

**PATENTABLE SUBJECT MATTER REQUIREMENTS:  
AN EVALUATION OF PROPOSED EXCLUSIONS TO INDIA'S PATENT  
LAW IN LIGHT OF INDIA'S OBLIGATIONS UNDER THE TRIPS  
AGREEMENT AND OPTIONS FOR INDIA**

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**Abstract**

In April 2005, the Technical Expert Group (the Expert Group) on patent law issues, headed by Dr. RA Mashelkar, considered the TRIPS Agreement's consistency of (a) limiting the grant of patents for pharmaceutical substances to new chemical entities or to new medical entities, and (b) excluding micro-organisms from patent eligibility.

In December 2006, the Expert Group submitted its report. The report indicated that (a) limiting the grant of patents for pharmaceutical substances to new chemical entities or to new medical entities, and (b) excluding micro-organisms from patent eligibility would be in contravention with India's obligation under the TRIPS Agreement. However, certain stakeholders criticized the report because the Expert Group took up the question of what is in India's national interest, instead of examining whether restricting patents in pharmaceuticals to new chemical entities and excluding micro-organism would violate TRIPS. The Expert Group later withdrew its report due to "technical inaccuracy and plagiarism." However, in the midst of this controversy, the main issue regarding the legality of limiting these grants and excluding eligibility was completely lost.

Through examination of the TRIPS Agreement in conjunction with the interpretation of other international treaties/conventions, this article presents evidence that neither of these two *per se* exceptions to patentable subject matter (*i.e.*, the availability of patents) is consistent with the obligations of India under the TRIPS Agreement. This article also proposes legal options available to India to safe-guard its national interests.

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## INTRODUCTION

In March 2005, the Indian government introduced the 2005 Patent (Amendment) Bill in the Parliament to fulfill India's international obligations under the Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement or TRIPS).<sup>1</sup> India's compliance with the TRIPS Agreement has been a very long and circuitous journey. The journey began with the 2003 Patent (Amendment) Bill under the National Democratic Alliance (NDA) Government led by the Bhartiya Janata Party (BJP), but the Bill soon lapsed due to a change in government at the centre and the consequent dissolution of the House of People.<sup>2</sup> The new Congress led United Progressive Alliance (UPA) government endorsed the Bill, but because of pressure from the Left Parties, the UPA was unsure of whether the Bill would go through Parliament before the TRIPS Agreement deadline of January 1, 2005.<sup>3</sup> Hence, the UPA passed the Bill as a presidential ordinance in order to meet the above deadline.<sup>4</sup> Under pressure from the Left parties, the UPA immediately made changes to the Ordinance and then introduced the Bill in the Parliament.<sup>5</sup> However, the Left Parties were not completely satisfied. In both Houses of the Parliament, the controversy regarding patentability of micro-organisms remained. In addition, both Houses bitterly debated whether the definition of 'pharmaceutical substance' meant a "new chemical entity (NCE)" or a "new medical entity (NME)."<sup>6</sup> Even though Parliament had not resolved these issues, rather than risk any further delays, the government did what it does best when it is caught in a spot—appoint a committee. Mr. Kamal Nath, the Minister for Commerce and Industry, strategically assured the Parliament that he would refer the contentious issues to an expert committee for a detailed

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<sup>1</sup> Agreement on Trade Related Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1125 (1994) [hereinafter TRIPS Agreement], available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

<sup>2</sup> Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 INDIAN J.L. & TECH. 15 (2005).

<sup>3</sup> See TRIPS Agreement, *supra* note, art. 65.4 (permitting developing country member who did not grant pharmaceutical product patents prior to the TRIPS Agreement to harmonize its national legislation on intellectual property rights with the international TRIPS obligations by Jan. 1, 2005).

<sup>4</sup> See Basheer, *supra* note 2.

<sup>5</sup> See Basheer, *supra* note 2.

<sup>6</sup> See Report of the Technical expert panel on Patent Law Issues (Dec. 2006) [hereinafter Report], available at [http://www.patentoffice.nic.in/ipr/patent/mashelkar\\_committee\\_report.doc](http://www.patentoffice.nic.in/ipr/patent/mashelkar_committee_report.doc).

examination. The government made this deft move to prevent any further stalling of the passage of the Indian Patent Act by the Left Parties. Parliament finally passed the Bill in the third week of March as the Patent (Amendment) Act, 2005.<sup>7</sup>

Under this backdrop, the Indian government, Ministry of Commerce and Industry, and Department of Industrial Policy and Promotion established the Technical Expert Group (the Expert Group) on patent law issues headed by Dr. RA Mashelkar.<sup>8</sup>

The government assigned the Expert Group with the task of examining whether the enactment of two proposed changes to India's patent law would be consistent with India's obligations under the TRIPS Agreement. The government gave the Expert Group two issues to examine:

- (a) whether it would be compatible with TRIPS to limit the grant of patents for pharmaceutical substance to *new chemical entities* or to *new medical entities* involving one or more inventive steps; and,
- (b) whether it would be compatible with TRIPS to *exclude micro-organisms* from patenting.<sup>9</sup>

In December 2006, the Expert Group submitted its report to the government and opined that 1) limiting the grant of patents for pharmaceutical substance to only new chemical entities was not compliant with TRIPS<sup>10</sup>, and 2) excluding micro-organisms from patent protection would be violate TRIPS.<sup>11</sup>

A group of critics and stakeholders severely criticized the Expert Group's recommendations by alleging that the group had based its recommendations on irrational or highly contestable assumptions without sufficient evidence in the report to support its

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<sup>7</sup> See Basheer, *supra* note 2.

<sup>8</sup> See Press Release, Government of India Press Information Bureau, Kamal Nath Constitutes Technical Expert Group on Patent Law Issues (Apr. 6, 2005) available at [http://commerce.nic.in/Apr05\\_release.htm](http://commerce.nic.in/Apr05_release.htm). The 5-member Technical Expert Group on patent law issues was constituted by Mr. Kamal Nath, Union Minister for Commerce & Industry, Govt. of India in Apr. 2005.

<sup>9</sup> See *id.* (emphasis in original); also O.M. No. 12/14/2005-IPR-III, Apr. 5, 2005 of Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion (conveying the terms of reference to the Technical Expert Group technical expert panel on patent law issues.) (on file with author).

<sup>10</sup> See Report, *supra* note 6.

<sup>11</sup> *Id.*

interpretation. For instance, according to the Secretary General of Indian Pharmaceutical Alliance, D.G. Shah, "as the title suggests, the reference to the group was on 'patent law,' but there is hardly any evidence in the report to support its interpretation. Most parts of the report are devoted to narrating the positions of various interest groups, but very little is devoted to what made the Technical Group take the view that to limit patentability to NCEs is not compatible with the TRIPS Agreement."<sup>12</sup> K.M. Gopakumar of CENTAD, an NGO that deals with international trade policies, was more critical in his response. He stated, "[t]he terms of reference clearly mention that the task was to find whether it would be TRIPS compatible to limit the grant of patent for a pharmaceutical substance to a new chemical entity or to a new medical entity involving one or more inventive steps. However, the committee does not answer this question and also cites so-called national interest to make its recommendation."<sup>13</sup>

The report later attracted huge controversy when many found that the Expert Group took its conclusion verbatim from an article authored by Shamnad Basheer for the UK's Intellectual Property Institute.<sup>14</sup> Basheer's article was submitted to the Mashelkar Committee during its consultation process. However, in an annexure to the report, the Expert Group not only included submissions of the work of Shamnad Basheer, but also all other submissions made during the consultation process.<sup>15</sup> The Expert Group later withdrew its report because of "technical inaccuracy and plagiarism". The allegation of plagiarism further reinforced the public health activists' claim that the Mashelkar Committee toed the line of multinational pharmaceutical industry by recommending that India needed to strengthen the patent law further than it did in 2005 to meet its obligations under the TRIPS Agreement.<sup>16</sup>

However, in the midst of this controversy, the main issue regarding the legality of limiting these grants and excluding eligibility was completely lost. Unfortunately, the debate

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<sup>12</sup> Joe C Mathew, *Mashelkar's View on Wider Patentability Flayed*, REDIFF NEWS, Jan. 16, 2007, <http://in.rediff.com/money/2007/jan/16patent.htm>.

<sup>13</sup> *Id.*

<sup>14</sup> Shamnad Basheer, *Limiting the Patentability of Pharmaceutical Inventions and Micro-organism: A TRIP Compatibility Review*, Intellectual Property Institute (2005), available at [http://www.altlawforum.org/ADVOCACY\\_CAMPAIGNS/mashelkar/IPI%20Report%20on%20India%20Patent%20Act%202006.pdf](http://www.altlawforum.org/ADVOCACY_CAMPAIGNS/mashelkar/IPI%20Report%20on%20India%20Patent%20Act%202006.pdf).

<sup>15</sup> See Report, *supra* note 6.

<sup>16</sup> Manoj Mitta, *Mashelkar Takes Back Report After Plagiarism Row*, THE TIMES OF INDIA, Feb. 22, 2007, available at <http://timesofindia.indiatimes.com/articleshow/1653926.cms>.

on the issue was very superficial and did not delve into the details of the legal nuances in the provisions of the TRIPS Agreement. In addition to criticizing the Mashelkar' Committee Report, some activists even questioned the academic integrity of Shamnad Basheer. Many alleged that since Interpat funded the UK's Intellectual Property Institute, Basheer's article did not reflect any independent judgment, but merely reiterated Interpat's industry position.<sup>17</sup>

In the current context, the Expert Group's report has not been well received by some of the stakeholders. Serious doubts have been raised about Basheer's work on purely academic grounds. More importantly, the key issue regarding the legal evidence to support the Expert Group Report's recommendations has been drowned out by the plagiarism controversy. In this context of negative polemic, this paper attempts to reexamine the issue from a purely legal perspective, and evaluate the proposed exclusions in terms of India's obligations under the TRIPS Agreement.

This article is divided into three parts. Part one provides a general overview of the fundamentals of patent systems, including the nature and purpose of patent rights, and the requirements for patentability. This discussion reveals that *per se* exclusions from patentability based solely on the subject matter of the invention are generally incompatible with patent eligibility analyses. Part two discusses the legal obligations of India under the TRIPS Agreement with respect to eligibility for patent protection. This section interprets these provisions as would a WTO Dispute Settlement Panel or the Appellate Body. This section also discusses how India's patent law would violate the TRIPS Agreement if Parliament makes the proposed amendments. This section also examines why the various exceptions in the TRIPS Agreement would not shelter India's proposed amendments from a TRIPS violation. Part three discusses India's national interest, specifically the options that the flexibilities in the TRIPS Agreement provide to India on a national level. The final part also examines the needs of the local pharmaceutical industry with respect to its standing and reputation in the WTO as a safe trading partner. This article concludes that India cannot accept the proposed exclusions without derogating its international obligations under the TRIPS Agreement and that the Expert Group's recommendations were legally in line with India's obligation under the TRIPS Agreement.

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<sup>17</sup> C. Park & A. Prabhala, *Patent Wrong*, TIMES OF INDIA, Feb. 12, 2007, available at <http://timesofindia.indiatimes.com/articleshow/1593525.cms>.

