India. It is significant to note that the working statements filed by Bayer for the patented drug Nexavar played a crucial role in ascertaining whether the reasonable requirements of the public with respect to the patented invention had been satisfied as per section 84(a) of the *Patents Act*.<sup>112</sup>

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<sup>103</sup> *The Patents Bill 1953*, *supra* note 14 at Cl. 105

*Power of Controller to call for information from patentee*—The Controller may, at any time during the continuance of the patent by notice in writing require a patentee or an exclusive licensee 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 and such periodical statements as to the extent to which the patent has been commercially worked in India, as may be specified in the notice.

<sup>104</sup> Ayyangar, *supra* note 7 at ¶ 167.

<sup>105</sup> *Id.* at ¶ 838.

<sup>106</sup> *Id.* at ¶ 840.

<sup>107</sup> *Id.* at ¶¶ 842–844.

<sup>108</sup> *Patents Act 1970*, *supra* note 20 at § 146.

<sup>109</sup> *Id.* at § 146(2).

<sup>110</sup> *The Patent Rules 2003*, at § 131.

<sup>111</sup> See *supra* note 29-30 and accompanying text.

<sup>112</sup> *Id.*

More recently, a public interest writ petition has been filed before the Delhi High court “to compel patentees and licensees to comply with the statutory mandate to declare information on the working of their patents, as per the *Patents Act, 1970 & Rules thereunder*.”<sup>113</sup> The petition alleged “a blatant disregard for an important statutory mandate, with close to 35% of the patentees failing to disclose their patent working status during 2009 to 2012.”<sup>114</sup> The petition further contended that even in instances where a working statement had been filed, “the disclosures [...] were either incomplete, negligent, or incomprehensible.”<sup>115</sup> The petition sought the Court to direct the Patent Office to enforce the statutory provisions with respect to commercial working of patented inventions in India and to form a committee to review the format of the information being collected in Form 27 so as to fulfill its objectives.<sup>116</sup> The matter was scheduled for further hearings in the summer of 2016.

#### IV. EXCLUSIONS FROM PATENTABILITY

As discussed earlier, the *Patents Bill 1953*, for the first time, included an enumerated list of what is not patentable (see below). However, as the bill died on the floor of the house, the list remained outside the purview of the Indian Patent Laws until 1970.

##### Section 3 of the Patents Bill 1953

3. What is not patentable.—The following shall not be patentable under this Act.—

- (a) an invention the use of which would be contrary to law or morality;
- (b) the mere discovery of new properties of a known substance;
- (c) a mere duplication of known devices or juxtaposition of known devices which function independently of one another;
- (d) a substance prepared or produced by a chemical process or intended for food or medicine other than a substance prepared or produced by any method or process of manufacture particularly described in the complete specification of the invention or by its obvious chemical equivalent.

Explanation.—In relation to a substance intended for food or medicine, a mere admixture resulting only in the aggregation of the known properties of the ingredients of that substance shall not be deemed to be a method or process of manufacture.

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<sup>113</sup> See *Shamnad Basheer vs. Union of India and others*, at E, W.P.(C) 5590/2015.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.* at E-F.

<sup>116</sup> *Id.* at 1.

In his *Report*, Justice Ayyangar was unequivocal in his support for the statute “specifying with clarity which ‘inventions’ alone are patentable and which ‘inventions’ should not be patentable.”<sup>117</sup> He reasoned that positively identifying patentable and non-patentable inventions would “(1) eliminate ambiguity and (2) prescribe in precise terms inventions for which patents should be refused in the interests of either of national economy or national health or well-being.”<sup>118</sup> Accordingly, the *Report* recommended revisions to Section 3 of the *Patents Bill 1953* to include an “exhaustive enumeration” of what is not patentable.<sup>119</sup> He also proposed to explicitly exclude food and medicinal products as well as products of chemical processes, while at the same time allowing patents to be granted for chemical processes themselves.<sup>120</sup> Justice Ayyangar’s focus primarily lay on patents for chemical products and inventions relating to food and medicine. This was hardly surprising considering the state of a 12-year-old nation wishing to protect its national interests and to build an industrial economy.

Moreover, the *Report* justified most of the exclusions as being “almost universally not patentable.”<sup>121</sup> The remaining exclusions were to “remove any doubt that might exist as regards the patentability of such inventions,”<sup>122</sup> or were based on the *UK Patent Act* and/or case law developed in the U.K.<sup>123</sup>

The recommendations of the *Ayyangar Report* for *Clause 3 – What is not patentable*<sup>124</sup> - were adopted almost verbatim in the *Patents Act 1970* as recitals in Sections 3 and 5 (see comparative chart below).<sup>125</sup>

Justice Ayyangar's recommendations for Section 3	Chapter II of the <i>Patents Act 1970</i> - Inventions not patentable
3. What is not patentable.—The following shall not be patentable under this Act and shall be deemed always not to have been patentable:—	3. What are not inventions:- The following are not inventions within the meaning of this Act,-
(1)(a) An invention which is frivolous or claims anything obviously contrary to well established natural laws.	(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;
(b) An invention the use of which would be contrary to law or morality or injurious to public health.	(b) an invention the primary or intended use of which would be contrary to law or morality or injurious to public health;
(c) The mere discovery of a scientific principle or the formulation of an abstract theory.	(c) the mere discovery of a scientific principle or the formulation of an abstract theory;

<sup>117</sup> *Id.* at ¶ 48.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.* at ¶ 327.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.* at ¶ 330 with respect to paragraphs (a), (b), (c), (g), and (h) of sub clause (I) of Cl. 3.

<sup>122</sup> *Id.* at ¶ 331.

<sup>123</sup> *Id.* at ¶¶ 332–35.

<sup>124</sup> *Id.*

<sup>125</sup> *Patents Act of 1970*, *supra* note 20, at §§ 3, 5.

(d) Methods of agriculture or horticulture.	(h) a method of agriculture or horticulture;
(e) Processes for medicinal, surgical, curative, prophylactic, and other treatment of man and processes for similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.	(i) any process for the medicinal, surgical, curative, prophylactic, or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products;
(f) A claim to a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.	(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
(g) A mere discovery of any new property or new use for a known substance, or of the mere new use of a known process, machine or apparatus.	(d) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;
(h) A mere arrangement or rearrangement or duplication of known devices each working in an old or well-known way.	(f) the mere arrangement or rearrangement or duplication of known devices each functioning independently of one another in a known way;
----	(g) a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture;
(2) No patent shall after the commencement of this Act be granted in respect of inventions claiming—(a) substances intended for or are capable of being used as food or beverage or as medicine (for men or animals) including sera, vaccines, antibiotics and biological preparations, insecticide, germicide or fungicide, and (b) substances produced by chemical processes including alloys but excluding glass.	5. In the case of inventions-(a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances themselves,
(3) Notwithstanding anything in sub-	5(b) (cont.) but claims for the methods

section (2) inventions of chemical processes for the manufacture or production of the substances mentioned in that subsection shall be patentable.	or processes of manufacture shall be patentable.
----	4. No patent shall be granted in respect of an invention relating to atomic energy falling within sub-section (1) of section 20 of the Atomic Energy Act, 1962.

The exclusion list enumerated in the *Patents Act 1970* has survived relatively unscathed for over four decades. However, the exclusion list received much attention in the 2002 and 2005 Amendments. Significantly, the *2002 Amendments*, among others, modified “Section 3 [...] to include exclusions permitted by TRIPS Agreement and also subject-matters like discovery of any living or non-living substances occurring in nature in the list of exclusions which in general do not constitute patentable invention.”<sup>126</sup> Section 3(g) of the *Patents Act 1970* was omitted and Sections 3(d) and 3(i) were amended in 2002.<sup>127</sup> The list of excluded subject matter under Section 3 also grew from 9 to 15 with the 2002 Amendments with the addition of new sections 3(j) to 3(p). Inventions that are, in effect, traditional knowledge or an aggregation or duplication of traditionally known component(s) were excluded under Section 3(p). Exclusions relating to literary, dramatic, musical or artistic work (Section 3(l)) were covered under copyrights, while exclusions relating to topography of integrated circuits (Section 3(o)) were covered under the *Semiconductor Integrated Circuits Layout-Design Act*.<sup>128</sup> Other provisions relating to a mere scheme or rule or method for performing mental act or method of playing game (Section 3(m)) and presentation of information (Section 3(n)) were typically excluded elsewhere in the world.

<sup>126</sup> Ayyangar, *supra* note 7, at ¶ 4(b).

<sup>127</sup> *Supra* note 4.

<sup>128</sup> See generally, Semiconductor Integrated Circuits Layout-Design Act, 2000, No. 37, Acts of Parliament, 2000 (India).

Section 3 of the Indian *Patents Act* 1970 as amended in 2002

3. What are not inventions.—The following are not inventions within the meaning of this Act,—

- (a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;
- (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;
- (c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;
- (d) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;
- (e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
- (f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;
- (g)..(omitted)
- (h) a method of agriculture or horticulture;
- (i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.
- (j) plants and animals in whole or any part thereof other than micro- organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;
- (k) a mathematical or business method or a computer program per se or algorithms;
- (l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

- (m) a mere scheme or rule or method of performing mental act or method of playing game;
- (n) a presentation of information;
- (o) topography of integrated circuits;
- (p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

The 2005 Amendments further tweaked the language of section 3(d) and repealed section 5 of the *Patents Act 1970*, to bring us to the exclusion list that is in force today.

Section 3(d) of the *Patents Act 1970* as amended in 2005

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

Of particular interest to this article are the exclusions under sections 3(d), 3(e), and 3(k). We now discuss these sections in further detail.

### 1. Section 3(d)

Chapter II of the *Patents Act* bears the heading "Inventions Not Patentable" and Section 3 has the marginal heading "What are not inventions."<sup>129</sup> As indicated by the Chapter heading and the marginal heading of Section 3, and as may be seen simply by going through Section 3, the section combines provisions of two different kinds: one that declares that certain things shall not be deemed to be "inventions" [for instance Clauses (d) & (e)]; and the other that provides that, though resulting from invention, certain things may not be the subject of a patent grant for other considerations [for instance Clause (b)].<sup>130</sup>

A perusal of the Parliamentary debate surrounding amendments to section 3(d) would reveal that the whole debate centered on medicines and drugs.<sup>131</sup> The amendment (by way of addition) in Clause (d) of Section 3 was proposed by the Government<sup>132</sup> in order to placate the fears of the then Opposition<sup>133</sup> concerning the introduction of product patents for pharmaceuticals and agricultural chemicals. It was on the Government's assurance that the proposed amendment in Section 3(d) (besides some other changes in the *Act*) would take care of the apprehensions about the abuse of product patents for medicines and agricultural chemical substances that the Bill was passed by the Parliament.<sup>134</sup>

During the course of Parliamentary debate, issues regarding patentability of microorganisms and the definition of "pharmaceutical substance" to mean "a new chemical entity" (NCE) or "new medical entity" (NME) were also raised. At the assurance of the then Commerce and Industry Minister these issues were referred to a Technical Expert Group on Patent Law Issues, which has come to be known as the "Mashelkar Committee."<sup>135</sup>

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<sup>129</sup> *The Patents Act*, *supra* note 5 at ch. II § 3.

