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## INDIA'S NEW "TRIPS-COMPLIANT" PATENT REGIME BETWEEN DRUG PATENTS AND THE RIGHT TO HEALTH

Prabhu Ram\*

### Introduction

Thanks to an array of measures post 1970, the Indian domestic pharmaceutical industry flourished in the absence of product patents.<sup>1</sup> The competitive generic market resulted in production of generic versions of blockbuster drugs at very low prices.<sup>2</sup> These generic drugs cost about 5% of the price of similar drugs sold by US and EU pharmaceutical firms.<sup>3</sup> Apart from the large domestic consumption, cheap Indian generic drugs have been favored by many millions of AIDS patients across the Third World.<sup>4</sup> Generic drugs from India played a key role in lowering the price of antiretroviral treatment by as much as 98%, making it feasible to scale up treatment more rapidly for 3.7 million Africans with AIDS lacking access to treatment.<sup>5</sup>

On March 23, 2005, the Indian Parliament passed the Patent (Amendment) Bill 2005 (Bill No. 32-C of 2005).<sup>6</sup> It was the third amendment to the Indian Patent Act (1970).<sup>7</sup> The amended Patent Act conforms to requirements set forth by the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>8</sup> Since the new law came into effect on January 1, 2005, there have been serious concerns regarding the role of the domestic Indian generic industry in the new product patents regime,<sup>9</sup> and the continued availability of essential medicines at affordable prices.<sup>10</sup>

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<sup>1</sup> S. Mukherjee, *The Journey of Indian Patent Law Towards TRIPS Compliance*, 35 IIC 125 (2004).

<sup>2</sup> Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?* (Natl. Bureau of Econ. Research, Inc. Working Paper No. 6366, 1998).

<sup>3</sup> Intl. Ctr. for Trade and Sustainable Dev., *Indian Parliament Approves Controversial Patents Bill* (Mar. 23, 2005). (available at <http://www.ictsd.org/weekly/05-03-23/story1.htm>).

<sup>4</sup> World Heal. Org., *India and Pharmaceutical Patents*. Heal. Tech. and Pharm. News 3 (May 2005) (available at [http://www.who.int/medicines\\_technologies/newsletter/htp\\_2005\\_May.pdf](http://www.who.int/medicines_technologies/newsletter/htp_2005_May.pdf)).

<sup>5</sup> Africa Focus Bull. *India/Africa: Threat to Generic Drugs*, (Mar. 7, 2005) (available at <http://www.africafocus.org/docs05/ind0503.php>).

<sup>6</sup> Text of the Patents (Amendment) Act, 2005, (Act No. 15 of 2005) (available at [http://www.ipindia.nic.in/ipr/patent/patent\\_2005.pdf](http://www.ipindia.nic.in/ipr/patent/patent_2005.pdf)).

<sup>7</sup> Text of the Patents Act, 1970, (Act No. 39 of 1970). (available at <http://ipindia.nic.in/ipr/patent/patAct1970-3-99.html>).

<sup>8</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights* Annex 1C (entered into force 1994), [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm).

<sup>9</sup> HealthGAP (Global Access Project) & Médecins Sans Frontières, *India's Patent Act to Block Access to Low-Cost Generic AIDS Drugs*, [http://www.healthgap.org/press\\_releases/04/121504\\_HGAP\\_MSF\\_transcript\\_india.doc](http://www.healthgap.org/press_releases/04/121504_HGAP_MSF_transcript_india.doc) (Dec. 15, 2004) (Civil society proponents have argued that undermining Indian generic drug manufacturers is not good for the long-term economic interest of India, and that when one examines the tremendous

This paper will analyze the new patent law's impact on the availability of essential drugs and examine the future of the Indian generic pharma industry. In the next section, the paper outlines the context underlying India's patent policy shift. Section II provides a critical analysis of the public health provisions in the Third Patent Amendment. The last section provides some thoughts on the road ahead.