## I. INTRODUCTION TO PATENT SYSTEM CONCEPTS

A basic understanding of patent systems reveals that *per se* exclusions of patentability based strictly on the invention's subject matter are usually contrary to the fundamental principles and motivations of patent protection.<sup>18</sup> Patent systems encourage innovation by making the development of inventions into new products and services commercially feasible.<sup>19</sup> Ultimately, patent systems benefit society and consumers by delivering new products and services based on technological innovation.<sup>20</sup> Patents facilitate the commercialization process by enabling innovators to appropriate from their investments by preventing, for a limited period, the unauthorized copying of the patented invention by competitors.<sup>21</sup> By doing so, the innovator can secure a commercially viable return on his or her investments in developing the invention into a new product or service.<sup>22</sup> Moreover, patent systems require clear and complete disclosures of the inventions in the text of the published patents.<sup>23</sup> Therefore, patent systems encourage the diffusion of knowledge for the benefit of society unlike an alternative system dependent on trade secrets.<sup>24</sup>

The proposed amendments to India's patent law exclude certain categories of subject matter from eligibility for patent protection. Consequently, excluding *per se* certain categories of subject matter from eligibility for patent protection, as the amendments to India's patent law propose, would (1) reduce the incentives for innovation with respect to that subject matter; (2) reduce the availability of new products and services connected with that

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<sup>18</sup> See e.g., 35 U.S.C. § 101 (the United States Supreme Court has repeatedly and consistently stated that there are only three categories of subject matter for which one may not obtain patent protection: (1) laws of nature; (2) natural phenomena; and (3) abstract ideas).

<sup>19</sup> Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property Rights and Development Policy* [hereinafter CIPR], available at [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfullfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf).

<sup>20</sup> David Encaoua, Dominique Gullec & Catalina Martinez, *Patent systems for encouraging innovation: Lessons from economic analysis* (Feb. 2005), available at <http://eurequa.univ-paris1.fr/membres/encaoua/pdf/The%20ECONOMICS%20OF%20PATENTS%20june%202005.pdf>.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> See e.g., 35 U.S.C. § 112.

<sup>24</sup> Gaurav Wahie, *Evaluating Trade Secrets Under The IPR Paradigm: The Hypothesis Of Trade Secrets As A Right Analysed In The Pure Hohfeldian Sense*, available at <http://www.legalservicesindia.com/articles/tradesecrets.htm>.

subject matter; and (3) limit the diffusion of knowledge of new discoveries. As detailed below, while Article 27 of the TRIPS Agreement provides discretion to WTO Members to exclude a small set of subject matter from patentability, India's proposed exclusions do not fall into this set.<sup>25</sup>

#### *A. Overview of common standards for patentability*

Patent systems impose a number of conditions on those wishing to obtain a patent for an invention. These conditions ensure that the government awards a patent only when justified, and that the rights provided under the patent correspond with the contribution made by the inventor. Most patent systems use three standards to determine if the government should patent an invention: 1) novelty of the invention, 2) inventive steps and, 3) industrial application.<sup>26</sup> The TRIPS Agreement also reflects these standards.<sup>27</sup> However, TRIPS does not define what an "invention" is, but only specifies the requirements that an invention should meet in order to be patentable.<sup>28</sup> This ambiguity leaves Members considerable freedom to determine what an invention is. In addition, Members may also exclude from patentability any substance that exists in nature as being a mere discovery and not an invention.

Apart from the above three standards, there are other two requirements that should be met for the inventions to be patentable: eligibility and adequate disclosure.

#### *1. Novelty*

Under the novelty standard, the invention must not be identically disclosed in the "prior art" (*i.e.*, the entirety of publicly accessible knowledge existing before the inventor

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<sup>25</sup> See TRIPS Agreement, *supra* note 1, art. 27. (providing that subject to the provisions of para. 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 and subject to para 4 of art. 65, para 8 of art. 70 and para.3 of this art., patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced).

<sup>26</sup> See Justine Pila, *Bound Futures: Patent Law and Modern Biotechnology*, 9(2) B.U.J. Sci. & Tech. Law 326, 378 (2003).

<sup>27</sup> See TRIPS Agreement, *supra* note 1, art. 27.1.

<sup>28</sup> *Id.*

filed the patent application).<sup>29</sup> This requirement generally means that the information must not have been available to the public prior to the original application date (the priority date).<sup>30</sup> Under most systems, information contained in publicly accessible forms (*e.g.*, printed publications, patents, information disseminated without restriction and accessible through routine effort) is included in the prior art.<sup>31</sup> TRIPS Article 27.1 grants WTO Members the authority to require a showing of novelty as a condition of granting a patent.<sup>32</sup>

Since a Member grants a patent when an inventor discloses something new, then if literature available to the public discloses the invention, the applicant (the “inventor”) can disclose nothing new in return for the grant. In that case, the inventor is not entitled to a patent. In addition, if the Member has already granted the inventor a patent, he or she may revoke the patent.<sup>33</sup> The disclosure may have taken place within the jurisdiction or elsewhere in the world.<sup>34</sup> Due to the nature of invention, the discovery of things already existing in nature, (*e.g.*, a new plant or mineral) is not an invention.

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<sup>29</sup> See, *e.g.*, Convention on the Grant of European Patents art. 54 (2), Oct. 5, 1973, 1065 U.N.T.S. 255 [hereinafter EPC], (providing that the prior art shall include “everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.”).

<sup>30</sup> European Patent Office (EPO) case law holds that the theoretical possibility of having access to information renders it available to the public (case T 444/88), whatever the means by which the invention was made accessible, and— in the case of prior public use —irrespective of whether particular reasons exist for analyzing the product (cases G 1/92). The United States requires complete disclosure in a single publication to destroy novelty, despite the fact that a skilled person may have been able to derive the invention without effort from a combination of publications. (EDTR: In re preceding sentence: Is this actually the law? I vaguely recall reading recent case law to the contrary. ) In addition, under U.S. law, oral disclosure of an invention outside the United States does not destroy novelty. This relative concept of novelty has allowed the patenting in the USA of knowledge and materials used by indigenous communities abroad. See, *e.g.*, Carlos Correa, THE QUAKER UNITED NATIONS OFFICE (QUNO), GENEVA, *Traditional Knowledge And Intellectual Property: Issues And Options Surrounding The Protection Of Traditional Knowledge* (2001), available at <http://www.iucn.org/themes/pbia/themes/trade/training/TK%20and%20Intellectual%20Property.pdf>.

<sup>31</sup> See *e.g.*, 35 U.S.C. § 102.

<sup>32</sup> See TRIPS Agreement, *supra* note 1, art. 27.1.

<sup>33</sup> See *e.g.*, 35 U.S.C. § 102(b).

<sup>34</sup> See 35 U.S.C. § 102(a).



## 2. *Inventive step*

This standard measures the degree of “inventiveness” of the invention relative to the prior art.<sup>35</sup> An invention must involve an inventive step—meaning that the invention must not have been obvious from the prior art to a person of ordinary skill in that particular field of technology at the time the inventor filed the patent application.<sup>36</sup> An invention that is “novel” can still lack an inventive step, and therefore the Member will deny the patent.<sup>37</sup> In other words, the invention must not merely be something new; it must represent a development over prior art.<sup>38</sup>

Inventive step, like novelty, must be measured at the time the inventor files the patent application, rather than after the inventor files the application and has gained additional perspective and knowledge.<sup>39</sup> The latter improperly employs hindsight to assess the merits of the invention.<sup>40</sup> TRIPS Article 27.1 grants WTO Members the authority to require a showing of inventive step or non-obviousness as a condition of granting a patent.

In Europe and in many other countries this requirement is generally described as an “inventive step,” in the United States lawmakers define the requirement as “non-

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<sup>35</sup> See 35 U.S.C. § 103 (specifies that a patent may not be obtained if it contains only obvious differences from prior art).

<sup>36</sup> See 35 U.S.C. § 103(a). The obviousness inquiry is highly fact specific and not susceptible to per se rules. For a patent to be non-obvious it must display “ingenuity beyond the compass” of a person of ordinary skill in the art.

<sup>37</sup> See TRIPS Agreement, *supra* note 1, art. 27.1 (provides that “... 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....” Thus, even if the applicant can demonstrate patentable subject matter, utility and novelty, the patent will not issue if the invention is trivial. In order to determine if an invention is trivial it is necessary to see if there was motivation in the prior art to do what the inventor has done. If the prior art does not explicitly, and with identity of elements, teach the invention, the patent applicant may still be thwarted if there are a number of references that, when combined, would produce the claimed invention.

<sup>38</sup> European Patent Office (EPO) jurisprudence distinguishes “inventive step” from technical progress. Therefore, technical progress comparisons with marketed products support for this requirement being satisfied are not sufficient. An inventor must demonstrate the presence of an inventive step with regard to the closest state of the art. See UNCTAD, PATENTS: SUBJECT MATTER AND PATENTABILITY REQUIREMENTS, 360 (2004) [hereinafter UNCTAD], available at [http://www.iprsonline.org/unctadictsd/docs/RB2.5\\_Patents\\_2.5.1\\_update.pdf](http://www.iprsonline.org/unctadictsd/docs/RB2.5_Patents_2.5.1_update.pdf).

<sup>39</sup> See UNCTAD *supra* note 38 at 360.

<sup>40</sup> *Id.*

obviousness”.<sup>41</sup>

### 3. *Industrial applicability*

The invention must be capable of being used in any kind of industry (including agriculture). Industry, in this sense, is any physical activity of a technical character.<sup>42</sup>

Members considerably differ in their treatment of industrial applicability. In the U.S., lawmakers apply the concept of “utility”.<sup>43</sup> Hence, an inventor can patent certain developments that do not lead to an industrial product in the U.S.. An invention only needs to be operable and capable of satisfying some function of benefit to humanity (i.e., useful).<sup>44</sup> This concept is broader than the industrial applicability required in Europe and other countries.<sup>45</sup> The U.S. rule permits the patentability of purely experimental inventions that cannot be made or used in an industry, or that do not produce a so-called technical effect.<sup>46</sup> These less stringent requirements are illustrated by the fact that the U.S. government grants a large number of patents on methods of doing business, and research tools, such as expression sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).<sup>47</sup> Surgical techniques and diagnostic procedures could arguably fail this requirement, but can be specifically excluded from patentability under Article 27.3 (a).<sup>48</sup>

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<sup>41</sup> See TRIPS Agreement, *supra* note 1, art. 27.1, n.5 (specifically permits a Member to consider “inventive step” synonymous with “non-obvious”).

<sup>42</sup> The technical character of an invention is a basic requirement of patentability. See TRIPS Agreement, *supra* note 1, art. 27.1 (“... patents shall be available ... in all fields of *technology* ...” (emphasis added)). Also See Guidelines for Examination in the European Patent Office [hereinafter EPO Guidelines] at Pt. C, Ch. IV, § 5.1 (June 2005), (provides that “...[i]ndustry’ should be understood in its broad sense as including any physical activity of ‘technical character’ i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts ...”), available at [http://www.european-patent.org/legal/gui\\_lines/pdf\\_2005/](http://www.european-patent.org/legal/gui_lines/pdf_2005/).

<sup>43</sup> See TRIPS Agreement, *supra* note 1, art. 27.1, n.5 (specifically permits a Member to consider “capable of industrial application” synonymous with “useful”).

<sup>44</sup> DONALD S. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW 2:50 (1992).

<sup>45</sup> See UNCTAD, *supra* note 38 at 361.

<sup>46</sup> It should be noted that “technical effect” has no official definition. The doctrine has its origins in German patent law. See GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCE INDUSTRIES: A TWENTIETH CENTURY HISTORY 81 (2003).

<sup>47</sup> The guidelines for examining utility were changed in the U.S. in 2001, possibly leading to the exclusion from patentability of some of these matters. See USPTO Utility Examination Guidelines 66 Fed. Reg. 1092 (Jan. 5, 2001).

<sup>48</sup> See UNCTAD, *supra* note 38 at 361.