<sup>130</sup> Section 3 (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.

<sup>131</sup> *Novartis AG ("Novartis") v. Union of India*, (2013) 6 SCC 1 ¶ 97 (India).

<sup>132</sup> At the time, the Government was headed by the Congress Party, under the leadership of Prime Minister Manmohan Singh.

<sup>133</sup> The Opposition was headed by the Bharatiya Janata Party, or BJP.

<sup>134</sup> *Id.* at ¶ 103.

<sup>135</sup> Dr. R. A. Mashelkar, the chair of the committee, served as Director General of the Indian Council of Scientific and Industrial Research, an organization that links the country's publicly funded research laboratories and institutions. It is the world's largest organization of its kind.

The Mashelkar Committee was, *inter alia*, asked to study “whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity (NCE) or to new medical entity involving one or more inventive steps.”<sup>136</sup> The *Patents Act* had not restricted patents to NCEs. Therefore, if the Mashelkar Committee had answered the question in the affirmative, there would have been pressure on the government to amend the *Patents Act* to provide for a more restrictive definition of patentable subject matter. However, as it happened, the Committee observed that it would not be TRIPS compatible to limit the grant of a patent for pharmaceuticals to NCEs alone, thereby indirectly supporting the argument for section 3(d).<sup>137</sup>

The Committee further observed that “every effort must be made to prevent the grant of frivolous patents and ‘ever greening.’”<sup>138</sup> The Mashelkar Committee, in fact, also added that “‘incremental innovations’ involving new forms, analogs, etc. but which have significantly better safety and efficacy standards, need to be encouraged<sup>139</sup>.”

With the promulgation of Section 3(d), an impression was created in the minds of a section of the pharmaceutical industry that no incremental innovation would be entitled to a patent in India. The notion became further galvanised due to challenges to section 3(d) by Novartis, a major pharmaceutical manufacturer as discussed below.

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<sup>136</sup> ¶ 2.0 page 2 ‘The Report of the Technical Expert Group – Revised, December 2009’ (commonly referred to as Mashelkar committee report, after the chairman of the group) was presented to the Government of India on 13 March, 2009 and is available at the website of Department of Industrial Policy & Promotion.

<sup>137</sup> *Id.*

<sup>138</sup> *Id.* ¶ 4.0.

<sup>139</sup> *Id.* ¶ 4.0.

### 1. The Novartis Case

#### a. Novartis' Patent Application Rejected by Patent Controller (January 2006)

In January 2006, the Patent Controller in Chennai,<sup>140</sup> in a major decision, denied Novartis' patent application that claimed a variation of the company's anti-leukemia drug marketed as Gleevec (or Glivec).<sup>141</sup> The application was for the beta-crystalline form of imatinib mesylate.<sup>142</sup> Novartis had previously obtained a patent in the United States for the drug imatinib, which also covered pharmaceutically acceptable salts.<sup>143</sup> Novartis then obtained regulatory (FDA) approval in the United States for the marketing of a salt form of the drug called imatinib mesylate.<sup>144</sup> The application before the Patent Controller in Chennai was for a specific form of the imatinib mesylate salt – the beta crystalline form.<sup>145</sup>

Examination of the application began in the Chennai branch of the Indian Patent Office in 2005.<sup>146</sup> By then, the application had already become the subject of considerable controversy. Advocacy groups (including the Cancer Patients Aid Association (CPAA)), and generic pharmaceutical manufacturers, filed pre-grant oppositions contending that the application lacked novelty, was obvious, and was not patentable under section 3(d).<sup>147</sup> The Patent Controller agreed and rejected the application.<sup>148</sup>

The patent rejection meant that other companies could manufacture and market generic versions of the drug and make imatinib mesylate available at less than one-tenth of Novartis' price.

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<sup>140</sup> The Indian Patent Office is divided among four cities. The head office is in Kolkata, and branch offices are located in Chennai, New Delhi and Mumbai. The Office of the Controller General of Patents, Designs and Trade Marks is in Mumbai. See *Novartis AG v. Union of India* (2013) 6 SCC 1. [judis.nic.in/supremecourt/imgs1.aspx?filename=40212](http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212).

<sup>141</sup> Novartis sold the drug at about 266.67 USD (12,000 INR) for a month's therapy as opposed to the price offered by other generic manufacturers of about 177.78 to 222.23 USD (8,000 to 10,000 INR) for a month's therapy.

<sup>142</sup> *Id.* at 8.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

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

<sup>146</sup> Novartis initially filed its patent application in 1997, but as patent law in the country at the time was undergoing a transition, the patent application lay dormant under an arrangement called "mailbox procedure" and the application was taken out of the 'mailbox' for consideration only after amendments were made w.e.f. January 1, 2005. *Id.* at ¶ 13–23 at 8–9.

<sup>147</sup> *Id.* at 23.

<sup>148</sup> *Id.*

In June 2006, Novartis AG and its Indian subsidiary, Novartis India, filed a series of writ petitions against the Government of India, CPAA, and four Indian generic manufacturers (Natco, Cipla, Hetero and Ranbaxy), before the Madras High Court.<sup>149</sup> These writ petitions challenged the decision of the Patent Controller declining the grant of a patent to Novartis, and they also challenged the validity of section 3(d), which was one among several grounds relied upon by the Controller in the refusal order.<sup>150</sup> Novartis contended that section 3(d) was not in compliance with Article 27(1) of the TRIPS Agreement, which requires WTO-member countries to grant patents “in all fields of technology” and “without discrimination as to... the field of technology.”<sup>151</sup> It also made the constitutional argument that the use of the term “efficacy” in section 3(d) was vague and ambiguous, and therefore violated the equality provision (Article 14) of the Indian Constitution.<sup>152</sup>

Over a period of time, the writ petitions challenging the decision of the Patent Controller were converted into statutory appeals by a statutory amendment<sup>153</sup> to the *Patents Act*. The amendment, which added Chapter XIX, Sections 116 to 117H, extended the jurisdiction of the Intellectual Property Appellate Board under Section 83 of the Trade Marks Act, 1999, to include jurisdiction, power, and authority to hear appeals from orders of the Controller under Section 15 of the *Patents Act*.<sup>154</sup> On the basis of that amendment, in April 2007, the Government of India notified the IPAB to hear appeals relating to patents and consequently, Novartis’ appeals were transferred to the IPAB.<sup>155</sup>

*b. Constitutional Validity of Section 3(d) Upheld by Madras High Court (August 2007)*

Meanwhile, in August 2007, the Madras High Court issued its decision<sup>156</sup> rejecting Novartis’ writ petitions challenging the validity of section 3(d). The Madras High Court refused to examine whether section 3(d) was in compliance with the TRIPS Agreement, concluding that such questions were for the exclusive jurisdiction of the WTO Dispute Settlement Body provided under Article 64 of the TRIPS Agreement.<sup>157</sup>

<sup>149</sup> *Id.* at 15.

<sup>150</sup> *Id.* at 15.

<sup>151</sup> 27(1) Agreement on Trade-Related Aspects of Intellectual Property art. 27.1, Apr. 15th, 1994, 1869 U.N.T.S. 299, [http://www.wto.org/english/res\\_e/booksp\\_e/analytic\\_index\\_e/trips\\_02\\_e.htm](http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_02_e.htm) [hereinafter TRIPs]; NAFTA art. 1709.1.

<sup>152</sup> Article 14 provides that, “The State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India.” INDIA CONST. art. 14.

<sup>153</sup> *Patents (Amendment) Act*, 2002, Act No. 38 of 2002 w.e.f April 2, 2007.

<sup>154</sup> *Id.*

<sup>155</sup> *Novartis AG v. Union of India* (2013) 6 SCC 1, [judis.nic.in/supremecourt/imgs1.aspx?filename=40212](http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212).

<sup>156</sup> (2007) 4 MLJ 1153.

<sup>157</sup> *Id.*

With respect to its constitutional argument, Novartis conceded during the oral proceedings that the meaning of the term “efficacy” was known, but it contended that because there was no clarity as to what constituted “enhancement of efficacy” and “significant enhancement of efficacy” as required by section 3(d), the law was vague and lent itself to arbitrary decisions by the Patent Controller.<sup>158</sup> The Government of India, CPAA and generic companies argued that section 3(d) was not in violation of the equality provision of the Indian Constitution as the concept of efficacy is well-known to persons in the pharmaceutical industry and it is impossible to lay down a “one size fits all” standard to determine what constitutes a significant enhancement of efficacy.<sup>159</sup> Dismissing the petition, the Madras High Court held that section 3(d) was not vague or arbitrary and therefore did not violate the Indian Constitution.<sup>160</sup> It held that the term “efficacy” was known in the pharmaceutical field to mean “therapeutic efficacy.”<sup>161</sup>

While dismissing Novartis’ writ petitions, the Madras High Court held: “We have borne in mind the object which the Amending Act wanted to achieve, namely, to prevent ever-greening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.”<sup>162</sup>

While Novartis AG did not challenge the judgment of the Madras High Court upholding the constitutional validity of section 3(d), it did argue against the dismissal of its patent application before the Intellectual Property Appellate Board (IPAB).

*c. Appeal on Merits Rejected on the Ground of Section 3(d) by IPAB (June 2009)*

After a series of procedures in which Novartis contested the constitution of the IPAB, Novartis’ appeal challenging the Patent Controller’s order was finally heard by a specially constituted Bench of the IPAB in November and December 2008.

In its decision issued in June 2009, the IPAB overturned the Patent Controller’s findings on novelty and inventive step and held that the beta-crystalline form of imatinib mesylate was new and involved an inventive step.<sup>163</sup>

However, the IPAB held that Novartis’ alleged invention did not satisfy the test of section 3(d) because Novartis did not provide data to show that the beta-crystalline form of imatinib mesylate exhibited significantly enhanced therapeutic efficacy over imatinib mesylate, the known substance.<sup>164</sup>

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<sup>158</sup> *Id.*

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Id.* at 19.

<sup>163</sup> IPAB Order No. 100 of 2009 dated 26<sup>th</sup> June, 2009. Order (No.100/2009) of the Intellectual Property Appellate Board, dated 26th June, 2009 <https://www.scrib.com/document/133340456/IPAB-Order-Ddataed-26-Jun-2009-in-Norvatis-v-Union-of-India>.