## I. Context

India became a party to the TRIPS Agreement in April 1994. At that time, India's current enactment of the Patent Act of 1970 directly contravened Article 27 of the TRIPS Agreement.<sup>11</sup> Upon coming into effect on January 1, 1995, TRIPS set out transitional periods for WTO members to introduce legislation complying with the obligations under TRIPS.<sup>12</sup>

For developing countries, like India, the deadline for complying with TRIPS was the year 2000.<sup>13</sup> In addition, Article 65.4 of TRIPS provided a special transitional provision for those countries that did not grant product patents. The provision provided an additional five years (until 2005), from the initial TRIPS transitional period, to introduce product patent protection.<sup>14</sup> India took advantage of this extra transition period.<sup>15</sup>

India had to provide a means by which patent applications could be filed during the transitional period. The "mailbox provision" allowed applicants to file for patents, thereby establishing filing dates, while at the same time permitting member countries to

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impact that lack of access would have on India and on importing countries, the speculated benefits, such as increased foreign direct investment, would not actually counterbalance the costs).

<sup>10</sup> Health GAP (Global Access Project), *Factsheet: Changes to India's Patents Act and Access to Affordable Generic Medicines after January 1, 2005*, [http://www.healthgap.org/press\\_releases/04/121404\\_HGAP\\_FS\\_INDIA\\_patent.pdf](http://www.healthgap.org/press_releases/04/121404_HGAP_FS_INDIA_patent.pdf) (Dec. 14, 2004)

(Civil society proponents have expressed fears about a steep rise in drug prices owing to the introduction of product patents in pharmaceuticals. While analyzing the impact of the new Indian Patent Act on access to essential medicines, it has to be pointed out that medicines patented prior to 1995 - medicines not protected by product patents in India - would remain available at the same prices. India would still be able to market generic versions of these drugs. The cause of concern would be the "drugs in the mailbox" (transitional period from 1995-2005), and for the new drugs approved post-2005).

<sup>11</sup> *Supra* n. 1 (According to Article 27 of the TRIPS, patents must be available for any inventions, whether products or processes, in all fields of technology. Until TRIPS, India excluded patents on products such as pharmaceuticals and foods).

<sup>12</sup> World Trade Org. *UNDERSTANDING THE WTO: THE ORGANIZATION, Least-developed countries*, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org7\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm) (July 15, 2005).

<sup>13</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights* Annex 1C, Art. 65 §2 (entered into force 1994), [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm) (Developing countries could delay implementation under TRIPS until 2000).

<sup>14</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights* Annex 1C, Art. 65 §4 (entered into force 1994), [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm) (India could delay granting product patents on pharmaceuticals and food for a further period of five years till 2005, upon the completion of the initial transition period from 1995-2000).

<sup>15</sup> WTO fact sheet: TRIPS and Pharmaceutical Patents.(available at [http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm04\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm)).

defer granting product patents.<sup>16</sup> In addition, India also had to provide “exclusive marketing rights” (EMRs) in exchange for permission to delay the granting of product patents until January 1, 2005.<sup>17</sup> EMRs are supposed to apply where a patent is granted for the same product in another WTO member country after 1995 (the date of entry into force of TRIPS), provided the other member country obtained marketing approval for the product.

In 1999, the first amendment of the Patent Act, 1970 introduced the requirements under the “transitional arrangements through Section 5(2), which allowed product patent applications to be filed through a ‘mailbox’, while Chapter IVA provided for the grant of Exclusive Marketing Rights (EMRs) if certain conditions were fulfilled.”<sup>18</sup> In 2002, the second amendment of the Patent Act provided for changes in the scope of patentable inventions, grant of new rights, extension of the term of protection, provision for reversal of burden of proof in cases of process patent infringement, and conditions for compulsory licenses.<sup>19</sup> This amendment was one more step in India’s journey towards TRIPS compliance. The final step was a requirement to introduce product patents in the area of chemicals, pharmaceuticals, and agricultural chemicals and food. The deadline for compliance was January 1, 2005.<sup>20</sup>

On December 26, 2004, India issued a presidential decree (hereinafter “the Ordinance”) to amend its law and meet this final deadline. The Ordinance, in addition to introducing product patents, also introduced many other substantial amendments.<sup>21</sup> The Patent (Amendment) Act of 2005 (hereinafter “the Act”), passed by the Indian Parliament, replaced that ordinance.<sup>22</sup> Several amendments were made to the Ordinance in the Act, and some contentious issues pertaining to patentability of new chemical entities and micro-organisms were referred to a technical panel.<sup>23</sup>

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<sup>16</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights* Annex 1C, Art. 70 §8 (entered into force 1994), [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm) (Developing countries had to allow inventors to file patent applications from January 1, 1995, and the decision on whether or not to grant any patent could be taken at the end of the transition period).