#### 4. Eligibility

The standards mentioned above identify which scientific and technological advances are “inventions” and, further, which “inventions” can be patented. In addition to using a general requirement for industrial applicability of the invention,<sup>49</sup> some countries precisely identify categories of subject matter that are not inventions, and which types of inventions the government will not patent.<sup>50</sup> Other countries define eligibility in broad terms, without *per se* exclusions.<sup>51</sup> The industrial application requirement of most countries is inclusive of virtually any type of commercial or industrial enterprise.<sup>52</sup> TRIPS Agreement limits the authority of WTO Members to define patent eligibility, and requires a showing of industrial application or usefulness as a condition of granting a patent.<sup>53</sup> Paragraphs two and three of TRIPS Article 27 provide *discretion* to Members to exclude certain limited categories of subject matter from patentability, none of which encompass the exclusions in the proposed amendment to Indian patent law.<sup>54</sup> . Pharmaceutical products and micro-organisms do not figure on this list of TRIPS’ designated subject matter exclusions. We will take up this important matter again in Section II.

#### 5. Adequate disclosure

This standard requires an applicant to provide technical information about the invention such that others are able to reproduce the full scope of what the inventor claims in

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<sup>49</sup> See, e.g., EPC, *supra* note 29, art. 57 (“[A]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.”).

<sup>50</sup> See, e.g., EPC, *supra* note 29, art. 52(2) (identifies discrete categories of subject matter that are not inventions); *i. d.* art. 52(4) (categorizes the inventions that are deemed to not possess an industrial application and are thus ineligible to be patented); *i. Id.* art. 53 (lists the inventions that are not to be patented regardless of whether they meet the standards of industrial applicability, novelty and inventive step).

<sup>51</sup> See 35 U.S.C. § 101 (The U.S. patent system defines “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” to be eligible to be patented.) The U.S. Supreme Court found that Congress chose the expansive language of 35 U.S.C. § 101 so as to include “anything under the sun that is made by man.” *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980). The U.S. patent law nevertheless excludes from eligibility subject matter that is not a process, machine, article of manufacture or composition of matter. See *Id.* It also holds as unpatentable inventions that are not “useful” – meaning, inventions that are abstract ideas or not distinguishable from laws of nature. See *Id.*

<sup>52</sup> See UNCTAD, *supra* note 38 at 361.

<sup>53</sup> See TRIPS Agreement, *supra* note 1, art. 27.

<sup>54</sup> See UNCTAD, *supra* note 38 at 356.

his or her patent application.<sup>55</sup> TRIPS Article 29.1 generally refers to the authority WTO Members have to impose disclosure requirements.<sup>56</sup>

These standards vary slightly in how different countries apply them.<sup>57</sup> In principle, however, nearly every country incorporates some form of these five functional requirements in their patent system.<sup>58</sup>

As noted above, the primary international authority defining the requirements of patent systems is the TRIPS Agreement. The other major treatises that influence international patent law standards are the Paris Convention for the Protection of Industrial Property (Paris Convention),<sup>59</sup> the Patent Cooperation Treaty (PCT),<sup>60</sup> and the Patent Law Treaty (PLT).<sup>61</sup> International patent law standards have evolved to reflect and apply these five basic standards in varying ways, and to address needs of inventors to secure patents in different countries.<sup>62</sup>

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<sup>55</sup> See 35 U.S.C. § 112 (specifies that once the first four patentability requirements are satisfied the applicant still must describe the invention with enough particularity such that those skilled in the art will be able to make, use and understand the invention that was made by the inventor).

<sup>56</sup> See TRIPS Agreement, *supra* note 1, art. 29.1 (providing that “[m]embers shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.”).

<sup>57</sup> See UNCTAD, *supra* note 38 at 362.

<sup>58</sup> *Id.*

<sup>59</sup> Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as revised at Stockholm on July 14, 1967) [hereinafter Paris Convention].

<sup>60</sup> Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 [hereinafter PCT].

<sup>61</sup> Patent Law Treaty, June 1, 2000, 39 I.L.M. 1047 [hereinafter PLT].

<sup>62</sup> Patent rights are territorial in nature. This means that patents confer rights over acts done within the territory of the country that issued the patent, with certain very limited exceptions (e.g., the right to prevent importation of a product made by using a patented process outside of the territory of the country). Moreover, patents issued by the countries of the Paris Union (including India) must be “independent” of patents issued in other countries, even where they are part of the same patent family. See Paris Convention, *supra* note 59, art. 4bis. The territorial nature of patents means that companies must pursue patents in each country in which they desire to have rights. To facilitate the procurement of patents in multiple jurisdictions, treaties provide a “right of priority” (See Paris Convention, *supra* note 59, art. 4), and facilitate the formalities associated with filing patent applications (e.g., PCT, *supra* note 60 and PLT, *supra* note 61).

*B. Nature of the Patent Rights*

Patents provide what are termed “exclusive rights.”<sup>63</sup> The principled basis for these exclusive rights has been established in international law, and defined more explicitly in the TRIPS Agreement.<sup>64</sup> International human rights’ norms also recognize the importance of protecting intellectual property rights, as evidenced by the Universal Declaration of Human Rights (UDHR), and the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>65</sup>

Article 28.1(a) of the TRIPS Agreement specifies that if a WTO Member issues a patent, this patent must confer on their owners the exclusive right to prevent the unauthorized making, using, selling, offering for sale, or importing of the patented invention.<sup>66</sup> In addition, Article 28.1(b) of the TRIPS Agreement requires that patents confer the right to prevent the unauthorized use of a product that results from a patented process invention, including importation of that product into the country where the process patent originated.<sup>67</sup>

Patents enable their owners to prevent the unauthorized use of the patented technology through legal interventions.<sup>68</sup> Specifically, patent owners can prevent unauthorized use of the patented technology by commencing an action in a court for

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<sup>63</sup> See CIPR, *supra* note 19 at 12.

<sup>64</sup> See TRIPS Agreement, *supra* note 1, arts.3, 4, 7 & 8.

<sup>65</sup> Universal Declaration of Human Rights, G.A. Res. 217A, at 71, U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc A/810, art. 27(2) (Dec. 12, 1948) [hereinafter UDHR] (providing that “[e]veryone has the right to the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author.”); International Covenant on Economic, Social and Cultural Rights, G.A. res. 2200A (XXI), 21 U.N.GAOR Supp. (No. 16) at 49, U.N. Doc. A/6316 art. 15.1(c) (1966), 993 U.N.T.S. 3, *entered into force* Jan. 3, 1976 [hereinafter ICESCR] (providing that “[t]he State Parties to the present Covenant recognize the right of everyone: . . . [t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”). At the same time, these agreements recognize the right to enjoy and share in scientific advancement and its benefits. See UDHR art. 27(1); ICESCR art. 15.1(b).

<sup>66</sup> See TRIPS Agreement, *supra* note 1, art. 28.1(a) (provides that “where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product.”).

<sup>67</sup> See TRIPS Agreement, *supra* note 1, art. 28.1(b) (provides that “where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.”).

<sup>68</sup> See CIPR, *supra* note 19 at 12.

infringement.<sup>69</sup> If infringement is proven, the court generally issues an injunction prohibiting the continued unauthorized use of the patented invention.<sup>70</sup> Ultimately, this ability to enjoin the unauthorized conduct gives effect to the patent right.<sup>71</sup> Part III of the TRIPS Agreement requires WTO Members to make available adequate and effective judicial and administrative procedures for enforcing intellectual property rights, including several procedures that are of particular importance to a viable patent right.<sup>72</sup>

Patent rights are generally defined by the claims of the patent. The patent claims reflect what is “novel,” what involves an inventive step and, what is industrially applicable.<sup>73</sup> The patent claims thus reflect and limit the scope of the patent rights.<sup>74</sup> The claims must avoid encompassing subject matter that is disclosed in or obvious from the prior art, or they will be subject to rejection or invalidity.<sup>75</sup> A valid patent claim can neither encompass what is literally described in or obvious from the prior art, nor it can include subject matter that is beyond what the inventor has described and enabled in the patent disclosure.<sup>76</sup>

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<sup>69</sup> Eugene R. Quinin, Jr., *Patent Infringement Damages*, The Source for Intellectual Property News & Information, available at [http://www.ipwatchdog.com/patent\\_damages.html](http://www.ipwatchdog.com/patent_damages.html).

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

<sup>71</sup> *Id.*

<sup>72</sup> See TRIPS Agreement, *supra* note 1, arts.34, 44, 50 (providing, respectively, the right to shift the burden of proving non-infringement to one suspected of infringing a process patent, permanent injunctive relief, and preliminary injunctive relief).

<sup>73</sup> Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, The South Centre (2000), available at <http://www.southcentre.org/publications/publichealth/publichealth.pdf>.

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> Most countries permit relief for patent infringement in situations where the infringing product does not literally meet each requirement of the claim, but is otherwise an insubstantial variation of the patented invention. In the United States, this relief is referred to as infringement through the doctrine of equivalents, and is applied as an equitable remedy. See *Warner-Jenkinson Co. v. Hilton-Davis Chem. Co.*, 520 U.S. 17 (1997); *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

## II. The ‘Proposed Exclusions’ Violates India’s Obligations under the TRIPS Agreement

The subject of the Technical Experts Group implicates the minimum patent protection standards established by the TRIPS Agreement.<sup>77</sup> An understanding of the compatibility (or lack thereof, in this situation) of these proposed measures with the TRIPS Agreement requires an evaluation of the text of the proposed measure in light of the text of the relevant provisions of the TRIPS Agreement. The current section is devoted to filling out this analytical framework.

The Dispute Settlement Panels and the Appellate Body has interpreted the TRIPS agreement pursuant to Articles 31 and 32 of the Vienna Convention on the Laws of Treaties.<sup>78</sup> This article will therefore follow the same approach.

Article 31(1) of the Vienna Convention on the Law of Treaties provides:

A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.<sup>79</sup>

To determine the ordinary meaning of a particular word, panels and the Appellate Body have often relied on dictionary definitions.<sup>80</sup> Moreover, pursuant to Article 31(3) of the Vienna Convention, WTO panels have also taken into account “subsequent practice in the application of the treaty” by its Members when interpreting the TRIPS Agreement.<sup>81</sup> Thus,

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<sup>77</sup> The WTO provides the institutional and legal foundation for the multilateral trading system that came into being on January 1, 1995. (See DING LU, GUANZHONG JAMES WEN, HUIZHONG ZHOU, CHINA’S ECONOMIC GLOBALISATION THROUGH THE WTO 176 (Ashgate Publishing Ltd.) (2003).

<sup>78</sup> Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331 [hereinafter Vienna Convention].

<sup>79</sup> See, e.g., Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, ¶ 7.13, WT/DS114/R (Mar. 17, 2000) (adopted Apr. 7, 2000); Panel Report, *United States – Section 110(5) of the United States Copyright Act*, ¶ 6.43, WT/DS160/R (June 15, 2000) (adopted July 27, 2000).

<sup>80</sup> See, e.g., Panel Report, *United States – Section 110(5) of the United States Copyright Act*, ¶¶ 6.108-1.110, WT/DS160/R; Appellate Body Report, *Canada – Term of Patent Protection*, ¶ 65, WT/DS170/AB/R (Sept. 18, 2000) (adopted Oct. 12, 2000); Appellate Body Report, *United States – Section 211 Omnibus Appropriations Act of 1998*, ¶¶ 137, 172, 187, 215, WT/DS176/AB/R (Jan. 2, 2002) (adopted Feb. 1, 2002).

<sup>81</sup> See, e.g., Panel Report, *United States – Section 110(5) of the United States Copyright Act*, ¶ 6.65, WT/DS160/R (“In our view, state practice as reflected in the national copyright laws of members before and after 1948, 1967, and 1971, as well as of WTO Members before and after the date that the TRIPS Agreement became applicable to them, confirms our conclusion about the minor exceptions doctrine.”).

the practice of WTO Members may also be helpful to an analysis of the meaning of the TRIPS Agreement, and references to such practice are included throughout this article.