<sup>164</sup> *Id.* at 14.

Primarily on the basis of this finding, the IPAB rejected Novartis' appeal and refused to grant it a patent for the *beta-crystalline form of imatinib mesylate*.<sup>165</sup>

*d. Proceedings Before the Supreme Court*

Challenging the IPAB's order, Novartis approached the Supreme Court directly by filing a special leave petition challenging the IPAB's interpretation and application of section 3(d).<sup>166</sup> Subsequently, CPAA and Natco filed cross-petitions challenging the IPAB's findings on other issues including novelty and inventive step.<sup>167</sup>

*i. Issues Involved*

The Supreme Court considered the following questions: Is Imatinib Mesylate, the salt version of the free base form of Imatinib, an invention that is patentable under Indian law?<sup>168</sup> Is the beta crystalline version of Imatinib Mesylate an invention patentable under Indian law?<sup>169</sup>

In answering the first question, the Supreme Court had to determine, *inter alia*, whether the mesylate salt form of imatinib had been disclosed in the prior art (in this case, a US patent referred to as the Zimmerman patent) and was publicly known. On the basis of the prior art cited, the Supreme Court examined the issue of patentability *de novo* and found that the mesylate salt form of imatinib was disclosed.<sup>170</sup>

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<sup>165</sup> *Id.* at 151.

<sup>166</sup> Novartis AG v. Union of India (2013) 6 SCC 1.  
[judis.nic.in/supremecourt/imgs1.aspx?filename=40212](http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212).

<sup>167</sup> *Id.*

<sup>168</sup> *Id.* at 3.

<sup>169</sup> *Id.* at 3.

<sup>170</sup> (a) The principal prior art was the Zimmermann patent (US Patent No. 5,521,184). The application for grant of the Zimmermann patent in the US specified that the invention related to derivatives of N-phenyl-2-pyrimidine-amine, one of which was imatinib and its compounds. The application further stated that the compounds of the derivatives included their respective salts. The application also stated that the invention was in relation to the treatment of tumors in warm-blooded animals by administering a compound or its pharmaceutically acceptable salt to such animals.

(b) The beta crystalline form of imatinib mesylate was later patented in the US in 2005. However, the drug Gleevec was launched in the market on the basis of the Zimmermann patent itself much before 2005. Novartis' application before the Food and Drug Administration, USA stated that the active ingredient in the drug for treatment of patients suffering from Chronic Myeloid Leukemia was imatinib mesylate and that the Zimmermann patent covered this drug.

(c) When Novartis applied for a patent for the beta crystalline form of imatinib mesylate in the US, the Board of Patent Appeals held that there was a presumption that the Zimmermann patent teaches a person skilled in the art, the manner of use of Imatinib or a pharmaceutically acceptable salt thereof in the treatment of tumors in warm blooded animals.

(d) When Natco Pharma Limited marketed a drug called Veenat 100 in the UK, Novartis issued a legal notice against Natco pointing out that the active pharmaceutical ingredient of Veenat 100 was imatinib mesylate, which was covered by the Zimmermann patent in Europe. As a result, the Court found that the mesylate salt form of imatinib had been disclosed and was covered by the Zimmermann patent.

With regard to the second issue, the Supreme Court observed that the beta crystalline form of imatinib mesylate, being a polymorph of imatinib mesylate, was directly covered under Section 3(d) of the *Patents Act*.<sup>171</sup> Novartis contended that any invention that met the requirements of novelty and inventive step under Section 2(1) of the Act could fall within the restrictions of Section 3(d).<sup>172</sup> Negating this argument, the Supreme Court referred to the parliamentary debates of 2005 where it was observed that Section 3(d) was amended to prevent abuse of product patents in medicines and agricultural products and to preclude the “evergreening” of pharmaceutical products.<sup>173</sup> The court noted that Section 3(d) was meant especially to cover pharmaceutical products, and it created a second tier of qualifying standards for patenting pharmaceutical products.<sup>174</sup>

*ii. Novartis’ Contentions*

Novartis contended that the scope of coverage under a claim in a patent is distinct from and wider than what is disclosed under the patent in its specification, meaning imatinib mesylate was covered under the Zimmermann (prior art) patent and ergo out of bounds for production by any person other than Novartis, but since it was not disclosed under the Zimmermann patent, there was all likelihood for it to be invented and consequently for it to be patented by Novartis in India.

Novartis further argued that a “conceivable” substance is not necessarily a “known” substance as required under Section 3(d) and that “known” meant well established and proven beyond doubt. It submitted that neither imatinib nor imatinib mesylate had any “known” efficacy in that sense and therefore the question of enhanced efficacy of the beta crystalline form of imatinib mesylate would not ensue. The Court, in rejecting the contention held that even the term “publicly known” although it may warrant a wider interpretation than “known” was, in fact, interpreted more narrowly than what was submitted by Novartis. On this basis, the Supreme Court held that the beta crystalline form of imatinib mesylate is a form of a known substance (i.e. imatinib mesylate) with known efficacy.

With respect to the first contention put forth by Novartis that there is a distinction between claim coverage and the disclosure in the specification<sup>175</sup>, the Supreme Court held that such distinction, if granted, would vitiate the very rationale of patent law. Patent law confers a monopoly on certain persons in respect of their inventions for a specific period of time in exchange for the consideration that the invention be unveiled and made available to the public for the public’s benefit. The court held that including undisclosed inventions under a patent would emaciate the fundamental logic underlying the grant of patent rights. On this basis, the Supreme Court held that imatinib mesylate and its pharmacological properties are known from the Zimmermann patent itself and therefore fail to constitute an invention that can be patented under Indian law.

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<sup>171</sup> Novartis AG v. Union of India (2013) 6 SCC 1.  
[judis.nic.in/supremecourt/imgs1.aspx?filename=40212](http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212).

<sup>172</sup> *Id.*

<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> (2013) 6 SCC 1 ¶ 136.

On the question of enhanced efficacy of the beta crystalline version over the salt version of imatinib mesylate, the Supreme Court observed that all the material on record compared the beta crystalline version of imatinib mesylate to the free base form of imatinib and there was nothing on record to compare the beta crystalline version with the intermediate salt version. The Supreme Court also held that enhanced “efficacy” of a medicine should be determined vis-a-vis its “therapeutic efficacy.” The Supreme Court further held that better flow, thermodynamic stability and lower hygroscopicity, while beneficial, do not determine efficacy of a medicine. On the basis of the unavailability of evidence to prove that the beta crystalline form of imatinib mesylate provided enhanced therapeutic efficacy over imatinib in its free base form, the court held that the beta crystalline version failed to pass the muster of Section 3(d) test.

The Supreme Court came to its conclusion after a detailed analysis of the facts and circumstances of this case and not on the considerations of excessive pricing of the drugs or Novartis’ profit-making motive. The court went on to specify that this case should not be interpreted to mean that Section 3(d) bars all incremental inventions.<sup>176</sup> With this judgment, the Court has significantly augmented the otherwise inchoate jurisprudence.

The Court went ahead to note that the marketed package of Gleevec specified that the drug contained imatinib mesylate in its salt form and not in the beta crystalline form. Therefore, it observed that the patent claim appeared to be a camouflage to obtain a patent for imatinib mesylate, the salt form, which was not otherwise possible under the Indian law.

It must be pointed out that the Supreme Court in *Novartis AG v. Union of India* did not delve into the question that whether Section 3(d) was a patent eligibility or patentability standard since this query did not have any bearing on its determination on validity in the facts of the case.<sup>177</sup> It, however, enunciated that for pharmaceuticals, Section 3(d) would not operate as a patentability standard but as a threshold for invention, i.e. a patent eligibility criteria.<sup>178</sup> Thus, the question as to what exactly is the impact of identifying Section 3(d) as a patent eligibility standard versus a patentability standard, remains unanswered. It can be argued that identifying it as a patent eligibility standard strengthens Section 3(d) itself, since it now becomes a threshold question prior to the tripartite patentability test.<sup>179</sup>

It would also mean that questions of anticipation and obviousness would not be blurred with the Section 3(d) screening and that the latter can operate as a neat and distinct test. For example, since methods of surgical treatment are not patent eligible [under Section 3(i)], there is no need for the Patent Office to examine whether the method is novel or obvious or capable of use, and the application can be discarded at the very outset. This particular question was answered by a Division Bench of the Delhi High Court in its recent judgment of December 2015 in *F.Hoffmann La Roche Ltd & Anr. Vs. Cipla Ltd*.<sup>180</sup>

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<sup>176</sup> *Id.*

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> “Tripartite Patentability Test” refers to screening based on tests of ‘novelty’ & ‘obviousness’ & ‘industrial application.’

<sup>180</sup> 2016 (65) PTC 1 (Del).

## 2. *Roche v. Cipla*

Hoffman La Roche Ltd. (Roche) was the holder of US patent '498 directed to the anti-cancer drug Erlotinib Hydrochloride (EH) (corresponding to IN '774).<sup>181</sup> However, the marketable physical form of the EH molecule comprised both polymorph A and B of EH, and further research revealed that polymorph B of EH was the more thermodynamically stable; Roche thus obtained a separate patent in the US for the polymorph B compound (U.S.'221).<sup>182</sup> Roche began selling a drug by the name Tarceva in which the active pharmaceutical ingredient was the B polymorphic form of EH and was hence covered by US '221.<sup>183</sup> Roche's patent application for the B polymorphic form in India (Patent Application DEL '507), however, was rejected by the Controller on the ground that the increased thermodynamic stability of Polymorph B fell below the Section 3(d) standard of enhanced therapeutic efficacy.

Roche sued Cipla in early 2008<sup>184</sup> over their lung cancer drug Erlolcip for infringing Patent IN '774 ("suit patent") for "A NOVEL [6, 7-BIS(2-METHOXYETHOXY) QUINAZOLIN-4-YL]- (3-ETHYNYLPHENYL) AMINE HYDROCHLORIDE" also known as Erlotinib Hydrochloride, which was licensed to Roche. Roche had been manufacturing this compound as an anti-cancer drug under the brand name Tarceva across the world and had introduced it in India in April 2006. The suit attracted worldwide attention because it was the first time that an Indian pharmaceutical manufacturer had made and sold a generic version of a patented drug following India's introduction in 2005 of a TRIPS-mandated product patent regime for pharmaceuticals.

After initial litigation in the Delhi High Court and the Supreme Court concerning the grant of interim relief, the substantive matter came up for trial before a Single Judge Bench of the Delhi High Court.<sup>185</sup> The Single Judge held that while Roche's patent IN '774 was valid (as the counter claim for revocation could not be proved), Roche was unable to prove through evidence that the alleged infringing product did, in fact, infringe their patent. The judge therefore held in favor of CIPLA, and Hoffman LaRoche appealed the decision to the Division Bench of the Delhi High Court.