<sup>17</sup> See *Agreement on Trade-Related Aspects of Intellectual Property Rights* Annex 1C, Art. 70 §9 (entered into force 1994), [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm).

<sup>18</sup> Text of the Patents (Amendment) Act, 1999, (Act. No. 17 of 1999). (available at [http://patentoffice.nic.in/ipr/patent/patact\\_99.PDF](http://patentoffice.nic.in/ipr/patent/patact_99.PDF)) (March 26, 1999).

<sup>19</sup> Text of the Patents (Amendment) Act, 2002, (Act. No. 38 of 2002). (available at <http://patentoffice.nic.in/ipr/patent/patentg.pdf>) (June 25, 2002).

<sup>20</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights* Annex 1C, Art. 65 §4 (entered into force 1994), [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm).

<sup>21</sup> Text of the Patent (Amendment) Ordinance (Ordinance No. 7 of 2004) (available at <http://lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf>) (The Ordinance introduced post-grant opposition. It reduced the grounds for pre-grant opposition. With reference to compulsory licensing, the Ordinance did not spell the royalty rate or the time frame. Lastly, software patenting was introduced. The Ordinance was an interim measure to fulfill India’s TRIPS obligations within the stipulated time.).

<sup>22</sup> Text of the Patents (Amendment) Act, 2005, (Act. No. 15 of 2005). (available at [http://www.ipindia.nic.in/ipr/patent/patent\\_2005.pdf](http://www.ipindia.nic.in/ipr/patent/patent_2005.pdf)). ( The Indian parliament passed the Patents (Amendment) Bill 2005 on March 23, 2005).

<sup>23</sup> Govt. of India Press Info. Bureau, *Kamal Nath Constitutes Technical Expert Group on Patent Laws*, [http://commerce.nic.in/Apr05\\_release.htm](http://commerce.nic.in/Apr05_release.htm) (April 6, 2005).

## II. Third Patent Amendment

One of the major changes that the third amendment brought about was India's recognition of product patents for 'food', 'drug', and 'pharmaceuticals' on January 1, 2005.<sup>24</sup> The Act repealed the controversial Section 5(1) of the Patents Act, 1970, which provided for process patents in this field, and also removed the definition of food.<sup>25</sup>

### A. Scope of Patentability

The Act amended the definition of "patent." Under the Patent Act, 1970, "patent" was defined to mean "a patent granted under this Act."<sup>26</sup> The amended law defines "patent" as "a patent for any invention granted under this Act."<sup>27</sup>

With reference to the inventive step, the Act states:

'inventive step' means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both that makes the invention not obvious to a person skilled in the art.<sup>28</sup>

In the Patent Act, 1970, "inventive step" was defined as "*a feature that makes the invention not obvious to a person skilled in the art.*"<sup>29</sup> The new definition for "inventive step" aims to raise the standard for an inventive step. For patent eligibility, an invention must involve an inventive step and technical advances as compared to existing knowledge, or it must have economic significance, or both. The use of the expression "economic significance" in the new law is interesting; it is neither a classical patentability criterion nor does it have anything to do with inventions. The Patent Controller is now required to independently assess the economic significance of an invention based on data furnished by the patent applicant himself.

While Section 2(1)(j) retains the old definition of "new invention," a new definition for "new invention" has been added in Section 2(l).

"New invention" is defined as

any invention or technology which has not been anticipated by the publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete

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<sup>24</sup> § 5, Patents Act, 1970 (The Act only recognized process patents for pharmaceuticals, food, agrochemicals, etc. The Patents (Amendment) Act, 2005 omitted § 5).