Finally, Article 32 of the Vienna Convention allows for supplementary means of interpretation in limited circumstances, and states as follows:

Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31:

- (a) Leaves the meaning ambiguous or obscure; or
- (b) Leads to a result which is manifestly absurd or unreasonable.<sup>82</sup>

Consequently, where helpful, this article refers to the negotiating history of the TRIPS Agreement.

The significant questions raised by India's proposed amendments relative to the TRIPS Agreement are addressed below.

#### *A. General framework of the TRIPS Agreement*

The Indian Parliament entered the TRIPS Agreement into force on January 1, 1995, after the conclusion of the Uruguay Round of negotiations and the creation of the WTO.<sup>83</sup> The TRIPS Agreement builds on intellectual property standards found in several pre-existing multilateral agreements including the Paris Convention;<sup>84</sup> the Berne Convention for the Protection of Literary and Artistic Works;<sup>85</sup> the International Convention for the Protection of

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<sup>82</sup> See Vienna Convention, *supra* note 78, art. 32.

<sup>83</sup> India became member of WTO on Jan. 1, 1995, See WTO member countries, available at [http://www.wto.org/English/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/English/thewto_e/whatis_e/tif_e/org6_e.htm).

<sup>84</sup> See Paris Convention, *supra* note 59. The current obligations of the Paris Convention are defined by the Stockholm Act of the Convention, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305.

<sup>85</sup> See Paris Convention, *supra* note 59. (as applied by the Paris Act of the Convention of July 24, 1971).



Performers, Producers of Phonograms and Broadcasting Organizations<sup>86</sup> (“Rome Convention”); and, the Treaty on Intellectual Property in Respect of Integrated Circuits.<sup>87</sup>

The primary objective of the TRIPS Agreement is to provide “effective and adequate protection of intellectual property rights”<sup>88</sup> and thereby, “contribute to the promotion of technological innovation and to the transfer and dissemination of technology.”<sup>89</sup> The TRIPS Agreement accomplishes this objective by establishing, in Part II, minimum substantive standards for the availability, scope, and use of intellectual property rights,<sup>90</sup> which the national law of each WTO Member must adopt. In Part III, the TRIPS Agreement establishes, minimum standards for the enforcement of intellectual property rights. In Part V, TRIPS provides dispute settlement procedures to resolve disagreements among WTO Members over compliance with TRIPS obligations.<sup>91</sup> Part VI provides certain transitional arrangements, including provisions allowing developing countries (*i.e.*, Article 65) and underdeveloped countries (*i.e.*, Article 66) additional time to implement certain TRIPS obligations relative to developed countries.<sup>92</sup>

Part I of the TRIPS Agreement sets forth general provisions and basic principles that apply throughout the other parts of the Agreement, including the cornerstone requirements of national treatment and most-favoured nation (MFN) treatment.<sup>93</sup> Within Part I, Article

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<sup>86</sup> See International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, Oct. 26, 1961, 496 U.N.T.S. 43.

<sup>87</sup> Treaty on Intellectual Property in Respect of Integrated Circuits (adopted in Washington on May 26, 1989), available at [http://www.wipo.int/export/sites/www/treaties/en/ip/washington/pdf/trtdocs\\_wo011.pdf](http://www.wipo.int/export/sites/www/treaties/en/ip/washington/pdf/trtdocs_wo011.pdf).

<sup>88</sup> See TRIPS Agreement, *supra* note 1, Preamble.

<sup>89</sup> See TRIPS Agreement, *supra* note 1, art. 7.

<sup>90</sup> See TRIPS Agreement, *supra* note 1, part I & II. The TRIPS Agreement attempts to balance the longer term objective of providing incentives for future inventions and creations, and the shorter term objective of allowing people to use existing inventions and creations. The Agreement requires Members to protect copyrights, trademarks, geographical indications, industrial designs, patents, integrated circuits, and data (including trade secrets and certain test data).

<sup>91</sup> See TRIPS Agreement, *supra* note 1, part V.

<sup>92</sup> With respect to underdeveloped countries, the Doha Declaration on the TRIPS Agreement and Public Health extended the transition period, such that they “will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016 . . .” See Doha WTO Ministerial 2001: Ministerial Declaration, WT/MIN (01)/DEC/2 (Nov. 20, 2001) [hereinafter Doha Declaration].

<sup>93</sup> See TRIPS Agreement, *supra* note 1, part I.

1.1 requires Members to implement the standards in TRIPS into their national laws. It also provides Members with the *discretion* to provide standards of protection that *exceed* the minimum standards specified in the Agreement.<sup>94</sup> As such, the TRIPS Agreement, similar to the Paris Convention, is a “minimum standards” agreement.<sup>95</sup>

Article 1.1 also provides that Members have discretion in how they implement the obligations of the TRIPS Agreement.<sup>96</sup> Specifically, it provides that “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”<sup>97</sup> This provision is designed to ensure that the standards of the Agreement are implemented in a manner that is compatible and effective within the national legal system of each WTO Member.<sup>98</sup> However, this provision does not authorize a WTO Member to disregard an obligation, or refuse to confer rights in a manner that meets the substantive standards of the TRIPS Agreement.<sup>99</sup>

The obligation to implement the TRIPS standards into national law ensures that intellectual property owners can actually obtain the legal rights specified in the Agreement.<sup>100</sup>

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<sup>94</sup> See TRIPS Agreement, *supra* note 1, art. 1.1 (“Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”).

<sup>95</sup> See Paris Convention, *supra* note 59, art. 19 (“It is understood that the countries of the Union reserve the right to make separately between themselves special agreements for the protection of industrial property, in so far as these agreements do not contravene the provisions of this Convention.”).

<sup>96</sup> See TRIPS Agreement, *supra* note 1, art. 1.1.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> WTO Members are free to decide how they will choose to give effect to the TRIPS obligations (in terms of their national legal systems and practices), as long as they comply with the provisions of the Agreement. The manner, by which such implementation is done, however, is subject to review through the WTO dispute settlement process. See e.g., Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 66, WT/DS50/AB/R (Dec. 19, 1997) (*adopted Jan. 16, 1998*) (“But, as in the case cited above before the Permanent Court of International Justice, in this case, the Panel was not interpreting Indian law ‘as such;’ rather, the Panel was examining Indian law solely for the purpose of determining whether India had met its obligations under the TRIPS Agreement. To say that the Panel should have done otherwise would be to say that only India can assess whether Indian law is consistent with India’s obligations under the WTO Agreement. This, clearly, cannot be so.”).

<sup>100</sup> See TRIPS Agreement, *supra* note 1, Preamble (“Recognizing, to this end, the need for new rules and disciplines concerning: ... the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights; ...”).

For example, if the national government does not grant an innovator a patent, that innovator cannot realize any of the rights specified in the Agreement. In this respect, the TRIPS Agreement's recognition that intellectual property rights have the attributes of personal property, and that the rights being addressed in the Agreement are "private" rights rather than rights between governments is very important.<sup>101</sup> The TRIPS Agreement also requires Members to grant rights in a timely fashion. Article 62.2 requires that procedures that the government establishes to grant a patent must not take so long as to result in an unwarranted curtailment of the period of protection (*e.g.*, at least 20 years from the filing date of the application resulting in the patent).<sup>102</sup>

Finally, through Article 2.1, the TRIPS agreement incorporates the substantive provisions of the Paris Convention and imposes these provisions as WTO obligations on all WTO Members.<sup>103</sup>

*B. The 'proposed exclusion' violate Article 27 of the TRIPS Agreement*

Part II, Section 5 of the TRIPS Agreement, sets forth certain requirements for applicants and the minimum substantive standards of protection that Members must provide to patent holders.<sup>104</sup> For purposes of analyzing the two proposed amendments to India's patent law, the critical TRIPS provision is Article 27, which defines (a) the subject matter that is *eligible* for patent protection, and (b) the requirements for *patentability* of such eligible subject matter.<sup>105</sup>

*1. The scope of patent eligibility under Article 27.1 is undeniably broad*

The proposal to exclude micro-organisms and certain pharmaceutical substances from the scope of subject matter eligible for patent protection is inconsistent with the broad scope

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<sup>101</sup> See TRIPS Agreement, *supra* note 1, Preamble ("Recognizing that intellectual property rights are private rights.").

<sup>102</sup> See TRIPS Agreement, *supra* note 1, art. 62.2 (provides that "[w]here the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.").

<sup>103</sup> See TRIPS Agreement, *supra* note 1, art. 2.1 ("In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).").

<sup>104</sup> See TRIPS Agreement, *supra* note 1, part II.

<sup>105</sup> See TRIPS Agreement, *supra* note 1, art. 27.

of eligibility TRIPS Article 27.1 requires.<sup>106</sup> The TRIPS Agreement requires WTO Members to grant patents on “any inventions” “in all fields of technology” subject only to specifically enumerated exceptions.<sup>107</sup> Indeed, Article 27.1 of the TRIPS Agreement addressed one of the main omissions of the Paris Convention—namely, a definition of what inventions must be eligible for patents.<sup>108</sup> Therefore, this new standard creates additional obligations that were not part of the Paris Convention—standards that apply to all WTO Members.

As the first sentence of Article 27.1 of the TRIPS Agreement provides: “[s]ubject 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.”<sup>109</sup>

Article 27.1 also requires Members to make patents available for both products and processes.<sup>110</sup> Thus, the ordinary meaning of Article 27.1 clearly indicates that unless an

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<sup>106</sup> See TRIPS Agreement, *supra* note 1, art. 27.1 (provides that “[s]ubject 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.”).

<sup>107</sup> See TRIPS Agreement, *supra* note 1, art. 27.1 (provides that “... [s]ubject 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.”).

<sup>108</sup> See Paris Convention, *supra* note 59. Under the Paris Convention, countries were free to exclude areas from patentability, as well as to provide special rules for certain types of inventions. In addition, they had freedom to define the requirements for patentability. TRIPS Agreement has changed this situation. Article 27.1 includes a general obligation of patentability addressing in this manner one of the major concerns raised by the pharmaceutical industry with respect to prevailing regimes prior to TRIPS Agreement. See TRIPS Agreement, *supra* note 1, art 27.1. In addition, all discrimination between sectors (as well as on the basis of the place of invention) has been banned. See UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (Cambridge University Press) (2005). This Resource Book has been prepared under the responsibility of the UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development.

<sup>109</sup> Article 10 of the WIPO Patent Law Treaty draft of 1991 was the basis for Article 27.1 of the TRIPS Agreement. See UNCTAD, *supra* note 38 at 354. The draft required that patents be available for inventions in all fields of technology, subject to the usual patentability requirements: novelty, industrial applicability, and possession of an inventive step. *Id.*

<sup>110</sup> Process patents can confer rights not only over the use of the process in question, but also over products obtained directly by the process. See TRIPS Agreement, *supra* note 1, art. 28.1(b) (“where the subject matter of a patent is a process, [a patent shall confer on its owner the exclusive rights] to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process”) see also Paris Convention, *supra* note 59, art. 5*quater* (“When a product is imported into a country of the Union where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, with regard to the imported product, that are accorded to him by the

invention is *specifically authorized to be excluded* from patent eligibility pursuant to Articles 27.2 or 27.3, a WTO Member may not refuse to grant it a patent, provided the invention is new, involves an inventive step and is industrially applicable.<sup>111</sup> The use of the phrases “*any inventions*” and “*all fields of technology*” make this point in the clearest of terms.<sup>112</sup>

In other words, the law of each WTO Member may not in a *per se* manner exclude inventions from *eligibility* unless they fall within classes of inventions that are specifically authorized to be excluded pursuant to Articles 27.2 and 27.3. For inventions not within these excluded categories, a WTO Member may deny the grant of a patent only if the invention fails to meet the *patentability* (as opposed to patent *eligibility*) requirements of the Agreement. Thus, a WTO Member must apply the evaluation of whether an invention is new, involves an inventive step, and is capable of industrial application in the same manner and with the same legal effect for pharmaceuticals or micro-organisms as the member does for all other classes of technology.