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<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> *Id.*

<sup>184</sup> *Id.* at ¶ 5.

<sup>185</sup> *F. Hoffmann-La Roche Ltd. vs. Cipla Ltd;* (2009) 40 PTC 125 (Del).

a. *Division Bench (DB) Judgment*

i. *Arguments Advanced*

At the Division Bench Cipla argued that Roche, by seeking an independent patent on the B polymorphic form, had clearly sought to distinguish that form from the invention disclosed in IN '774/US '498. Further, it contended that the fact that the application for the B polymorphic form failed on Section 3(d) grounds meant that the provision could “not be (then) utilized as a tool to enhance the ambit of a patent to cover even those forms which have either been abandoned by the patentee itself or rejected in India.”<sup>186</sup> Thus, Cipla argued that it was not possible to construe the claims in IN '774 to include the B polymorphic form in light of the rejection under Section 3(d).

Roche contended that Section 3 (d) of the *Patents Act* was not applicable to the instant case, as the section prohibited only derivatives of “a known substance.” Erlotinib did not meet the criterion of being “salts, esters, polymorphs, particle size, or mixture of isomers, etc.” of a “known substance,” as stipulated in the explanation to Section 3(d), and was therefore outside the scope of the section. Rather, Erlotinib was a novel compound that differed from any cited as prior art.<sup>187</sup>

ii. *Court's Observations*

In its judgment, the Division Bench included an important focus on the impact of the Indian Patent Office's rejection on the basis of Section 3(d) of Hoffman LaRoche's separate patent application (DEL'507) for the B polymorphic form of EH, and the company's allegation of infringement.<sup>188</sup> The Division Bench observed that the test for infringement necessitates first determining the meaning and scope of the claims in the patent at suit, and then comparing the properly construed claim with the allegedly infringing product.<sup>189</sup> Since Section 3(d) deals with incremental variations,<sup>190</sup> the court felt obliged to construe the purpose and scope of Section 3(d), and in so doing, it shed important light on the interpretation of the section.

The Division Bench analyzed various provisions of Section 2 of the Patent Act dealing with the requirements of patentability and related those provisions to Section 3(d). The court observed:

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<sup>186</sup> *Id.* at ¶ 52.

<sup>187</sup> Issues concerning prior art and local manufacture were also raised, but they will not be discussed here.

<sup>188</sup> *Id.*

<sup>189</sup> Earlier courts had interpreted the test as simply comparing the patented product with the allegedly infringing one.

<sup>190</sup> As noted, Section 3(d) speaks of “the enhancement of ... known efficacy,” and “differ[ing] significantly in properties with regard to efficacy.”

Section 3 of the Act lays down a threshold for patent eligibility and is not an exception to Section 2(1)<sup>191</sup> (j)<sup>192</sup> as urged by learned Senior counsel for Cipla. Section 2(1)(j) provides a theoretical definition of an invention while Section 3 illustratively outlines what are not inventions. In other words, for subject matter that falls outside the scope of Section 3, a qualitative analysis needs to be employed to ascertain whether it satisfies the conditions of Section 2(1)(j), while for subject matter that falls within the scope of Section 3, an analysis under Section 2(1)(j) need not be employed as it will be rejected at the threshold.<sup>193</sup>

Thus, the steps in analyzing a new chemical entity in respect of which a patent application is made will be:

A new chemical entity (NCE) that is structurally dissimilar but functionally similar to an existing chemical entity is thus merely a substance under Section 3(d). If the substance has an added layer of enhanced efficacy then it would be treated as a “new product” and would be eligible for assessment under Section 2(1)(j) to ascertain whether its formation involved an inventive step. If the new product involved one or more inventive steps, then it would qualify as a pharmaceutical substance.<sup>194</sup>

Therefore, the court negated the proposition that Section 3(d) is a patentability standard. In terms of the conceptual distinction between the two, the Division Bench noted that while the novel/non-obvious/industrial application standard for patentability addresses the worthiness of a product to be granted monopoly rights, Section 3(d) seeks to prevent evergreening and the exploitation of those monopoly rights.

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<sup>191</sup> The *Patents Act*, 1970, No. 39, Acts of Parliament, 1970 (India) § 2(1)(l)(as amended in 2005) (“new invention” means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art.”)

<sup>192</sup> *Id.* §2(1)(j) (“invention” means a new product or process involving an inventive step of capable of industrial application.”).

<sup>193</sup> *F.Hoffmann La Roche Ltd & Anr. Vs. Cipla Ltd*, (2016) 65 PTC (Del).

<sup>194</sup> *Id.* at 62.

The Division Bench also addressed the impact on the determination of infringement of the Section 3(d) challenge to the B polymorph. The court held that “merely because an inventor applies for a latter patent that is already objectively included in a prior patent, but which inventor subjectively feels needs a separate patent application, doesn’t mean it is to be taken at face value and therefore neither Section 3(d) or abandonment of subsequent patent application can be used to read into terms of prior application, which has to be construed on its own terms.”<sup>195</sup>

The Court went on to examine Section 3(d) and found it contained a deeming fiction in relation to “salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance;”<sup>196</sup> namely, that they are to be considered the same substance as the known substance.

The Division Bench then held that the deeming fiction in Section 3(d) implies that when a patent application for a substance is rejected by virtue of Section 3(d) because it is a derivative of a known substance, that substance would automatically be deemed to be covered and disclosed by the prior art on the basis of which the application was rejected, i.e., the known substance if under patent:

We understand Section 3(d) as a positive provision that in fact recognizes incremental innovation while cautioning that the incremental steps may sometimes be so little that the resultant product is no different from the original. The inherent assumption in this is that an infringement of the resultant product would therefore be an infringement of the original i.e. the known substance and by no stretch of imagination can Section 3(d) be interpreted as constituting a defense to infringement.<sup>197</sup>

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<sup>195</sup> *Id.* at 66.

<sup>196</sup> *Id.*

<sup>197</sup> *Id.* at 73.

### 3. Conclusion

The uncertainty surrounding the interpretation of Section 3(d) has been interred to a great extent by the Supreme Court and the Delhi High Court in the *Novartis* and *Roche* landmark judgments. The judgment in *Novartis* focused on the nuances of Section 3(d) and has detailed the essentials<sup>198</sup> required for a patent application to pass muster under Section 3(d). Subsequently, the Delhi High Court's Division Bench judgment explained the significance and connotations of Section 3(d) vis-à-vis the provisions of Section 2 of the Act, especially the tripartite patentability test. What seems clear is that Section 3(d), apart from influencing the prosecution of a patent application, influences the construction of the claims of the patent of a known substance whose "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance"<sup>199</sup> is sought to be patented independently (but fails because of Section 3(d)).

What also emerges from the case law is that the terms "disclosed" and "covered" by a patent refer to two separate concepts. "Covered" connotes whether a certain product can be said to be within the four corners of the claims of the patent at suit. It is relevant in an infringement analysis. The ruling of the court in the *Roche* case would mean that the salts, esters, etc. would be deemed to be covered by the patent, if so claimed, and thus any manufacture thereof would infringe the original patented product. "Disclosed" refers to whether the patent adequately teaches a certain aspect of an invention; whether chemical composition, structure, and use, etc., is relevant to a validity analysis. Thus, there might be cases, like *Roche*, where a patent covers a salt, ester, etc., for the purpose of infringement, but does not actually teach the distilling out or manufacture of that particular salt, ester, etc.

#### B. Sections 3(k) and 3(m)

Sections 3(k) and 3(m) were added to the Section 3 exclusion list with the 2002 Amendments. The exclusions under these sections are for mathematical or business methods, computer programs *per se*, or algorithms (Section 3(k)), and for mere schemes or rules or methods for performing mental acts or methods for playing a game (Section 3(m)). They are analogous to the exceptions under Article 52 of the *European Patent Convention* (EPC):

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<sup>198</sup> *Novartis Ag. v. Union of India*, (2013) 6 SCC 1 (India) (The Supreme Court essentially held that a substance can be stated to have enhanced "efficacy" for the purposes of § 3(d) of the *Patents Act* only if its ability to cure a disease is enhanced as compared to a 'known' substance in question. However, the Supreme Court has not made any finding on the question of the mode of proving enhance efficacy and has left that question open.).

<sup>199</sup> The *Patents Act*, 1970, No. 39, Acts of Parliament, 1970 (India).

Patentable inventions:

1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

(3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Although most of these exceptions are universally accepted, Sections 3(k) and 3(m) have attracted significant attention in India over the past decade. Prior to the enactment of the 2005 amendments, the Government of India promulgated the *Patents (Amendment) Ordinance 2004*.<sup>200</sup> The ordinance was necessitated to meet the January 1, 2005, deadline to bring India's patent laws in compliance with the TRIPS Agreement.<sup>201</sup> After much deliberation it was deemed necessary to, among other things, "modify and clarify the provisions relating to the patenting of software related inventions when they have technical application to industry or in combination with hardware."<sup>202</sup> The ordinance proposed splitting Section 3(k) into 3(k) relating to computer programs *per se* and 3(k)(a) relating to mathematical or business methods and algorithms:

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<sup>200</sup> Patents (Amendment) Ordinance, 2004, No. 7, Acts of Parliament, 2004 (India).

<sup>201</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

<sup>202</sup> *Id.* at Statement of Objects and Reasons.

Sections 3(d) and 3(k) of the *Patents Act* 1970 in the Patents (Amendment) Ordinance 2004

3. In section 3 of the principal Act,—

(a) in clause (d), for the words “new use”, the words “mere new use” shall be substituted;

(b) for clause (k), the following clauses shall be substituted, namely:—

“(k) a computer program per se other than its technical application to industry or a combination with hardware;

(ka) a mathematical method or a business method or algorithms;”.

The 2004 Ordinance lapsed in due course and was replaced by the 2005 Amendments. It is significant to note the 2005 Amendments did not adopt the changes to Section 3(k) as proposed in the 2004 Ordinance. The language of Section 3(k) reverted back to the one introduced by the 2002 Amendments, and that language continues to be in force. This reversal in the language has been the basis for much debate and confusion regarding the scope of the exclusion under section 3(k), particularly with respect to the interpretation of inventions related to computer programs *per se*.