<sup>25</sup> *Id.* at §§5(1), 2(1)(g).

<sup>26</sup> *Id.* at §2(1)(m).

<sup>27</sup> §2(1)(m), Patents (Amendment) Act, 2005.

<sup>28</sup> *Id.* at §2(1)(ja).

<sup>29</sup> §2(1)(ja), Patents Act, 1970.

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>30</sup>

The interpretation of “invention” in Section 2(1)(j) depends on this new definition for “new invention.” The above exhaustive definition puts the onus on the patent applicant to clarify the novelty and patentability of a newly claimed invention. This amendment presents a check on the granting of patents with frivolous claims.

Lastly, the Act also provides a new definition for a “pharmaceutical substance” as “*any new entity involving one or more inventive steps.*”<sup>31</sup> The above definition is quite broad, and definitely has a bearing on determining patentability for pharmaceuticals. Ideally, “new entity” should have been stated clearly as a “new drug molecule” for specificity.

### *B. Exceptions to Patentability*

With regards to *what is not patentable*, the Act dropped the earlier provision contained in the Ordinance;<sup>32</sup> that provision created the possibility for the grant of a patent on a second medical use of a known drug. The amended Section 3(d) reads thus:

(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 the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs 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.<sup>33</sup>

It follows from the above statements that patents would not be available on the following grounds:

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

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<sup>30</sup> §2(1)(l), Patents (Amendment) Act, 2005.

<sup>31</sup> *Id.* at §2(1)(ta).

<sup>32</sup> § 3(d), Patents (Amendment) Ordinance (2004).

<sup>33</sup> § 3(d), Patents (Amendment) Act (2005).

One can argue that a minor alteration to an existing drug molecule, resulting in “*enhancement of its known efficacy*” could lead to the grant of a patent on that molecule.

The word “*mere*” has been deleted from qualifying “*new use*,”<sup>34</sup> patents available only in instances where the *discovery* is not *mere*.

With reference to the lengthy explanation accompanying the above provision, the Act states that patents would not be available on new forms of a known substance unless it “*differ[s] significantly in efficacy*.”<sup>35</sup> Efficacy will thus be the important deciding factor for grants of patents on drug molecules. This would help both domestic and foreign pharmaceutical companies secure patents on “genuine innovations” only, and would reduce the opportunity for companies to extend their patent monopoly through minor modifications or “fence patents” around a drug molecule. While the onus of passing the “efficacy” test has been put on the patent applicant, a lot would depend upon the specifications and the claims therein.

### C. Compulsory Licensing

Compulsory Licensing is a procedure whereby a Government can allow any company, agency or designated person the right to make a patented product, or use a patented process under licence, without the consent of the original patent holder.<sup>36</sup> Under Section 84(1) of the amended Act, an application can be made for compulsory license three years after the grant of a patent: “At any time after the expiration of three years from the date of the grant a patent, any person interested may make application to the Controller for grant of compulsory license.”<sup>37</sup> A reasonable time period extending up to six months has been introduced, allowing the Controller to grant compulsory licenses in those cases where the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions without any success.<sup>38</sup>

This time period for issuance of a compulsory license remains a cause of concern. As per the Act, applications for compulsory licenses can only be made after a period of three years once the patent has been issued.<sup>39</sup> In addition, the six month time-frame could result in further delay in the issuance of a compulsory license.

With respect to exporting drugs to a country which makes a request for a generic drug, the Act has simplified the compulsory licensing procedure; countries that put in a request for generic drugs do not have to issue a compulsory license:

92A. (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having

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<sup>34</sup> § 3(d), Patents (Amendment) Ordinance (2004).

<sup>35</sup> § 3(d), Patents (Amendment) Act (2005).

<sup>36</sup> World Trade Org., *FAQ on Compulsory licensing of pharmaceuticals and TRIPS*, (available at [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)). (Oct. 21, 2005).

<sup>37</sup> § 84(1)(c) of the Act.

<sup>38</sup> *Id.* at §84(6) (The explanation has been inserted at the end of §84(6) of the Act).