## 2. Article 27.1 prohibits “discrimination” as to “the field of technology” of the invention

Paragraph 1 of Article 27 also establishes the principle of non-discrimination based on the field of technology. It specifies that WTO Members may not refuse patents for inventions in a particular technological field simply because the invention falls within that technological field (subject to several exceptions that are inapplicable to India and the proposed amendments).<sup>113</sup> Specifically, the second sentence of Article 27.1 provides, in pertinent part that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology...”<sup>114</sup> The prohibition against discrimination,

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legislation of the country of importation, on the basis of the process patent, with respect to products manufactured in that country.”).

<sup>111</sup> See TRIPS Agreement, *supra* note 1, art. 27.1.

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

<sup>113</sup> See TRIPS Agreement, *supra* note 1, art. 27.2 (provides that “[m]embers 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, ... “); see also TRIPS Agreement, *supra* note 1, art. 27.3 (provides that “[m]embers 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. ...”).

<sup>114</sup> See TRIPS Agreement, *supra* note 1, art. 27.1.

among other things, means that a WTO member may not deny a patent for inventions in one technology sector that meet the requirements of the national law for novelty, inventive step and industrial application (as they are used to measure patentability for inventions in other technological fields).

The WTO Dispute Settlement Panel in *Canada—Patent Protection of Pharmaceutical Products* has shed some light on the meaning of the anti-discrimination provision of Article 27.1. In that decision, the panel addressed the meaning of the phrase “without discrimination” as it is used in Article 27.1.<sup>115</sup> The panel began by distinguishing the two different types of discrimination: *de jure* and *de facto* discrimination.<sup>116</sup> *De jure* discrimination refers to discrimination as a matter of law, based on explicit differences in treatment evident from the terms of a law or regulation itself.<sup>117</sup> *De facto* discrimination arises from discrimination as a matter of fact that is not evident from reviewing the explicit terms of the law alone.<sup>118</sup> Thus, discrimination based on field of technology that is evident in the law itself, is considered *de jure* discrimination.

In considering the word “discrimination,” the panel cautioned that

... [g]iven the very broad range of issues that might be involved in defining the word ‘discrimination’ in Article 27.1 of the TRIPS Agreement, ... it would be better to defer attempting to define that term at the outset, but instead to determine which issues were raised by the record before the Panel, and to define the concept of discrimination to the extent necessary to resolve those issues.<sup>119</sup>

The panel found no evidence of *de jure* discrimination on the face of the law at issue in the dispute, but then it considered whether the effect of the law could nevertheless be

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<sup>115</sup> Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) (adopted Apr. 7, 2000).

<sup>116</sup> *Id.* at ¶ 7.94.

<sup>117</sup> *Id.*

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

<sup>119</sup> *Id.* at ¶ 7.98.

considered *de facto* discrimination pursuant to TRIPS Article 27.1.<sup>120</sup> The panel explained as follows:

[D]e facto discrimination is a general term describing the legal conclusion that an ostensibly neutral measure transgresses a non-discrimination norm because its actual effect is to impose *differentially disadvantageous consequences on certain parties*, and because those differential effects are found to be wrong or unjustifiable. Two main issues figure in the application of that general concept in most legal systems. One is the question of de facto discriminatory effect - whether the actual effect of the measure is to impose *differentially disadvantageous consequences on certain parties*. The other, related to the justification for the disadvantageous effects, is the issue of purpose—not an inquiry into the subjective purposes of the officials responsible for the measure, but an inquiry into the objective characteristics of the measure from which one can infer the existence or non-existence of discriminatory objectives.<sup>121</sup>

The panel found that the complaining party, the EC, had not presented sufficient evidence to demonstrate that the challenged provision had either a “discriminatory effect limited to patented pharmaceutical products” or a “discriminatory purpose.”<sup>122</sup> Therefore, the panel did not find *de facto* discrimination under Article 27.1.<sup>123</sup>

By contrast, because the proposed amendments to India’s patent law, which would impact the fields of technology eligible for patent protection, would appear on the face of the law itself, the analysis by a panel in this situation would be one of *de jure*, rather than *de facto*, discrimination. In this case, the discrimination is directed at pharmaceutical substances and micro-organisms.

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<sup>120</sup> *Id.* at ¶¶ 7.99-100.

<sup>121</sup> *Id.* at ¶ 7.101. (*emphasis added*).

<sup>122</sup> *Id.* at ¶¶ 7.102-04.

<sup>123</sup> *Id.* at ¶ 7.105.

3. *Article 27 authorizes specific exclusions from patent eligibility that do not exempt the subject matter excluded in India's 'proposed exclusion'*

Pursuant to TRIPS Article 27.1, the government must grant patents to all inventions in all fields of technology if they are otherwise patentable, unless they are specifically excluded by Articles 27.2 or 27.3.<sup>124</sup> The only inventions that the government may exclude from patent eligibility are inventions falling within the specific categories the TRIPS Agreement defines in Articles 27.2 and 27.3.

Of importance is the fact that none of the exclusions specified in Articles 27.2 and 27.3 are required exclusions. Thus, consistent with TRIPS Article 1.1, WTO Members may elect to not exclude from patentability the classes of inventions specified by these provisions.

As detailed herein, India cannot justify the exclusions for patent eligibility proposed in its patent law by virtue of paragraphs two or three of TRIPS Article 27.

Since there is no indication that India would accompany its proposed exclusions from patent eligibility with a ban on the sale of the inventions at issue, the exclusions simply could not fit within the scope of the *ordre public* and morality exception of TRIPS Article 27.2.

In particular, a requirement that a chemical compound constitutes a “new chemical entity,” in addition to being novel, involving an inventive step, and being industrially applicable, would be inconsistent with the obligations of Article 27. The phrase “new chemical entity” does not appear anywhere in Article 27.2 or 27.3. In fact, TRIPS Article 39.3 reveals that the TRIPS drafters were fully aware of the concept of “new chemical entity,” but consciously chose not to use this phrase anywhere when advising as to what types of inventions the government could deem ineligible for patenting.

Similarly, the clear terms of Article 27.3 explain that Members do not have the discretion to exclude “micro-organisms” from patentability (unless they were to fit within a different exception). This section states, “Members may also exclude from patentability ... plants and *animals other than micro-organisms*.”

While the TRIPS Agreement does not use or define the term “*new medical entity (NME)*”, the term “*new chemical entity (NCE)*” appears for the first time in International Intellectual Property agreements in the TRIPS Agreement of 1994, under Article 39.3:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize *new chemical entities*, the submission of undisclosed test or other data, the

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<sup>124</sup> See TRIPS Agreement, *supra* note 1, art. 27.1.



origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.<sup>125</sup>

According to the United States' Food and Drug Administration (FDA), a new molecular entity (NME) or new chemical entity (NCE) means a drug that contains no active moiety and has been approved by FDA under section 505(b) of the Federal Food, Drug, and Cosmetic Act.<sup>126</sup>

Other than Articles 27.2 and 27.3, no other provisions of the TRIPS Agreement permit India to exclude certain inventions from eligibility for patent protection on a *per se* basis. The "exceptions to rights conferred" in TRIPS Article 30 relate only to "the exclusive rights conferred by a patent," and not to the issues of patentability covered by TRIPS Article 27. Article 30 provides that "[m]embers may provide limited exceptions to the exclusive rights conferred by a patent, provided that such *exceptions do not unreasonably conflict with a normal exploitation* of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."<sup>127</sup> Nor do the provisions in TRIPS Article 31, related to "Other Use without Authorization of the Right Holder," involve the issue of *eligibility* for patent protection.<sup>128</sup> Similarly, the General Council approved a pending amendment to the TRIPS Agreement, on December 6, 2005, which does not relate to patent eligibility, but instead to the use of patent rights.<sup>129</sup> Finally, the "principles" listed in TRIPS Article 8.1, related to protecting public health and nutrition and promoting the public interest, allow only for measures that "are consistent with the provisions of this Agreement", including Article 27.<sup>130</sup>

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<sup>125</sup> See TRIPS Agreement, *supra* note 1, art. 39.3.

<sup>126</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (1938).

<sup>127</sup> See TRIPS Agreement, *supra* note 1, art. 30.

<sup>128</sup> See TRIPS Agreement, *supra* note 1, art. 31 ("other use" refers to use other than that allowed under Article 30).

<sup>129</sup> See Amendment of the TRIPS Agreement, WT/L/641 (Decision of Dec. 6, 2005), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm).

<sup>130</sup> See TRIPS Agreement, *supra* note 1, arts. 8.1 & 27.

*a. Article 27.2 authorizes exclusions from patent eligibility only if necessary to protect ordre public and morality*

TRIPS Article 27.2 permits WTO Members to exclude inventions from patent eligibility where “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.” In other words, if a WTO Member prohibits the commercial exploitation of a particular invention because doing so “is necessary” to protect *ordre public* or morality, he or she *may* also elect to refuse to grant patents on such inventions, even though those inventions might be novel, involve an inventive step and be capable of industrial application.

Thus, a WTO Member may not elect to *permit* general sale, supply or use of the invention, but then refuse to grant patents on that product under the justification of Article 27.2. Instead, Article 27.2 authorizes a WTO Member to exclude inventions from patent eligibility in order to prevent commercial exploitation, which would endanger *ordre public*<sup>131</sup> or morality<sup>132</sup>. By contrast, the negotiating history reveals that negotiators presented text (Brussels Draft) to the Ministerial Conference in Brussels in December 1990 that included a broader exception, which allowed parties to exclude from patentability inventions that “the prevention within their territory of the *publication* or any exploitation of which is necessary to protect public morality or order . . .”<sup>133</sup> The fact that the negotiators chose to delete the reference to “publication” and focus instead solely on commercial exploitation confirms the understanding that Article 27.2 requires consideration of the effect of commercial exploitation of an invention on morality and *ordre public*, not the effect of the granting and publishing of a patent itself.

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<sup>131</sup> A more accurate meaning for this term would be “public policy,” which concerns the public law principles from which one cannot derogate without endangering the institutions of a given society. See DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 222 (Sweet & Maxwell) (2d ed. 2003).

<sup>132</sup> This concept is different from the concept of *ordre public* as it depends mostly on the culture of a given country or region. It appears to correspond to the French concept of “*bonnes mœurs*”. See GERVAIS, *supra* note 131, at 223.

<sup>133</sup> *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Negotiations*, TNC/W/35 Rev.1 (Dec. 3, 1990), reprinted in GERVAIS, *supra* note 131, at 218.

With respect to the proposed amendments to India's patent law, to the extent that the subject matter that these amendments would exclude from patentability (*i.e.*, micro-organisms and certain pharmaceuticals) could continue to be marketed in India after passage of the amendment (which appears to be the case), such an amendment could not be justified by TRIPS Article 27.2.

The *objective* nature of the phrase “*is necessary* to protect . . .” in TRIPS Article 27.2 is important to note. This objective character is highlighted by relevant context, via comparison of this provision with the formulation of the security exception in TRIPS Article 73(b). TRIPS Article 73(b) provides that “[n]othing in this Agreement shall be construed: . . . to prevent a Member from taking any action which *it considers necessary* for the protection of its essential security interests.”<sup>134</sup> Thus, the difference between “*is necessary*” in Article 27.2, on the one hand, and “which [a Member] *considers necessary*” in Article 73(b), on the other, emphasizes that a panel must consider what is and is not necessary for morality and *ordre public* from an objective perspective.