#### 1. *The Indian Patent Office Perspective on Section 3(k)*

In 2013, the Indian Patent Office released draft guidelines for the examination of computer related inventions (the “Draft Guidelines”). In that draft, the Patent Office contended that “the re-instatement of the original phraseology of section 3 (k) [in the 2005 Amendment] clearly indicates that the legislature intended to retain the original scope of exclusion and did not approve its widening under this sub-section as attempted through the ordinance.”<sup>203</sup>

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<sup>203</sup> Office of the Controller General of Patents, Designs and Trademarks, Guidelines For Examination Of Computer Related Inventions 6 (2013), [http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1\\_36\\_1\\_2-draft-Guidelines-cris-28june2013.pdf](http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_36_1_2-draft-Guidelines-cris-28june2013.pdf).

It is debatable whether the language and clarification proposed by the 2004 Ordinance in fact attempted to “widen” the scope of exclusion under Section 3(k) or merely to clarify the exclusions for computer programs *per se*. Nevertheless, the Draft Guidelines went on to categorically reject “a computer programme which may work on any general purpose known computer” as not meeting the requirements of the law as to patent-eligible subject matter.<sup>204</sup> The Draft Guidelines emphasized that a novel hardware feature must be present for a computer program to be considered patentable. In this regard, the Draft Guidelines cautioned examiners to focus on “the underlying substance of the invention, not the particular form in which it is claimed.”<sup>205</sup> Moreover, the Draft Guidelines asserted that, without disclosure of structural features, “means plus function claims shall be rejected as these means are nothing but computer program *per se*.”<sup>206</sup>

The emphasis on novel hardware as a precursor to patent eligibility was roundly criticized by the industry as a “no new hardware - no patent” approach, going against the legislative intent of restricting the “exclusion only to stand alone computer programs, i.e., ‘computer programs *per se*.’”<sup>207</sup>

A little over two years later, the patent office issued the “final” guidelines for examination of computer related inventions in August 2015, the “August Guidelines”.<sup>208</sup> The August Guidelines sought to determine patent eligible subject matter based on considering “the claims, taken as a whole” and not denying a patent if in substance the claims “do not fall in any of the excluded category.”<sup>209</sup> The August Guidelines did not attach much significance to the exclusion of the clarifying amendments proposed by the 2004 Ordinance. Instead, it placed more emphasis on the legislative history; in particular, the deliberations of the Joint Parliamentary Committee (JPC) entrusted to review the 2002 Amendments as well as the submissions of the Department of Industrial Policy and Promotion on this matter. The *JPC Report* on the 2002 Amendments with respect to the term “*per se*” used in conjunction with computer programs concluded that:

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<sup>204</sup> *Id.* at 20.

<sup>205</sup> *Id.* at 32.

<sup>206</sup> *Id.* at 36.

<sup>207</sup> See National Association of Software and Services Companies, Comments On The Draft Guidelines On Computer Related Inventions (2013), [http://ipindia.nic.in/iponew/CRI\\_Comments\\_Feedbacks/related\\_doc/NASSCOM-feedback%20to%20CRI%20guidance.pdf](http://ipindia.nic.in/iponew/CRI_Comments_Feedbacks/related_doc/NASSCOM-feedback%20to%20CRI%20guidance.pdf).

<sup>208</sup> Indian Patent Office, Guidelines For Examination Of Computer Related Inventions (2015), [http://www.ipindia.nic.in/iponew/CRI\\_Guidelines\\_21August2015.pdf](http://www.ipindia.nic.in/iponew/CRI_Guidelines_21August2015.pdf).

<sup>209</sup> *Id.* at 10, (“Form and Substance” discussion at § 6 of the Draft Guidelines, which emphasises the exclusion aspect of the determination.).

This change has been proposed because sometimes the computer program may include certain other things, ancillary thereto or developed thereon. The intention here is not to reject them for grant of patent if they are inventions. However, the computer programs as such are not intended to be granted patent. This amendment has been proposed to clarify the purpose.<sup>210</sup>

In view the legislative intent as evident above, the August Guidelines directed the examiners that when claims are not directed to a computer program “in itself,” have industrial applicability, and fulfill other criteria for patentability, then “the patent should not be denied.”<sup>211</sup>

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<sup>210</sup> Report of the Joint Parliamentary Committee on the Patents (Second Amendment) Bill, 1999, presented to the Rajya Sabha on December 19, 2001, ¶ 15, Cl. 4. Online: <http://164.100.47.5/webcom/MoreInfo/PatentReport.pdf>. Last accessed March 17, 2016.

<sup>211</sup> Office of the Controller General of Patents, Designs and Trademarks, Guidelines For Examination Of Computer Related Inventions 12 (2015), Guidelines for Examination of Computer Related Inventions published by the Indian Patent Office on August 21, 2015. Online: [http://www.ipindia.nic.in/iponew/CRI\\_Guidelines\\_21August2015.pdf](http://www.ipindia.nic.in/iponew/CRI_Guidelines_21August2015.pdf).

However, any euphoria surrounding the clarity brought by the August Guidelines was short lived. Bowing to pressure from certain sections of stakeholders, the Patent Office put the August Guidelines “in abeyance”<sup>212</sup> and replaced them with yet another version in February 2016, “the February Guidelines.”<sup>213</sup> A detailed analysis in respect of assessing subject matter eligibility for inventions involving interactions between novel software and known hardware is conspicuous in its absence from the February Guidelines. Earlier, the August Guidelines had indicated that when such interactions go beyond “normal” interactions, and bring “a further technical effect,” the claims may not be considered as excluded subject matter under Section 3(k).<sup>214</sup> The August Guidelines set out six criteria to ascertain whether claims have the requisite technical advancements to escape the exclusion under Section 3(k).<sup>215</sup> These criteria are analogous to the factors identified by the England and Wales High Court in *AT&T Knowledge Ventures LP and CVON Innovations Limited vs. The Comptroller General of Patents*.<sup>216</sup>

Instead, the February Guidelines adopted a three-stage test for examining computer-related inventions under Section 3(k) of the *Patents Act 1970*:

- (1) Properly construe the claim and identify the actual contribution;
- (2) If the contribution lies only in mathematical method, business method or algorithm, deny the claim;

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<sup>212</sup> Office Order 70 (2015), [http://ipindia.nic.in/officeCircular/officeOrder\\_14December2015.pdf](http://ipindia.nic.in/officeCircular/officeOrder_14December2015.pdf).

<sup>213</sup> Office of the Controller General of Patents, Designs and Trademarks, Guidelines For Examination Of Computer Related Inventions (2016), [http://www.ipindia.nic.in/iponew/GuidelinesExamination\\_CRI\\_19February2016.pdf](http://www.ipindia.nic.in/iponew/GuidelinesExamination_CRI_19February2016.pdf).

<sup>214</sup> Office of the Controller General of Patents, Designs and Trademarks, Guidelines For Examination Of Computer Related Inventions (2015), Guidelines for Examination of Computer Related Inventions published by the Indian Patent Office on August 21, 2015. Online: [http://www.ipindia.nic.in/iponew/CRI\\_Guidelines\\_21August2015.pdf](http://www.ipindia.nic.in/iponew/CRI_Guidelines_21August2015.pdf).

<sup>215</sup> *Id.* at 13–14 (The criteria are: (i) whether the claimed technical feature has a technical contribution on a process which is carried on outside the computer; (ii) whether the claimed technical feature operates at the level of the architecture of the computer; (iii) whether the technical contribution is by way of change in the hardware or the functionality of hardware; (iv) whether the claimed technical contribution results in the computer being made to operate in a new way; (v) in case of a computer programme linked with hardware, whether the programme makes the computer a better computer in the sense of running more efficiently and effectively as a computer; (vi) whether the change in the hardware or the functionality of hardware amounts to technical advancement. If answer to ANY of the above questions is in affirmative, the invention may not be considered as excluded under section 3 (k) of the *Patents Act, 1970*).

<sup>216</sup> *AT&T Knowledge Ventures, LP, CVON Innovation Ltd. vs. and the Comptroller General of Patents*, [Eng. & Wales 2009] EWHC 343 (Pat), ¶ 40 [hereinafter AT&T].

(3) If the contribution lies in the field of computer programme, check whether it is claimed in conjunction with a novel hardware and proceed to other steps to determine patentability with respect to the invention. The computer programme in itself is never patentable. If the contribution lies solely in the computer programme, deny the claim. If the contribution lies in both the computer programme as well as hardware, proceed to other steps of patentability.<sup>217</sup>

The three-stage test adopted in the February Guidelines is based on the approach adopted by Court of Appeals of England and Wales in *Aerotel Ltd. vs. Telco Holdings Ltd. & Others*.<sup>218</sup> Since 2006, the *Aerotel* approach was reviewed in a number of decisions by the UK courts and found to be appropriate.<sup>219</sup> However, the UK courts have recognized the difficulty in assessing “whether an invention has made a technical contribution to the art”<sup>220</sup> and have relied on the “signposts” described in *AT&T*.<sup>221</sup> These “signposts” were adopted in the August Guidelines, but were omitted from the February Guidelines.

Moreover, the February Guidelines fail to take into cognizance the nascent jurisprudence evolved in this area through the decisions of the Delhi High Court and the Intellectual Property Appellate Board (IPAB). We now turn our analysis to some of these decisions.

## 2. Case examples

Indian Patent No. 21090, entitled “Method for Controlling a Wind Turbine and a Wind Turbine,” was granted to Alloys Wobben. Enercon India, a subsidiary of Enercon GmbH, filed a petition for revocation of the patent before the IPAB on the grounds that the claims of the patent lacked novelty; were obvious; were directed to patent ineligible subject matter under section 3(k) of the *Patents Act*; and did not clearly define the scope of the invention. The IPAB held that the patent was invalid for lacking novelty and for being obvious in light of the prior art.<sup>222</sup> However, the IPAB found that the claims directed to a method for controlling a wind turbine based on varying at least one operational setting within pre-defined limits were patent eligible and did not fall under the exclusions of Section 3(k).<sup>223</sup>

Specifically, the IPAB held that a wind turbine cannot be controlled manually, but by using:

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<sup>217</sup> *February Guidelines*, *supra* note 137, § 5.

<sup>218</sup> *Aerotel Ltd. vs. Telco Holdings Ltd. & Others* Rev 1, [Eng. & Wales 2006] EWCA Civ 1371 at ¶ 40.

<sup>219</sup> *See, e.g.*, *HTC Europe Co Ltd v Apple Inc* (Rev 1) [2013] EWCA Civ 451 at ¶ 44.

<sup>220</sup> *Id.* at ¶ 45.

<sup>221</sup> *AT&T*, *supra* note 149.

<sup>222</sup> Intellectual Property Appellate Board Order No.224/2010, <http://www.ipabindia.in/Pdfs/Order-224-10-ORA-20-09-PT-CH.pdf>.

<sup>223</sup> *Id.*, at ¶ 86.10.