<sup>39</sup> *Id.* at §84(1).

insufficient or no manufacturing 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 patented pharmaceutical products from India.*<sup>40</sup>

#### *D. Mailbox Applications*

The Act in Section 11A introduced a new proviso:

**Provided** also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1<sup>st</sup> day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises.<sup>41</sup>

Indian generic drug manufacturers have been manufacturing generic versions of branded drugs. Under the Act, such generic drug manufacturers that had made significant investment and were marketing the product before January 2005 can continue marketing the product in the new regime. The Act grants them immunity from infringement suits from patent holders. They would only have to pay a reasonable royalty to the patentee.

A majority of 7,520 patent applications in the mailbox belong to multi-national companies (MNCs), while Indian drug companies have filed 1,406 applications.<sup>42</sup> Compared to these numbers, the US Food and Drug Administration (USFDA) approved only 297 new chemical entities (NCEs) in the period from 1995-2004.<sup>43</sup> The unusually large number of patent applications filed by MNCs points to the fact that they are not related to NCEs, and involve either frivolous or preventive pleas.

While the law has stated that the generic manufacturers would have to pay a “reasonable royalty” to the patent holder, it has not defined “reasonable.”<sup>44</sup> Ideally, the royalty rate should have been fixed at 4%, following the practice adopted by Canada for many years, or at 5% following South Africa.<sup>45</sup>

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<sup>40</sup> *Id.* at §92A(1).

<sup>41</sup> *Id.* at §11A.

<sup>42</sup> K. G. Narendranath, *Patent mailbox opens, Pfizer is top applicant*, Fin. Express (March 21, 2005) (available at [http://www.financialexpress.com/fe\\_full\\_story.php?content\\_id=85782](http://www.financialexpress.com/fe_full_story.php?content_id=85782)).

<sup>43</sup> Sudip Chaudhuri, *TRIPS and the Changes in the Pharmaceutical Patent Regime in India* (Indian Inst. Of Mgt. Working Paper No. 535, 2005).

<sup>44</sup> §11A (The Act has mentioned that a “reasonable royalty” needs to be paid to the patent holder. However, it has not specified the rate to be paid).

<sup>45</sup> *GSK and BI Issue Anti-retroviral Licences*,

<http://www.compcom.co.za/resources/Comp%20Comm%20March%20HTML/1%20GSK&BI.html>.

(Oct. 21, 2005) (South African Competition Commission in 2003 found GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) guilty of excessive pricing for AIDS drugs. The royalty rates were reduced from 30% to 5% in the case of GSK, and from 15% to 5% in the case of BI).



### *E. Opposition to a Patent*

Chapter V which concerns opposition was given a new chapter heading: “Opposition Proceedings to Grant of Patents.”<sup>46</sup> Section 25(2), introduced by the Ordinance, was deleted with an objective of strengthening pre-grant opposition.<sup>47</sup> In the Ordinance, the post-grant opposition system had been introduced, and grounds pertaining to pre-grant opposition had been considerably reduced to two.<sup>48</sup>

The Act now provides for two different stages of patent opposition: pre-grant, upon the publication of the application; and post-grant, upon the grant of a patent.<sup>49</sup> All 11 grounds for pre-grant opposition have been restored in Section 25 of the Patents Act.<sup>50</sup> While an interested person can initiate post-grant opposition,<sup>51</sup> the Act allows any person to institute a pre-grant opposition on the same grounds as the post-grant opposition.<sup>52</sup>

In addition, a minimum period of six months has been introduced for making representation from the date of publication, as compared with the earlier timeframe of three months.<sup>53</sup>

### *F. Publication*

The Act amends Section 11A of the Patents Act, which prescribes the initial publication requirement.<sup>54</sup> The Act states that “the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application.”<sup>55</sup>

There are two points for concern pertaining to Section 11A. First, the patent applicant’s option to demand an early publication of the patent application permits him to prevent research and development by other companies on pre-patent information. Second, the Act does not make the publication of the complete specification available to the public. Fears have been expressed that this could “greatly hamper opposition proceedings.”<sup>56</sup>

### *G. Data Exclusivity*

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<sup>46</sup> Ch. V, Patents (Amendment) Act, 2005. (In the Patents Act, 1970, Chapter V was entitled “Opposition to Grant of a Patent”).