Article 27.2 also clarifies that a Member may not exclude an invention from patent eligibility simply because a national law regulates or prohibits its exploitation, but that instead the Member must objectively justify the exclusion based on necessity to protect morality or *ordre public*. This is consistent with Article 4*quater* of the Paris Convention, which provides that,

[t]he grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law.<sup>135</sup>

Dispute Settlement Panels and the WTO Appellate Body have provided guidance on the meaning of exceptions similar to TRIPS Article 27.2 that appear in Article XX of the General Agreement on Tariffs and Trade 1994 (“GATT 1994”).<sup>136</sup> A panel that analyzes

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<sup>134</sup> See TRIPS Agreement, *supra* note 1, art. 73(b) (emphasis added).

<sup>135</sup> See Paris Convention, *supra* note 59, art. 4*quater*.

<sup>136</sup> The General Agreement on Tariffs and Trade, 1867 U.N.T.S. 190, 33 I.L.M. 1125, 1154 (1994) [hereinafter GATT], available at [http://www.wto.org/english/docs\\_e/legal\\_e/gatt47\\_e.pdf](http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf).

TRIPS Article 27.2 would likely refer to these earlier decisions for guidance. Specifically, Article XX provides a general exception to GATT obligations, allowing Members to adopt or enforce measures that, among other reasons, are “(a) necessary to protect public morals,” or “(b) necessary to protect human, animal or plant life or health.” The panel in *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, following the practice of previous panels, found that a Member invoking Article XX (b) must prove:

- (a) That the policy in respect of the measures for which Article XX is invoked falls within the range of policies designed to protect human life or health; and,
- (b) The inconsistent measures for which the exception is invoked are necessary to fulfill the policy objective.<sup>137</sup>

Panels have found a measure is “necessary” in cases where “there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which [the Member] could reasonably be expected to employ to achieve its health policy objective.”<sup>138</sup> Determining whether or not an alternative measure is reasonably available “must be assessed in light of the economic and administrative realities facing the Member concerned.”<sup>139</sup> Thus, if a class of inventions may present a threat to public health, and appropriate regulatory measures are reasonably available to resolve those concerns, a prohibition on commercial exploitation would not be “necessary” under Article 27.2.

Since no indication exists that India is contemplating a ban on commercial exploitation of pharmaceutical substances or micro-organisms to coincide with the proposed exclusions on patentability, no need exists for a panel to even consider the justification for such exclusions. In other words, if India does not prevent within its territory “the commercial exploitation” of this subject matter, then its exclusions simply would not fall within the scope of Article 27.2.

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<sup>137</sup> Panel Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 8.169, WT/DS135/R (Sep. 18, 2000) (adopted as modified by the Appellate Body Apr. 5, 2001).

<sup>138</sup> *Id.* at ¶ 8.172 (quoting GATT Panel Report, *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, ¶ 75 BISD 37S/200.).

<sup>139</sup> *Id.* at ¶ 8.208.

*b. Article 27.3(a) authorizes exclusions for a limited set of method inventions*

In TRIPS Article 27.3, the exception for certain “methods”<sup>140</sup> does not cover India’s proposed exclusions from patent eligibility for “micro-organisms” and certain pharmaceutical substances. Specifically, Article 27.3(a) provides that WTO Members may exclude certain *methods* from patent eligibility, notwithstanding whether those methods meet the requirements of being novel, involving an inventive step, and being industrially applicable. Article 27.3(a) provides that “Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical *methods* for the treatment of humans or animals.”<sup>141</sup>

Initially, one should recognize the importance in the fact that the scope of Article 27.3(a) is limited to inventions which are diagnostic, or therapeutic and surgical *methods*, where the ordinary meaning of “method” is “[a] mode of procedure; a (defined or systematic) way of doing a thing.”<sup>142</sup> Such *method* must be for the “treatment of humans or animals” before it is subject to the Article 27.3(a) exception.<sup>143</sup> By contrast, *compounds*, *compositions* and *machines* that are used in diagnosis, therapy, or surgery involving humans or animals are *not* excluded under the authority of Article 27.3(a), as these inventions are not “method” inventions.<sup>144</sup>

As noted above, while Article 27.3(a) allows WTO Members to exclude methods used for the surgical, diagnostic or therapeutic treatment of humans or animals from patent

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<sup>140</sup> See TRIPS Agreement, *supra* note 1, art. 27.3 (provides that “[m]embers 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, ....”) (emphasis added).

<sup>141</sup> TRIPS Agreement, *supra* note 1, art. 27.3(a) (emphasis added).

<sup>142</sup> 1 THE NEW SHORTER OXFORD ENGLISH DICTIONARY 1752 (Lesley Brown ed., 1993).

<sup>143</sup> Historically, many countries excluded therapeutic, surgical and diagnostic methods from patentability prior to entry into force of the TRIPS Agreement, and thus they advocated for the inclusion of the exception now included in TRIPS Agreement. See TRIPS Agreement, *supra* note 1, art. 27.3(a). The EPC, for example, excluded such methods based on the reasoning that there was no industrial applicability (or utility) for such creations. See EPC, *supra* note 29, art. 52(4). In general, most of these exclusions focused on methods that were actually practiced on the human or animal body, thus reflecting the reference to surgical, diagnostic or therapeutic methods.

<sup>144</sup> See, e.g., EPC, *supra* note 29, art. 52(4) (clarifying that exclusion for methods does not apply to “substances or compositions”, but strictly to the method itself). Article 52(4) states as follows: “Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”

protection it does not *oblige* its Members to do so. A Member could, for example, limit the exclusions to only some (or none) of the classes of methods Article 27.3(a) references.

Of importance to remember is that Article 27.1 of the TRIPS Agreement obliges WTO Members to grant patents for both products and processes.<sup>145</sup> Therefore, new uses of known products are eligible for patent protection. In particular, the narrow scope of the Article 27.3(a) exception does not exclude methods for utilizing a newly discovered property of a compound or composition for use in preparation of a medicament. A Member must grant a patent to these methods, provided the method is novel, involves an inventive step and is industrially applicable.<sup>146</sup> The exception in Article 27.3(a) does not cover such a method because it is not strictly a “diagnostic, therapeutic, [or] surgical” method for treatment. This interpretation is consistent with the practice of most countries that follow the EPC model. The EPC model uses “Swiss claims” through which the innovative development of using a previously known therapeutic compound or agent can be patented (*e.g.*, through protection in the form of use of the compound to prepare a medicament for the treatment of a particular disease).<sup>147</sup> In such cases, the claim is drafted as a method of using the compound or agent *to produce a medicine* for a new treatment modality, rather than a method for *direct* treatment of humans or animals.

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<sup>145</sup> See TRIPS Agreement, *supra* note 1, art. 27.1 (provides that “[s]ubject to the provisions of paragraphs 2 and 3, *patents shall be available* for any inventions, whether *products or processes*, in all fields of technology...”) (emphasis added).

<sup>146</sup> See TRIPS Agreement, *supra* note 1, art. 27.1 (provides that “... 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*...””) (emphasis added).

<sup>147</sup> See EPO Guidelines, *supra* note 42 at Pt. C, Ch. IV, § 4.2 (“A claim in the form ‘Use of a substance or composition X for the manufacture of a medicament for therapeutic application Z’ is allowable for either a first or ‘subsequent’ (second or further) such application (‘second medical use’-type of claim or ‘Swiss-type’ claim), if this application is new and inventive . . .”). In 1984, the Enlarged Board of Appeal (“EBA”) of the European Patent Organization received seven cases dealing with the issue of patentability of a so-called “second medical indication.” See Case G 5/83 at ¶¶ 7, 9, O.J. 3/1985, 64. The EBA acknowledged the established practice in the Swiss patent system of permitting “second (and subsequent) medical indications by means of a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified (new) therapeutic application.” *Id.* at ¶ 19. The EBA further reasoned that, in its interpretation of the concept of the “state of the art” as defined in Article 54 of the EPC, there was no intention to exclude second (and subsequent) medical indications from patentability “other than by a purpose-limited product claim.” *Id.* at ¶ 22.

*c. Article 27.3(b) authorizes exclusions for a sub-set of plants, animals, plant varieties, and biological processes*

Article 27.3(b) effectively addresses three distinct issues. First, it confirms that WTO Members *must* grant patents on micro-organisms and other living organisms other than plants or animals, provided the organism is novel, involves an inventive step, and is industrially applicable.<sup>148</sup> Second, it authorizes, but does not require, WTO Members to exclude from patent eligibility plant and animal inventions, regardless of whether those inventions are novel, involve an inventive step, and are industrially applicable.<sup>149</sup> Third, it imposes an obligation on certain WTO Members (*i.e.*, those that exclude plants from patent eligibility) to grant *sui generis* protection for plant varieties.<sup>150</sup>

As expressed in the TRIPS Agreement, Article 27.3(b) provides that Members may exclude from patentability:

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>151</sup>

To clarify what *is* and *is not* excluded by this provision, one must consider the ordinary meaning of three key terms: 1) plants, 2) animals, and 3) micro-organisms. As clearly illustrated in the text of Article 27.3(b), Members cannot exclude micro-organisms from patent eligibility. The ordinary meaning of micro-organism is “an organism too small to be seen except with the aid of a microscope, as a bacterium or virus.”<sup>152</sup> Historically, within this group, scientists have classified organisms such as self-propagating individual cell lines of animal (*e.g.*, human), plant, fungi, algae, protozoa, bacteria, or viral origin.<sup>153</sup> The International Patent Classification (IPC) is maintained by the World Intellectual Property

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<sup>148</sup> See TRIPS Agreement, *supra* note 1, art. 27.3(b).

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

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

<sup>151</sup> *Id.* (emphasis added).

<sup>152</sup> 1 THE NEW SHORTER OXFORD ENGLISH DICTIONARY 1766 (Lesley Brown ed., Clarendon Press) (1993).

<sup>153</sup> See J. COOMBS, MACMILLAN DICTIONARY OF BIOTECHNOLOGY 188 (1986) (“microorganism” refers to an organism that can belong to one of five classes or organisms: bacteria, fungi, algae, protozoa or viruses).

Organization (WIPO), and used by the industrial property offices of more than 100 countries, four regional offices, and the International Bureau of WIPO.<sup>154</sup> The IPC provides guidance to a WTO panel as to the meaning of “micro-organisms” as relevant state practice (both before and after the TRIPS Agreement).<sup>155</sup> Specifically, it categorizes micro-organisms under Category C12, and states that “viruses, undifferentiated human, animal or plant cells, protozoa, tissues and unicellular algae are considered as micro-organisms.”<sup>156</sup> Further, the IPC distinguishes micro-organisms as being in an entirely separate classification (C12) from plants (A01H) and animals (A01K), confirming that the WTO panel should consider them as three distinct categories of organisms.<sup>157</sup>

The ordinary meaning of “plant” is a “living organism other than an animal, typically fixed to a substrate, able to subsist wholly on inorganic substances, and moving chiefly by growth”<sup>158</sup> and “a living organism (such as a tree, grass, or fern) that absorbs water and inorganic substances through its roots and makes nutrients in its leaves by photosynthesis.”<sup>159</sup> Finally, the term “animal” refers to a “living organism having sensation and voluntary motion, without rigid cell walls, and dependent on organic substances for food.”<sup>160</sup> In addition, “a living organism which feeds on organic matter, has specialized sense organs and nervous system, and is able to move about and to respond rapidly to stimuli.”<sup>161</sup> Such definitions illustrate that a Member cannot consider a single-celled organism to be a “plant” or an “animal,” and consequently cannot exclude it from patentability without violating the

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<sup>154</sup> The International Patent Classification [hereinafter IPC] is based on the Strasbourg Agreement Concerning the International Patent Classification, which was concluded in 1971 and entered into force in 1975. See About the International Patent Classification, <http://www.wipo.int/classifications/ipc/en/general/>.