[A]dvanced computer technology, which would read the signal from the external conditions and carry out the corrections in its internal operating units[,] . . . this technical process control associated with or directed to a computer set up to operate in accordance with a specified program (whether by means of hardware or software) for controlling or carrying out a technical process control such as the above, cannot be regarded as relating to a computer program per se or a set of rules of procedure like algorithms and thus are not objectionable from the point of view of patentability, more so when the claims do not claim, or contain any algorithm or its set of rules as such, but only comprise of some process steps to carry out a technical process or achieve a technical effect finally the maximum power output by controlling the wind turbine.<sup>224</sup>

In *Yahoo Inc. vs. Assistant Controller of Patents and Rediff.com*,<sup>225</sup> the IPAB considered, among others, the patent eligibility of Yahoo's claims directed to influencing the positioning in a search result listing by a search engine. The Controller had rejected the claims as being directed to patent ineligible subject matter under Section 3(k) of the *Patents Act*. Rediff.com had filed a pre-grant opposition before the Controller and was also made a party to the appeal before the IPAB.

The IPAB extensively canvassed the jurisprudence in the UK, Europe, the USA and Australia and concluded that limitations on patenting business methods were prevalent world over.<sup>226</sup> The IPAB also delved into the policy rationale for including explicitly providing a listing of "what is not patentable"<sup>227</sup> and concluded that "in India, the law specifically excludes business methods. There is clear statutory language excluding business method patents and no administrative acceptance of them."<sup>228</sup>

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<sup>224</sup> *Id.* at ¶ 79.

<sup>225</sup> IPAB Order No.2222011, <http://www.ipabindia.in/Pdfs/Order-222-11-OA-22-10-PT-CH.pdf>.

<sup>226</sup> *Id.* at ¶ 32 *et seq.*

<sup>227</sup> *Id.* citing Ayyangar at ¶ 32.

<sup>228</sup> *Id.* at ¶ 38.

Turning to the subject of Yahoo's application, the IPAB held that:

[T]he service product seeks to place the facts (bid amount) or advertisement (information) in hierarchy based on the payments made. This is nothing but doing the advertisement business electronically. Even the technical advance that is claimed over the existing art is only an improvement in the method of doing business and S.3(k) is clear that business method cannot be patented, the fact that there is an advance has not improved the case. Therefore, we affirm that this ground alone is sufficient to reject the present application.<sup>229</sup>

The IPAB, interestingly, opined that determination of patent eligibility under Section 3 of the *Patents Act* was a threshold question, prior to proceeding to the analysis for novelty, non-obviousness, and other issues.

The Act defines "what is an invention" and then marks out which inventions are not patentable. So the first test is the patentability test. If what is submitted falls within the S.3 subjects, then we need not explore further. If it does not, then we examine whether it is an invention as defined in S(2). If it satisfies the definition, it will have to cross the tests of novelty, non-obviousness, anticipation, disclosure, etc.<sup>230</sup>

This approach was later confirmed by the Division Bench of the Delhi High Court in *Roche v. Cipla*, discussed earlier. Accenture Global Service GmbH's Indian Patent Application No. 01398/DELNP/2003, entitled "Distributed Development Environment for Building Internet Applications by Developers at Remote Locations," was rejected by the Controller as being directed to computer program per se and hence directed to patent-ineligible subject matter under section 3(k) of the *Patents Act*. The Controller's order followed a two-part framework for examination of the claimed subject matter:

1. A hardware implementation performing a novel function is not patentable *if that particular hardware is known or is obvious irrespective of the function performed.*

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<sup>229</sup> *Id.* at ¶ 48.

<sup>230</sup> *Id.* at ¶ 19.

2. If the novel features of the invention resides in a set of instructions [program] designed to cause the hardware to perform the desired operations *without special adoption of the hardware or modification of the hardware, then the matter claimed either alone or in combination is not patentable* [emphasis added].<sup>231</sup>

Accenture contended that the Controller's framework for determining patent eligibility was unsubstantiated in law. The IPAB agreed that the Controller relied on standards "neither mentioned in the Indian Patent Act nor in the Patent Office Manual or in guidelines by the Indian Courts in such matters."<sup>232</sup> The IPAB held that the Controller's order was "based on ill-founded premises far from being logical and reasonable."<sup>233</sup> Upon remand from the IPAB, the Controller granted the patent stating that the patent claimed a system "which is having [sic] the improvement in web services and software" and hence is not software, *per se*.<sup>234</sup>

In March 2015, the Delhi High Court had the opportunity to clarify the scope of the exclusions under Sections 3(k) and 3(m) of the *Patents Act*.<sup>235</sup> Opposing Ericsson's (Telefonaktiebolaget LM Ericsson) motion for a permanent injunction, Intex contended, among others, that Ericsson's patents in suit were invalid as they were directed to patent ineligible subject matter.<sup>236</sup> The patents in suit were eight patents granted to Ericsson in India and related to three technology areas in telecommunications, namely, Adaptive Multi-Rate Speech Codec; Features in 3G phones; and Enhanced Data Rates for GSM Evolution (EDGE). Specifically, Intex contended that Ericsson's patents were directed to mathematical methods, algorithms, computer program per se (all patent ineligible subject matter under Section 3(k) of the *Patents Act*), or were directed to a mere scheme or rule or a method for performing a mental act (patent ineligible subject matter under Section 3(m) of the *Patents Act*) and hence invalid.<sup>237</sup>

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<sup>231</sup> IPAB Order No.283/2012 at para. 9, [http://www.ipabindia.in/Pdfs/Order-283-2012-OA-22-2009-PT-DEL%20\(Final\).pdf](http://www.ipabindia.in/Pdfs/Order-283-2012-OA-22-2009-PT-DEL%20(Final).pdf).

<sup>232</sup> *Id.* at ¶ 11.

<sup>233</sup> *Id.*

<sup>234</sup> Controller's Order in 1398/DELNP/2003 dated May 10, 2013, <http://ipindiaservices.gov.in/decision/1398-DELNP-2003-2646/1398DELNP2003.pdf>.

<sup>235</sup> Telefonaktiebolaget LM Ericsson vs. Intex Technologies (India) Ltd., High Court of Delhi, I.A. No. 6735/2014 in CS(OS) No.1045/ 2014 [(hereinafter Ericsson)].

<sup>236</sup> *Id.* The eight patents are IN 203034, 203036, 203086, 213723, 229632, 234157, 240471, and 241747.

<sup>237</sup> *Id.* at ¶¶ 107–08.

The Delhi High Court, similar to the IPAB in *Yahoo*, considered<sup>238</sup> at length the legislative history of Sections 3(k) and 3(m); the provisions of Article 27 of the TRIPS agreement; the position of the European Union, the UK, and the USA, including the US Supreme Court's decision in *Alice Corp. vs. CLS Bank International*,<sup>239</sup> and concluded that "prima facie [...] any invention which has a technical contribution or has a technical effect and is not merely a computer program per se [...] is patentable."<sup>240</sup> However, the Court acknowledged that Intex's revocation petitions were pending and that the issues of patent eligibility under Sections 3(k) and 3(m) have to be considered on their merit in the revocation proceedings. Nevertheless, the Court held that it was "not impressed with the argument of the defendant that the injunction be refused on this ground."<sup>241</sup>

### 3. Conclusion

It is evident that the nascent jurisprudence evolving in India with respect to subject matter eligibility under Sections 3(k) and 3(m) of the *Patents Act 1970* is harmonious with that in the UK and Europe and to some extent the USA as well. There are certain clear exceptions under Sections 3(k) and 3(m) the Indian *Patents Act 1970* – mathematical methods; business methods; algorithms; mere schemes or rules or methods for performing mental acts; and methods for playing a game are patent ineligible. Similarly, claims directed to computer-readable medium are also not patent eligible as they are considered to be computer program *per se*. However, computer-related inventions where the actual (or technical) contribution lies in novel hardware or a combination of (known) hardware and software are patent eligible. The August Guidelines, by adopting the *AT&T* signposts for the determination of technical contribution were in line with the decisions of the IPAB and that of the Delhi High Court, especially in following the UK jurisprudence. However, the February Guidelines, although incorporating the basic *Aerotel* test, fell short by not following the decisions of the IPAB and the directions provided by the Delhi High Court. The February Guidelines' stated objectives of fostering "uniformity and consistency" in the examination of computer-related inventions and of bringing "clarity in terms of exclusions expected under section 3(k)" for speedy examination of eligible applications<sup>242</sup> would have immensely benefitted had the February Guidelines included the *AT&T* signposts as determinants of technical advancement. Currently, the February Guidelines are being actively reviewed, and there is yet hope that these deficiencies may be addressed in the near future.

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<sup>238</sup> *Ibid.*, at ¶¶ 110–120.

<sup>239</sup> 134 U.S. 2347 (2014).

<sup>240</sup> *Ericsson*, *supra* note 154 at ¶ 120.

<sup>241</sup> *Ibid.*

<sup>242</sup> *February Guidelines*, *supra* note 137 at section 1.3.

## V. DISCLOSURES RELATED TO FOREIGN APPLICATIONS

Justice Ayyangar believed that “[the] national economy would be better served if the continental or the American system, whereunder publication of the invention before the priority date in any part of the world constitutes anticipation, were adopted.”<sup>243</sup> Accordingly, the *Ayyangar Report* recommended to dispense with the “geographical limitation as to anticipation under the Indian law.”<sup>244</sup> The *Report* also recommended to do away with the “‘fifty years’ rule as to anticipatory documents” proposed in the *Patents Bill 1953*.<sup>245</sup> However, there was a practical problem in adopting these recommendations: “the Examiner in the Patent Office might naturally not have adequate facilities for determining novelty on the basis of publications abroad . . .”<sup>246</sup> In order to overcome this difficulty, Justice Ayyangar opined that “it would be useful to require the applicant to furnish [...] whether [the applicant] has made any application for a patent for the same or substantially the same invention as in India in any foreign country or countries, the objections, if any, raised by the Patent Offices of such countries on the ground of want of novelty or unpatentability or otherwise and the amendments directed to be made or actually made to the specification or claims in the foreign country or countries up to the date of acceptance of the application.”<sup>247</sup> As if a pre-cursor to present day Patent Prosecution Highway mechanisms, Justice Ayyangar believed that “this information would be of great use for a proper examination of the application.”<sup>248</sup> Additionally, Justice Ayyangar suggested that applicants undertake to keep the Controller apprised on any further foreign applications made and of the orders made on such applications after the date of the Indian application.<sup>249</sup> These proposals were justified based on Rule 39 of the Canadian Patent Rules and a resolution passed at the Commonwealth Conference on Patents and Trade Marks at Canberra.<sup>250</sup> Thus, the genesis for Section 8 of the *Patents Act, 1970* can be traced back to the *Ayyangar Report* of 1959.