<sup>47</sup> § 25, Patents (Amendment) Ordinance, 2004. (Section 25(2) of the Ordinance denied a person making an opposition representation the right of becoming a party to any proceedings under the Act, a provision viewed as restrictive to the scope of opposition).

<sup>48</sup> *Id.*

<sup>49</sup> § 25, Patents (Amendment) Act, 2005.

<sup>50</sup> *Id.* at §25(1).

<sup>51</sup> *Id.* at §25(2).

<sup>52</sup> *Id.* at §25(1).

<sup>53</sup> Rule 55(1A), of the Patent (Amendment) Rules, 2005.

<sup>54</sup> §11A, Patents (Amendment) Act, 2005.

<sup>55</sup> *Id.* at §11A(7).

<sup>56</sup> AMTC, *A Critical View of the New Indian Patent (Amendment) Act 2005*, AMTC (March 2005).

Pharmaceutical companies have to submit test and clinical data to the national health authorities to obtain marketing approval for a new drug.<sup>57</sup> The national health authorities keep the innovator data confidential against “unfair commercial use” for a certain time period,<sup>58</sup> thus barring generic manufacturers from using the submitted innovator data for the stipulated period.

The US and EU grant “data exclusivity” for five years<sup>59</sup> and eleven years,<sup>60</sup> respectively. Most often, companies use data exclusivity provisions to seek a period of monopoly in a country even if it does not have any patents on the product in the country.<sup>61</sup> As such, data exclusivity provisions have considerable implications for developing countries like India.

So far, India has not introduced provisions pertaining to data exclusivity in the three amendments to the Patents Act, 1970. India is now considering amendments to the Drugs & Cosmetics Act, 1940 and the Indian Insecticides Act, 1968 incorporating provisions for data protection.<sup>62</sup>

Once data exclusivity is introduced, generic companies would have to do their own safety and efficacy tests. The huge cost involved in this exercise could result in generic companies being barred from producing a generic version of a product for a period extending effectively beyond 20 years.<sup>63</sup> It may also result in the ineffective use of a compulsory license due to data exclusivity provisions, were such a license issued to a generic manufacturer.<sup>64</sup>

#### H. “Bolar” Provision

The “Bolar” provision is the best known of the many limited exceptions to the patentee’s exclusive rights under Article 30 of the TRIPS.<sup>65</sup>

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<sup>57</sup> Médecins Sans Frontières, *Data Exclusivity in International Trade Agreements: What Consequences for Access to Medicines?*, <http://www.accessmed-msf.org/documents/Data%20exclusivity%20May%2004.pdf> (May 2004) (Provides an in depth discussion of data exclusivity).

<sup>58</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights* Annex 1C, Art. 39 §3 (entered into force 1994), [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm).

<sup>59</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b (1994); 21 U.S.C. §§ 301 note, 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

<sup>60</sup> Art. 10, Directive 2004/27/EC (March 31, 2004) (Directive 2004/27/EC of the European Parliament and Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use). (available at [http://www.ebe-efpia.org/docs/pdf/PharmaLeg\\_Directive.pdf](http://www.ebe-efpia.org/docs/pdf/PharmaLeg_Directive.pdf)).

<sup>61</sup> *Supra* n. 58.

<sup>62</sup> Padmini Jayashree, *Consultative Committee Recommends Data Protection*, Express Pharma Pulse (March 24, 2005) (available at <http://www.expresspharmapulse.com/20050324/coverstory01.shtml>).

<sup>63</sup> Padmashree Gehl Sampath, *Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry* (WHO-CIPIH Studies 2005: 37) (available at <http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf>).

<sup>64</sup> Médecins Sans Frontières, *supra* n. 58.