<sup>155</sup> The sixth edition of the IPC, which was in force prior to entry into force of the TRIPS Agreement, is available at [http://www.wipo.int/classifications/fulltext/new\\_ipc/ipc6/eindex.htm](http://www.wipo.int/classifications/fulltext/new_ipc/ipc6/eindex.htm).

<sup>156</sup> International Patent Classification, 8<sup>th</sup> Edition, available at <http://www.wipo.int/classifications/ipc/ipc8/?lang=en>.

<sup>157</sup> *Id.* According to the International Patent Classification A01H includes new plants or processes for obtaining them; plant reproduction by tissue culture techniques, A01K includes animal husbandry; care of birds, fishes, insects; fishing; rearing or breeding animals, not otherwise provided for; new breeds of animals and C12 includes biochemistry; beer; spirits; wine; vinegar; microbiology; enzymology; mutation or genetic engineering.

<sup>158</sup> 2 THE NEW SHORTER OXFORD ENGLISH DICTIONARY 2237 (Lesley Brown ed., 1993).

<sup>159</sup> THE OXFORD COMPACT ENGLISH DICTIONARY 864 (2d ed. rev. 2003).

<sup>160</sup> 1 THE NEW SHORTER OXFORD ENGLISH DICTIONARY 80 (Lesley Brown ed., 1993).

<sup>161</sup> THE OXFORD COMPACT ENGLISH DICTIONARY 36 (2d ed. rev. 2003).



TRIPS Agreement. Moreover, single-celled organisms that are microscopic would fall within the definition of micro-organism.

Indeed, the structure of TRIPS Article 27.3(b), within the context of the other paragraphs of Article 27, obligates Members to grant patents on living organisms, *other* than any organism that falls within the scope of the ordinary meaning of the terms plants or animals, including, but not limited to, an obligation to make micro-organisms eligible for patent protection. This obligation stems from two aspects of the text. First, Article 27.3(b) is conditional on the overarching obligations of Article 27.1 to grant patents on *any* invention in *all fields of technology* not explicitly excluded by Articles 27.2 and 27.3, and that is novel, involves an inventive step, and is industrially applicable.<sup>162</sup> Thus, a Member may exclude from patentability only those inventions that are explicitly identified in Article 27.3(b) (*i.e.*, plants and animals). Any other living organism inventions must remain eligible for a patent, including, in particular, micro-organisms, unless they are subject to another exception. Second, the explicit exemption of “micro-organisms” from the authority to exclude plant and animal inventions found in Article 27.3(b) reinforces the fact that all organisms *other* than plants and animals *must* remain eligible for a patent.<sup>163</sup>

This interpretation is confirmed by the negotiating history of the provision. The final text of Article 27.3(b) provides a much more narrow authority to exclude living organism inventions than certain negotiating parties to the Uruguay Round had originally proposed.<sup>164</sup> Notably, in the draft of July 23, 1990, prior to the Brussels draft, a number of developing countries sought a *mandatory* exclusion of all living organisms from patentability (*i.e.*, one that would require all WTO Members to refuse patents on living organisms).<sup>165</sup> Others sought

<sup>162</sup> See TRIPS Agreement, *supra* note 1, art. 27.

<sup>163</sup> As early as 1980, the U.S. Supreme Court held that a live, human-made micro-organism is patentable subject matter under U.S. patent law. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>164</sup> See *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Negotiations*, ¶¶ (b)B, (c)B TNC/W/35 (Rev.1 of 3, Dec. 1990) (emphasis added) reprinted in GÉRAIS, *supra* note 131, at 218. The proposed bracketed text in paragraph 3(b)B would have allowed Members to exclude from patentability “Plants and animals, including microorganisms, and parts thereof and processes for their production. As regarding biotechnology inventions, further limitations should be allowed under national law.” *Id.* Moreover, the proposed bracketed text in paragraph 3(c)B would have allowed parties to exclude from patentability “[c]ertain products and processes for the manufacture of those products, on grounds of public interest, national security, public health or nutrition, including food, chemical and pharmaceutical products and process for the manufacture of pharmaceutical products.” *Id.*

<sup>165</sup> See The Anell Draft, Report to the General Negotiating Group (GNG) on the status of work in the TRIPS Negotiating Group, July 23, 1990 (W/76), reprinted in GÉRAIS, *supra* note 131, at 219.

a more comprehensive and unconditional authority to exclude living organisms (including micro-organisms) from patent eligibility.<sup>166</sup> Ultimately, negotiators did not adopt these proposals for broad exceptions.

Consequently, the negotiating history confirms that lawmakers considered the proposed amendments to India's patent law to exclude micro-organisms as a possibility in the early stages of negotiations of the TRIPS Agreement, but squarely rejected them in the final agreement.

Finally, Article 27.3(b) impacts the broad requirement for patentability of Article 27.1 in several other ways. It provides Members the discretion to exclude from patentability "essentially biological processes for the production of plants or animals *other than the non-biological and microbiological processes*."<sup>167</sup> Thus, the possibility of excluding essentially biological processes does *not* extend to non-biological or microbiological processes.<sup>168</sup> Article 27.3(b) also requires that plant *varieties* be protected by patents, a *sui generis* system, or both. Some Members suggested a *sui generis* system that was a UPOV-type system.<sup>169</sup> WTO Members are not mandated to adopt this precise system of protection, but are free to develop another type of protection for their plant varieties, as long as it is an effective one.

4. *The context, object and purpose, and negotiating history of the TRIPS Agreement confirms that pharmaceutical substances must be eligible for patent protection*

Other provisions of the TRIPS Agreement provide relevant context that reinforces the conclusion that India's proposed amendments would violate the Agreement. Specifically, TRIPS Articles 70.8 and 70.9 provide a system for preserving future patent rights and for

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<sup>166</sup> *Id.*

<sup>167</sup> TRIPS Agreement, *supra* note 1, art. 27.3(b) (emphasis added). Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biological inventions [hereinafter EC Biotech Directive] explains that "[a] process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection." EC Biotech Directive, art. 2. As per the European Patent Office, the concept of "essentially biological process" is also related to the degree of technical intervention made on the biological process. *See* EPO Guidelines, *supra* note 42, at Pt. C, Ch. IV, § 3.4.2.

<sup>168</sup> The EC Biotech Directive defines "microbiological process" as "any process involving or performed upon or resulting in microbiological material." *See* EC Biotech Directive, art. 2.

<sup>169</sup> UPOV is the French abbreviation for the "International Union for the Protection of New Varieties of Plants." It was adopted in Paris in 1961. *See* [www.upov.int](http://www.upov.int).

granting current exclusive marketing rights in pharmaceutical products in certain Members who did not extend patent protection to pharmaceutical products as of the date the TRIPS Agreement went into effect.<sup>170</sup> India was one such country. The so-called “mailbox” and “exclusive marketing rights” provisions would have been unnecessary if Members had the discretion under Article 27.1 to simply exclude pharmaceutical product inventions from patent eligibility. Also important to note is that these transitional measures contain no limitations related to the “significance” of the particular attributes of the pharmaceutical product in question.<sup>171</sup> Thus, if a pharmaceutical product is a particular salt or polymorph of a previously known active ingredient, a Member must grant it protection under Articles 70.8 and 70.9. Logically, that product must be eligible for a patent.

An interpretation of TRIPS Article 27.1 that would authorize *per se* exclusions for certain types of pharmaceutical product inventions would also plainly conflict with what was the accepted outcome of the intellectual property negotiations of the Uruguay Round. When the Uruguay Round of negotiations began, approximately 50 countries did not grant patents on pharmaceutical products.<sup>172</sup> Many bitterly fought over the concession that these countries made to grant pharmaceutical product patents. At the conclusion of negotiations on the TRIPS Agreement, these countries, led by India, advocated for the inclusion of TRIPS Article 65.4, which provided an additional implementation period for certain developing countries to make pharmaceutical products, among other inventions, eligible for patent protection.<sup>173</sup> Dozens of these countries have subsequently implemented pharmaceutical product protection standards without any *per se* exclusions or other conditions.<sup>174</sup> By contrast, WTO Members have granted an extension to underdeveloped countries such that they are not obligated to

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<sup>170</sup> See TRIPS Agreement, *supra* note 1, arts. 70.8 & 70.9.

<sup>171</sup> See TRIPS Agreement, *supra* note 1, art. 70 (specifies that “this Agreement gives rise to obligations in respect of *all subject matter* existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement.”) (emphasis added).

<sup>172</sup> See Memorandum of the International Bureau of WIPO on Exclusions from Patent Protection HL/CM/INF/1, available at [www.wipo.int](http://www.wipo.int). (accessed on Jan. 14, 2008). This Memorandum was elaborated in order to present information on what fields of technology used to be excluded from patent protection under the patent laws of every country in the world.

<sup>173</sup> See TRIPS Agreement, *supra* note 1, art. 65.4 (extending the deadline to Jan. 1, 2005).

<sup>174</sup> E.g., Brazil and India amended their patent laws to start granting patents on medicines in 1996 and 2005, respectively to comply with their international obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights.

implement the patent or undisclosed information sections of the TRIPS Agreement, with respect to pharmaceutical products, until January 1, 2016.<sup>175</sup> India is not considered an underdeveloped country, and thus not subject to this exclusion.

### III. INDIA'S NATIONAL INTEREST AND OPTIONS

India's socio-economic context, where millions are unable to access the public healthcare system, requires that India balance the right of access to affordable medicines with patent rights. The main justifications of the proponents<sup>176</sup> of *proposed exclusion* are that an exclusion would prevent a phenomenon commonly known as 'ever-greening'<sup>177</sup> of pharmaceutical products, and that it would further public health aims by restricting the extent of patentability of pharmaceutical inventions, so as to keep the prices of drugs to pre-1995 levels. They argue that the objective and principles of the TRIPS Agreement mentioned in Articles 7 and 8, in conjunction with Paragraph 4 of Doha Declaration provide sufficient flexibility to enable this objective.<sup>178</sup>

Article 7 states:

The *protection and enforcement* of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to *social and economic welfare*, and to a balance of rights and obligations .<sup>179</sup>

Article 8 states:

1. Members may, in formulating or amending their national laws and regulations, adopt measures necessary to *protect public health and nutrition* and *to promote the public interest in sectors of vital importance to their socio-*

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<sup>175</sup> See Doha Declaration, *supra* note 92, para. 7.

<sup>176</sup> K. M. Gopakumar, *Mashelkar Committee Report: A Critique*, Center for Trade and Development (CENTAD), available at [http://www.centad.org/focus\\_33.asp](http://www.centad.org/focus_33.asp) (accessed on Jan. 14, 2008).

<sup>177</sup> 'Ever-greening' is a term used to refer loosely to inappropriate extensions in the period of patent exclusivity for a pharmaceutical product. See Basheer, *supra* note 14, at 39.

<sup>178</sup> See TRIPS Agreement, *supra* note 1, arts. 7 & 8 and Doha Declaration, *supra* note 92, para 4.

<sup>179</sup> See TRIPS Agreement, *supra* note 1, art. 7 (emphasis added).

*economic and technological development*, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.<sup>180</sup>

Paragraph 4 of Doha Declaration states:

We agree that the TRIPS Agreement does not and *should not prevent members from taking measures to protect public health*. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be *interpreted and implemented* in a manner supportive of WTO members' *right to protect public health* and, in particular, *to promote access to medicines for all*.<sup>181</sup>

While Article 7 and 8 are general provisions that certainly provide flexibility to the member States to frame laws balancing the availability of patent rights with their socio-economic goals, many doubts exist regarding whether these Articles provide the freedom to the member States to interpret the TRIPS Agreement in so wide a manner as to bring about renegotiation of basic balance of TRIPS Agreement.<sup>182</sup>

Moreover, since the R&D capabilities of local industry have not yet reached that critical level where it can engage in discovery or development of new chemical entities, the incentives for sequential pharmaceutical developments are as necessary as or even more necessary than the creation of NCEs or NMEs. At present, the local pharmaceutical industry directs most of the R&D activities towards minor modifications of drugs that foreign countries have developed. Therefore, patent protection for incremental innovation can be of immense value to the industry as it caters to the local requirements of India such as NDDS. NDDS are formulations that are developed specifically suited to the local environmental

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<sup>180</sup> See TRIPS Agreement, *supra* note 1, art. 8 (emphasis added).