Section 8 of the *Patents Act, 1970*<sup>251</sup> requires patent applicants to disclose to the Indian Patent Office information regarding foreign patent applications. It is pertinent to note that failure to adhere to this provision at the stage of prosecution before the Patent Office may result in revocation of a patent after it has been granted<sup>252</sup> or may serve as a ground of opposition, both at the pre- and post-grant stages.<sup>253</sup> Over the last decade, this provision has become one of the main grounds for either seeking revocation of patents or for seeking denial of equitable relief during infringement proceedings.

<sup>243</sup> Ayyangar, *supra* note 7 at ¶ 378.

<sup>244</sup> *Ibid.*, at section heading between paragraphs 110 and 111. Prior to changes to Section 13(2) in the *Patents Act, 1970*, based on Clause 12 of the *Ayyangar Report*, anticipatory publications were limited to India.

<sup>245</sup> *Ibid.*, at section heading between paragraphs 113 and 114.

<sup>246</sup> *Ibid.*, at ¶ 113.

<sup>247</sup> *Ibid.* at ¶ 350.

<sup>248</sup> *Ibid.*

<sup>249</sup> *Ibid.* at ¶ 351.

<sup>250</sup> *Ibid.* at ¶ 352.

<sup>251</sup> *Patents Act, 1970*, *supra* note 19 at section 8.

Information and undertaking regarding foreign applications.

(1) Where an Applicant for a Patent under this Act is prosecuting either alone or jointly with any other person an application for a Patent in any country outside India in respect of the same or substantially

### A. Interpretation of Section 8(1)

Under Section 8(1), the applicant is required to file a completed statement and undertaking (Form 3) in respect of patent(s)/patent application(s) for the same or substantially the same invention, filed outside India as on the date of filing of the application in India.<sup>254</sup> This undertaking has to be filed within 6 months from the date of filing of the Indian Patent Application.<sup>255</sup> As per the ordinary meaning of the words used in Section 8(1)(b), if there are any subsequent patent filings (such as a new application, divisional application, continuation application etc.) in other jurisdictions for the same or substantially the same invention, the applicant has to file an updated Form 3 within 6 months (a new application, divisional application etc.) from the date of filing such new foreign applications.<sup>256</sup> The submission of Form 3 is a statutory obligation on the part of the applicant, even if the Controller does not request such information. The present format for Form-3 includes a column for “status” and the status updates include abandonment, publication, opposition, allowance, grant, or rejection / revocation.

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the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or subsequently within the prescribed period as the controller may allow-

(a) a statement setting out detailed particulars of such application; and

(b) an undertaking that, up to the date of grant of Patent in India, he would keep the Controller informed in writing, from time to time, of detailed particulars required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

(2) At any time after an application for Patent is filed in India and till the grant of a Patent or refusal to grant of a Patent made thereon, the Controller may also require the Applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the Applicant shall furnish to the controller information available to him within such period as may be prescribed.”

<sup>252</sup> Section 64, Patents Act, 1970

Revocation of Patents

(m) that the Applicant for the Patent has failed to disclose to the Controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge.

<sup>253</sup> Section 25, Patents Act, 1970

Opposition to the Patent

(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground—

(h) that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;

(2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:—

(h) that the patentee has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;

<sup>254</sup> Rule 12 of the Patent Rules, 2003

12. Statement and undertaking regarding foreign applications.—(1) The statement and undertaking required to be filed by an applicant for a patent under sub-section (1) of section 8 shall be made in Form 3.

(1A).The period within which the applicant shall file the statement and undertaking under sub-section (1) of section 8 shall be six months from the date of filing the application.

### B. Interpretation of Section 8(2)

Under Section 8(2), the applicant may be required by the Controller to submit certain prescribed details, as regards corresponding foreign applications.<sup>257</sup> Under Rule 12(3) of the Patents Rules, 2003, the Controller may request information relating to the objections raised by other patent offices and any other particulars, including the claims allowed.<sup>258</sup> The Controller usually requires details such as search and/or examination reports issued by all the major Patent Offices, such as USPTO, EPO and JPO etc., and amendments made to the corresponding applications. As per Rule 12(3), the patent applicant needs to provide the necessary information requested by the Controller, within 6 months from the date of request.<sup>259</sup>

### C. Jurisprudence Surrounding Section 8 Related Issues

Until recently, there existed unwarranted discrepancy owing to contradictory interpretations of Section 8 by the Delhi High Court and the Intellectual Property Appellate Board (IPAB). The contradiction was specifically on the issue of whether compliance under Section 8 is strict to the extent that mere non-compliance, despite non-establishment of advertence or intention in such non-compliance, will be sufficient to prevent grant of the patent or to revoke the patent, as the case may be.<sup>260</sup>

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Explanation.—For the purpose of this rule, the period of six months in case of an application corresponding to an international application in which India is designated shall be reckoned from the actual date on which the corresponding application is filed in India.  
(2) The time within which the applicant for a patent shall keep the Controller informed of the details in respect of other applications filed in any country in the undertaking to be given by him under clause (b) of sub-section (1) of section 8 shall be six months from the date of such filing.  
(3) When so required by the Controller under sub-section (2) of section 8, the applicant shall furnish information relating to objections, if any, in respect of novelty and patentability of the invention and any other particulars as the Controller may require which may include claims of application allowed within six months from the date of such communication by the Controller.

<sup>255</sup> *Supra* note 111.

<sup>256</sup> *Supra* note 111.

<sup>257</sup> *Supra* note 111.

<sup>258</sup> *Supra* note 111.

<sup>259</sup> *Supra* note 111.

<sup>260</sup> 2012 (52) 1 PTC (Del), IPAB Order No. 166 of 2012.

On the one hand, the Delhi High Court in *F.Hoffmann-La Roche Ltd. v. Cipla Ltd.*<sup>261</sup> held that under Section 64 of the *Patents Act*, there exists discretion to revoke or not to revoke the patent for non-compliance of Section 8 of the *Patents Act* based on the facts and circumstances of each case. The Court held that the discretion exists owing to the wording of Section 64 of the Act, which deals with the revocation of patents.<sup>262</sup> Thus, exercising its discretion, the Court held that Roche's patent could not be revoked solely on the ground of non-compliance of Section 8 of the *Patents Act*.

Thereafter, the Delhi High Court in *Koninklijke Philips Electronics N.V v. Maj. (Retd) Sukesh Behl & Anr*<sup>263</sup> specifically observed that that to fall foul of Section 8 of the Act, one must show that there was deliberate or willful suppression of information and that the information which was not submitted was material to the grant of the patent in India. Philips filed for permanent injunction against Sukesh Behl and others for infringing its DVD Video/DVD ROM Disc patents, especially patent No. 218255. Sukesh Behl filed a counter-claim for revocation of the patent under Section 64(1)(m)<sup>264</sup> of the *Patents Act* for non-compliance with the provisions of Section 8 of the Act, read with Rule 12 of the Patent Rules, 2003<sup>265</sup>. Philips later filed a letter containing the updated list of pending foreign applications before the Controller. Furthermore, Philips' patent attorney also filed an affidavit along with the above letter stating that the omission was inadvertent as the details on one page of the document sent by Philips were accidentally missed and was with no intention to suppress any information from the Indian Patent Office.

Subsequently, Sukesh Behl filed an application under Order XII Rule 6 of the *Civil Procedure Code, 1908*<sup>266</sup> to pass a decree on the basis of the alleged admission made by Philips with respect to lack of disclosure of information under Section 8 of the *Patents Act*. The Court observed that although Philips did not deny that a part of the information regarding pending foreign applications was not disclosed, there was also no admission that such withholding of information was a result of deliberate or willful suppression<sup>267</sup>. The Court further held that the question as to whether the undisclosed information was material to the grant of the patent would have to be put to trial and could not be conclusively determined at a preliminary stage<sup>268</sup>.

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<sup>261</sup> 2012 (52) 1 PTC (Del).

<sup>262</sup> 2012 (52) 1 PTC (Del) at ¶ 156. Section 64 of the *Patents Act* provides in part as follows: "Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds...."

<sup>263</sup> 2013 (56) PTC 570 (Del).

<sup>264</sup> *Supra* note 109.

<sup>265</sup> *Supra* note 111.

<sup>266</sup> Order XII Rule 6 *Judgment on admissions*.- (1) Where admissions of fact have been made either in the pleading or otherwise, whether orally or in writing, the court may at any stage of the suit, either on the application of an party or of its own motion and without waiting for the determination of any other question between the parties, make such Order or give such judgment as It may think fit, having regard to such admissions.

(2) Whenever a judgment is pronounced under sub-rule (1) a decree shall be drawn up in accordance with the judgment and the decree shall bear the date on which the judgment was pronounced.

<sup>267</sup> 2013 (56) PTC 570 (Del) paragraph 13.

<sup>268</sup> *Id.*

On the other hand, the IPAB followed a more rigid approach towards Section 8 compliance and did not adopt the interpretation provided by the above rulings of the Delhi High Court. In *Tata Chemicals Limited v. Hindustan Unilever Limited & Anr.*,<sup>269</sup> the IPAB was called on to rule on whether failure to submit an adverse International Preliminary Examination Report (IPER) in response to a request by the Controller under Section 8(2) was sufficient to revoke the patent. The IPAB first noted that the information relating to the applications under the Patent Co-operation Treaty (PCT), such as the International Search Report (ISR) and the IPER, would be covered within the scope of a Section 8(2) request.<sup>270</sup> The IPAB held that this failure was *per se* sufficient to revoke the patent.<sup>271</sup> The patentee attempted to argue that the prior art cited in the IPER was anyway cited by the Patent Office during its own examination and accordingly, no serious prejudice was caused.<sup>272</sup> However, the IPAB rejected this argument and adopted the following reasoning:

The respondent cannot be heard to say that since European Patent No.1106578, the prior art was anyway considered by the Controller and no prejudice was caused by not disclosing the ISR or IPER. It is not enough that the Examiner knew that this prior art was there, the respondent ought to have disclosed the results of the IPER. The IPER rejected the claims 1 to 3 on both the grounds of novelty and inventive step. It is not for us to conjecture what effect this might have had on the examiner here if he had the benefit of the IPER. This is the object and purpose of enacting Section 8. The Report says that this information would be of great use for a proper examination of the application. It is no answer to say anyway the office looked at EP'578. The Patent Office did not see the IPER. The learned counsel for the respondent submitted that this lapse is of a de-minimis nature, we do not think that honestly furnishing the information or particulars allows a de-minimis qualification . . . . The knowledge of the prior art is not the same as the opinion of the EPO[which issued the IPER].<sup>273</sup>

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<sup>269</sup> IPAB Order No. 166 of 2012.