<sup>65</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights* Annex 1C, Art. 30 (entered into force 1994), [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm) (countries “may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably

The amended Patent Act provides for Bolar exception in Section 107A(a):

any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product.<sup>66</sup>

This would allow a generic drug manufacturer to produce or import patented drugs for the purpose of development and submission of information for regulatory trials before patents expire. In other words, but for the “Bolar” exception in Indian patent law, generic manufacturers would be forced to wait for the patents to expire before embarking on the mandatory tests necessary for regulatory approvals. This would allow Indian generic manufacturers to compete among themselves, ensuring the continued availability of medicines at low costs for domestic, as well as international, consumers.

### *I. Parallel Imports*

Parallel imports occur when patented medicines produced or sold abroad with the consent of the patent owner are subsequently imported into the domestic market at cheaper prices without the consent of the owner.<sup>67</sup> Parallel importation works on the principle that the patent owner’s rights have been exhausted through the first sale.

In the Patent Act, 1970, Section 107A(b) contained a provision regarding parallel imports.<sup>68</sup> This has since been streamlined further to avoid unnecessary delays. Section 107A(b) of the amended Act now reads as follows:

Importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights.<sup>69</sup>

### *J. Exceptions for Experimental or Educational Purposes*

The Patent Act provides an exception for research and development from the ambit of patents, including for the purposes of research, experiments or education.

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conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”).

<sup>66</sup> §107A(a), Patents (Amendment) Act, 2005.

<sup>67</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights Annex 1C, Art. 28* (entered into force 1994), [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm) (patent owner cannot legally prevent the importation of patented products from another country. Parallel imports are subject to Article 6 (of TRIPS) on “exhaustion”).

<sup>68</sup> §107A(b), Patents (Amendment) Act, 2005 (requiring that the foreign exporter was “duly authorized by the patentee to sell and distribute the product”. This has now been amended to read “duly authorized under the law”).

<sup>69</sup> *Id.*

Section 47(3) of the Patent Act addresses the experimental use of a patented invention, solely for the purpose of research or education, including “imparting of instructions to pupils”:

any machine, apparatus or other article in respect of which the patent is granted, or any article made by the use of the process in respect of which a patent is granted, may be made or used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.<sup>70</sup>

As such, third parties could experiment with patented products and make new manufacturing processes. However, such products cannot be used commercially without prior approval from the patent holder.

### Conclusion

The changes to the new Patents Act could enable India to continue playing the pioneer role that it played in the pre-TRIPS period, making drugs available at cheap prices to consumers both domestically, and around the world.

The Act has some clear provisions to protect the interests of the domestic generic manufacturers. It has achieved a reasonably fine balance among stringent IP measures, while making use of some of the flexibilities that TRIPS offers. The amended Patents Act has an effective opposition system for challenging frivolous patents, limited patentability exceptions, elaborate provisions pertaining to compulsory licensing, and parallel importation.

For India’s domestic consumers, medicines patented pre-1995 would continue to be available at the same prices. Consumers could expect a slight price increase for medicines that are the subject of mailbox patents. Prices for medicines that are the subject of patents issued after 2005 would probably be higher. The effective use of the compulsory licensing provisions could result in continued domestic access to medicines at cheap costs for the drugs in the mailbox and after. In addition, the National Pharmaceutical Pricing Authority (NPPA) and India’s price regulatory policy, the Drug Price Control Order (DPCO), could play a key role in keeping a check on prices.

With the new level playing ground from 2005 onwards, research-based Indian generic manufacturers could supply new markets with their low cost medicines, and claim higher levels of IP protection in the EU and the US. Indian companies are adopting new strategies to expand the market for their low cost drugs.<sup>71</sup>

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<sup>70</sup> § 47(3), Patents (Amendment) Act, 2005.

<sup>71</sup> Cheri Grace, *The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China: Considerations for Access to Medicines* (DFID-HSRC, 2004) (available at [http://www.dfidhealthrc.org/Shared/publications/issues\\_papers/ATM/Grace2.pdf](http://www.dfidhealthrc.org/Shared/publications/issues_papers/ATM/Grace2.pdf)).

While addressing the issue of access to medicines, and the right to health, this new Indian patent law could herald the beginning of a new chapter, provided the provisions in the new law are utilized effectively.