<sup>270</sup> *Id.* at ¶ 105.

<sup>271</sup> *Id.* at ¶¶ 107, 111.

<sup>272</sup> *Id.* at ¶ 106.

<sup>273</sup> *Id.*

The finding in the *Tata Chemicals* decision was based on the language used in the statute as well as the object and purpose of Section 8 as was stated in the *Ayyangar Report*.<sup>274</sup> The IPAB observed that the purpose for introducing this provision was to ensure that it would be an advantage for the Indian Patent Office to know the objections raised by the patent offices outside India regarding the patentability, anticipation and/or claim amendments if any made or to be made.<sup>275</sup>

The IPAB reiterated its strict interpretation of Section 8 in *Fresenius Kabi Oncology Limited v. Glaxo Group Limited and The Controller of Patents*<sup>276</sup> as well as in *Ajantha Pharma Ltd. v. Allergan Inc.*<sup>277</sup> The IPAB in *Fresenius* also held that divisional applications would also fall within the scope of “same and substantially the same” invention under Section 8 and thus information relating to divisional applications needed to be provided.<sup>278</sup>

While emphasizing strict compliance under Section 8 of the *Patents Act*, the IPAB has also simultaneously held that Section 8 must be carefully applied and that it was never intended to be a bonanza for all those who want an inconvenient patent removed.<sup>279</sup> The IPAB observed that an applicant seeking revocation for non-compliance of a patent under Section 8 may not merely state that the requirements have not been fulfilled.<sup>280</sup> It was observed that the initial burden is on the person seeking to challenge the patent or patent application for non-compliance under Section 8 to show how exactly Section 8 was not complied with.<sup>281</sup> The IPAB also held that such person must also plead as to how the invention disclosed in a particular foreign application is the “same or substantially the same invention.”<sup>282</sup>

The IPAB has also reprimanded the Patent Office for issuing vague requests seeking compliance under Section 8 as part of the examination reports in the course of prosecution of the patent application. In *Glaxo Group Limited v. The Controller of Patents*,<sup>283</sup> the IPAB held that the Patent Office must seek relevant information. The IPAB essentially emphasized that information routinely sought by the Patent Office, such as seeking office actions/amendments from “any one of the major patent offices etc.,” is misleading as the patent applicant may be able to satisfy the burden under Section 8(2) by just giving relevant information from any one of the patent offices across the world and thereby avoid giving pertinent information in respect of applications in other patent offices and thereby defeating the objective behind the provision.<sup>284</sup>

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<sup>274</sup> *Id.* at ¶ 91.

<sup>275</sup> IPAB Order No. 161 of 2013 at ¶ 66.

<sup>276</sup> IPAB Order No. 161 of 2013.

<sup>277</sup> IPAB Order No. 173/2013 at ¶ 69.

<sup>278</sup> IPAB Order No. 161 of 2013 at ¶ 73.

<sup>279</sup> IPAB Order No. 161 of 2013 at ¶ 60.

<sup>280</sup> *Id.* at ¶ 71.

<sup>281</sup> *Id.*

<sup>282</sup> IPAB Order No. 161 of 2013 at ¶ 71.

<sup>283</sup> Order No. 161/2013 at ¶ 75.

<sup>284</sup> IPAB Order No. 166 of 2013 at ¶ 75.

While the interpretation by the Delhi High Court regarding the standard of willful or deliberate suppression as opposed to strict compliance was raised before the IPAB, the IPAB in a consistent line of cases,<sup>285</sup> held that the Act does not make any qualification to the obligation to submit information or the requirement to revoke the patent for failure to submit that information. Thus, the trend as derived from the judicial pronouncements by the IPAB pointed to strict compliance under Section 8, albeit the person seeking revocation needs to satisfy its basic minimum burden of proof.<sup>286</sup>

One must be mindful of the fact that orders of the High Court are binding on the IPAB owing to hierarchy of judicial precedents. Thus, the orders of the Delhi High Court with respect to the interpretation of Section 8 as early as 2012 ought to have been followed by the IPAB thereafter. However, probably owing to the lapse on the part of the arguing counsels in the IPAB cases, in citing the High Courts' interpretation, the IPAB continued to follow a strict approach.

The position was restored with the Division Bench (two judge bench) order of the Delhi High Court in the case of *Maj. (Retd.) Sukesh Behl & Another v. Koninklijke Philips Electronics*<sup>287</sup>, the appellate forum that adjudicated and upheld the earlier order of the Delhi High Court in the *Koninklijke Philips Electronics N.V v. Maj. (Retd) Sukesh Behl & Anr*<sup>288</sup>. In upholding the interpretation of Section 8 as stated in the previous orders of the Delhi High Court, the interpretation of Section 8 is now settled.

The Division Bench held that the word "may" used in Section 64(1) itself indicates the intention of the legislature that the power conferred thereunder is discretionary.<sup>289</sup> Further, the Bench held that the mere fact that the requirement of furnishing information about the corresponding foreign applications under Section 8(1) is mandatory, it is not the determinative factor of the legislative intent of Section 64(1).<sup>290</sup> Therefore, the Bench held that though any violation of the requirement under Section 8 may attract Section 64(1)(m)<sup>291</sup> for revocation of the patent, such revocation is not automatic. Thus the power to revoke a patent under Section 64(1) is discretionary, and consequently it is necessary for the Court to consider the question as to whether the omission on the part of the plaintiff was intentional or whether it was a mere clerical and bona fide error.<sup>292</sup>

In *Ericsson v. Intex*,<sup>293</sup> the Delhi High Court once again reiterated that to run afoul of Section 8, there must be lack of intent to comply with the disclosure requirement. Furthermore, the Court held that (emphasis added):

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<sup>285</sup> *Ajantha Pharma Ltd. v. Allergan Inc* IPAB Order No. 173/2013; *Glaxo Group Limited v. The Controller of Patents* IPAB Order No. 161 of 2013.

<sup>286</sup> IPAB Order No. 166 of 2013 at ¶ 71.

<sup>287</sup> FAO (OS) No. 16 of 2014; Order dated Nov 7, 2014.

<sup>288</sup> 2013 (56) PTC 570 (Del).

<sup>289</sup> FAO (OS) No. 16 of 2014 at ¶ 37.

<sup>290</sup> FAO (OS) No. 16 at ¶ 37.

<sup>291</sup> Section 64(1)(m) provides that a patent may be revoked on the grounds "that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge."

<sup>292</sup> FAO (OS) No. 16 at ¶ 40.

<sup>293</sup> *Ericsson, supra* note 159 at ¶ 104.

So long as Indian Patent Office [is] informed of all the major jurisdictions in which patents have been granted and substantial details are placed on record, the obligation of complying with Section 8 stands satisfied unless the Controller of Patents seeks some more detail(s) in order to satisfy his own conscious in order to understand the compliance of said provision. *The said Section should not be interpreted in the manner that every shred of paper filed in every foreign country has to be filed in the Indian Patent Office.*<sup>294</sup>

#### D. Conclusion

The law with respect to the determination as to whether a patent can be revoked based on non-compliance of Section 8 of the *Patent Act* is now settled and is in tune with such requirements in other jurisdictions, such as the USA, and is also in line with the objective behind Section 8 as set out in the *Ayyangar Report*. This position of law is also reassuring for patent applicants and patentees alike that their substantive right of the patent is no longer at stake merely on account of clerical or bona fide errors in complying with the requirements under Section 8 of the *Patents Act*.

### VI. FINAL NOTES

Almost sixty years on, Justice Ayyangar's recommendations continue to impact Indian Patent laws. Several key provisions of the Ayyangar report have become mainstays of the *Patents Act* 1970, and have survived the trilogy of amendments at the turn of the millennium. The provisions relating to Compulsory Licenses and Working of Patents; Exclusions from Patentability; and Disclosures related to Foreign Applications have been subject of much debate. However, the jurisprudence in these seemingly controversial aspects of the Indian patent law have slowly but significantly evolved over the last decade.

In *Nexavar*, the IPAB and the Bombay High Court clarified the scope of the grounds on which a compulsory license may be granted.<sup>295</sup> The Supreme Court, by refusing to review the orders of the Bombay High Court, upheld the High Court's decision. Therefore, the jurisprudence on the compulsory licensing regime is largely settled in India. *Nexavar* in particular has established some ground rules for the operation of the compulsory license regime.<sup>296</sup> Those ground rules as derived by the judiciary from the statutory provisions ensure that the compulsory licensing provisions are no longer a threat to innovation but only seek to balance patent rights and public interest considerations in specific factual circumstances.<sup>297</sup>

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<sup>294</sup> *Id.* at ¶ 103.

<sup>295</sup> *Bayer Corporation vs. Union of India* 2014 (60) PTC 277 (Bom).

<sup>296</sup> 2014 (60) PTC 277 (Bom).

<sup>297</sup> *Id.* at ¶ 19.

The requirement of filing particulars related to Working of Patents remains a persistent issue. However, by accepting a public interest litigation, the Delhi High Court now has the opportunity to dispel the uncertainty surrounding the nature and the extent of the information required under the mandatory Form 27 filings.

The Supreme Court of India has categorically upheld the exclusions under the provisions of Section 3(d). In *Gleevec* and *Terceva*, the Supreme Court and the Delhi High Court, respectively, have provided much needed clarity on the scope of the exclusions.<sup>298</sup> The Delhi High Court confirmed that Section 3 serves as a threshold test which must be assessed prior to determining patentability under the definition of an invention under Section 2(1)(j) of the *Patents Act*.<sup>299</sup>

The IPAB and the Delhi High Court have consistently sought to harmonize the exclusions under Sections 3(k) and 3(m) of the *Patents Act* for computer-implemented inventions with the international jurisprudence, particularly with that of the UK. It is expected that the Indian Patent Office will revise the recently released guidelines for the examination of computer-related inventions having regard to the nascent jurisprudence on this issue.

The Delhi High Court's decisions with respect to the scope and effect of the disclosure requirements under Section 8 of the *Patents Act* have come as a relief to patentees. The law in India is now along the lines of the disclosure provisions in the USA. The Department of Industrial Policy and Promotion, for its part, has committed to examining the feasibility of joining the WIPO Digital Access Service (DAS), and the Indian Patent Office has begun to participate in the WIPO Centralized Access for Search and Examination (CASE) system with the goal of improving processing efficiency.

While patent jurisprudence in India continues to evolve, it is heartening to note that the Indian courts have attempted to maintain a fine balance between public interest and private rights. At the same time, the courts have ensured that India remains compliant with her international obligations, without departing from the spirit with which Justice Ayyangar set out to reform India's patent laws all those years ago.

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<sup>298</sup> *Novartis Ag v. Union of India & Ors* (2013).

<sup>299</sup> *Id.*

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