<sup>181</sup> See Doha Declaration, *supra* note 92, para. 4 (emphasis added).

<sup>182</sup> See Basheer, *supra* note 14, at 30-34.

conditions. For example, Ranbaxy has licensed its NDDS on ciprofloxacin to Bayer AG, which enabled a patient to take medicine just once a day.<sup>183</sup>

India can tackle the issue of ‘ever-greening’ by not granting secondary patents on the basis of trivial and insignificant changes to the original pharmaceutical product and by ensuring that generic versions of the original drug can be marketed after patent protection has expired. Ensuring that regulatory approval for the original product is retained as a reference product for generic copies can aid the issue of ‘ever-greening’.<sup>184</sup>

Article 27 states that “patents shall be available for any inventions ... provided that they are *new, involve an inventive step and are capable of industrial application*.”<sup>185</sup> Hence, this provision certainly provides some flexibility to the member States to define the patentability criteria in a manner that suit their national interest. However, the word ‘invention’ has to be vested with some basic meaning. At the very least, this word must denote something of “technical” import. If the member States were free to interpret according to their whims and fancy, we could end up with a situation where a member State may argue that it did not need to grant patents at all, since its unique lexicon suggests that nothing ever amounts to an “invention” under Article 27. In short, this freedom of interpretation would render the term “invention” redundant and such a result would derogate the basic tenet of treaty interpretation well-accepted under international law: one cannot read a treaty term in a manner as to render it redundant.

The Indian government has, in fact, utilized this provision and has made wide-ranging provisions in the Patent (Amendment) Act, 2005 to prevent the grant of patents to trivial and insignificant pharmaceutical inventions. For example,

**‘New Invention’:** The Patent (Amendments) Act, 2005 defines the term ‘New Invention’ as

[A]ny 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

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<sup>183</sup> See Padmashree Ghel Sampath, UNITED NATIONS UNIVERSITY-INSTITUTE FOR NEW TECHNOLOGIES (UNU-INTECH), *Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry*, (2005), available at <http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf>.

<sup>184</sup> See Basheer, *supra* note 14, at 40.

<sup>185</sup> See TRIPS Agreement, *supra* note 1, art. 27.1 (emphasis added).

date of filing of a 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>186</sup>

Since the ‘novelty’ standard under the Act is ‘absolute’ and not ‘relative,’ fewer pharmaceutical inventions would clear the ‘novelty’ test.

**‘Inventive step’:** The Patent (Amendments) Act, 2005 makes a critical change to the earlier ‘non-obviousness’ or ‘Inventive step’ test. The definition now reads,

‘inventive step’ means a feature of an invention that involves *technical advance* as compared to the existing knowledge or having *economic significance* or both and that makes the invention not obvious to the person skilled in the art.<sup>187</sup>

Thus, while the basic yardstick, i.e. ‘*not obvious to the person skilled in the art*’ remains the same, the requirement of ‘technical advance’ or have an ‘economic significance’ has made the definition of ‘inventive step’ susceptible to being interpreted in a manner that renders it more onerous to satisfy. Hence, a proper application of this ‘inventive step’ or ‘non-obviousness’ will render non-meritorious pharmaceutical inventions non-patentable.

**The ‘New Use’ Exclusion:** Section 3(d) of the Patent Act, 1970 excluded a “new use for a known substance” from the ambit of ‘invention.’ The 2005 Act has expanded on this exception by providing that “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” would not be patentable.<sup>188</sup> This Act then states (via an explanation to the section) that salts, esters, ethers, polymorphs, metabolites, etc. shall be considered as the same substance unless they “differ significantly in properties with regard to efficacy .”<sup>189</sup>

If the patent office construes the term of ‘efficacy’ strictly, this term could be very useful in curbing new grants of patents for incremental pharmaceutical innovations. On the other hand, if the patent office interprets the term ‘efficacy’ liberally by the patent office, a

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<sup>186</sup> See The Patent (Amendment) Act § 2(1)(l), No. 15 of 2005; India Code (2005).

<sup>187</sup> See *Id.* at § 2(1)(ja), No. 15 of 2005; India Code (2005).

<sup>188</sup> See Basheer *supra* note 2, at 23.

<sup>189</sup> *Id.*

good number of formulations may qualify as new substances, upon showing an increased efficacy.

**Patent eligibility and subject matter exclusions:** Apart from ‘new use’ exclusion, the Patent Act has several patent eligibility or subject matter exclusions such as the ‘*method of treatment*’ exception<sup>190</sup> and the ‘*product of nature*’ exclusion. The patent office could use these exclusions to limit the range of patentable pharmaceutical inventions.

Thus, the provisions are in place in the statute books and an effective application of the above patentability criteria in Patent Offices and the Courts would ensure that trivial and insignificant changes do not merit patent protection.

As explained earlier, if a Member denies a patent to a micro-organism on the ground of *ordre public* or *immorality*, one has to also forego the commercialization of the said micro-organism. Prohibiting all forms of ‘micro-organisms’ is not feasible; especially when biotechnology offers immense opportunity and potential. Therefore, India may not provide for a *per se* exclusion of ‘micro-organism’ from patentability, and instead use the flexibilities the TRIPS agreement provides in order to limit the scope of protection for micro-organisms. The various options available to India in this regard are presented below:

**Definition of ‘Micro-organism’:** TRIPS does not define the ‘micro-organism.’ The dictionary/scientific definition of ‘micro-organism’ is not conclusive, since there are several such definitions, embodying different approaches.<sup>191</sup> Hence, India should use the ambiguity associated with defining the term ‘micro-organism’ to its advantage and define ‘micro-organism’ in precise terms that suit its socio-economic interests.

**The ‘discovery exception’:** Although the ‘discovery exception is not explicitly mentioned in TRIPS, most patent regime exclude mere ‘discoveries’ or ‘law of nature’ from patentability.<sup>192</sup> Apparently, India’s position is also that the discoveries are not patentable. However, explicit use of the word ‘discovery,’ ‘mere discovery,’ and ‘invention’ in Section

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<sup>190</sup> See The Patent (Amendment) Act § 3(i), No. 15 of 2005; India Code (2005). (excludes from patentability, ‘any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings....’).

<sup>191</sup> See Basheer, *supra* note 14, at 52.

<sup>192</sup> See The Patent (Amendment) Act § 3(c), No. 15 of 2005; India Code (2005) (excludes the “discovery of any living thing or non-living substances occurring in nature.”).



three shows the intention of the legislature for these words to have different meaning and their patentability to differ case by case. Hence, one may remove the ambiguity, if any, in the word ‘discovery’ and strengthen the ‘discovery’ exception by stipulating that mere isolation or purification of a micro-organism by known procedures will not render it patentable. Rather, only truly ‘invented’ micro-organisms, such as genetically modified ones, would be patentable.

**‘Patentability’ criteria:** Article 27 gives some leeway to the members’ States to define ‘patentability’ criteria in a manner that suits their specific national interests. They could specifically use this flexibility to apply to patent applications claiming micro-organisms. This use could be in the form of examination guidelines, which the patent office would apply strictly to ensure that it only grants truly meritorious inventions patent protection. Using a guideline-based approach rather than substantive law is a better approach because a guideline-based approach has the advantage of flexibility and ease of amendment in light of changing technologies and policy considerations.<sup>193</sup>

The above discussion demonstrates that without accepting the ‘proposed exclusions’ and amending the Patents (Amendment) Act, 2005, India can still effectively address its public health concerns and the needs and aspiration of the pharmaceutical industry by utilizing the freedom that the TRIPS Agreement and Doha Declaration leaves for the members States. This use of TRIPS and the Doha Declaration would not only establish India’s standing in the WTO, but would also enhance its reputation as a safe trading partner.

## CONCLUSION

The foregoing discussion clearly establishes that the Technical Expert Group rightly recommended that (a) limiting the grant of patents for pharmaceutical substances to new chemical entities or to new medical entities, and (b) excluding micro-organisms from patent eligibility will be in contravention with India’s obligation under the TRIPS Agreement. The recommendation of the Expert Group is supported by the following aspects of the TRIPS Agreement:

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<sup>193</sup> See *Basheer*, *supra* note 14, at 60.

In pursuance of Article 27 of the TRIPS Agreement, WTO Members must make patents “available for *any invention* whether products or processes, *in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application”.<sup>194</sup> These exclusions violate the clear and broad mandate of TRIPS Article 27.1 by denying patents for inventions that satisfy the other criteria for patentability.

By denying patent protection solely on the grounds that the invention is a micro-organism or certain type of pharmaceutical substance, India’s amendments would also violate the requirement in TRIPS Article 27.1 that “patents shall be available . . . without discrimination as to ...the field of technology.”

The specific discretion provided to Members in TRIPS Article 27.2 and 27.3 with respect to subject matter that may be excluded from patentability does not cover India’s proposed exclusions. . Indeed, TRIPS Article 27.3 specifically provides that micro-organisms, in particular, may *not* be excluded from patentability. No other provision of the TRIPS Agreement justifies the inconsistency of India’s proposed amendments with TRIPS Article 27.

The above discussion sufficiently clarifies that the recommendations of the Technical Expert Group on patent issues headed by Dr. RA Mashelkar were perfectly in consonance with the India’s international obligation under the TRIPS Agreement. The problem was that the Expert Group did not provide any legal evidence in support of its recommendations. India must reject the ‘proposed exclusions’ in order to avoid a successful challenge by WTO Members under Article 27 of the TRIPS Agreement. No one can demonstrate that the TRIPS Agreement allows Members to refuse to grant patents on pharmaceutical inventions or micro-organisms that are new, involve an inventive step, and are capable of industrial application.

Pharmaceutical products, in particular, are chemical compounds. Unless a Member prohibits *any* commercialization of a particular chemical compound for reasons, within the meaning of TRIPS Article 27.2, of *ordre public* or morality, or to avoid serious prejudice to the environment, that compound, as well as a pharmaceutical product incorporating that chemical compound, must be *eligible* to be patented.<sup>195</sup> The reason is because chemical

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<sup>194</sup> See TRIPS Agreement, *supra* note 1, art. 27.1 (emphasis added).

<sup>195</sup> See Basheer, *supra* note 14, at 58,59.

compounds do not fall within any of the categories of subject matter that a Member may exclude under Articles 27.2 and 27.3. Nor do micro-organisms fall within those categories.

Looking beyond its international legal obligations, India must also provide for patentability of micro-organisms and pharmaceutical substances in order to create the proper incentives to foster the future growth of its research-based pharmaceutical and biotechnology industries. In this manner, rejection of the 'proposed exclusions' will be an important step toward continuing the advancement not only of the economic welfare of the Indian population through growing businesses, but also of the development of micro-organisms and pharmaceutical substances that contribute to national and global health.

Besides, the TRIPS Agreement, as discussed above, leaves significant freedom for members States to determine the 'patentability criteria' as per their socio-economic and welfare needs. Applying a low threshold may facilitate the patenting of incremental developments, which predominate in domestic industry in developing countries like India. However, this tactic would unduly restrain competition and increase litigation costs in key areas such as pharmaceuticals where extensive patenting of minor developments has become normal practice.<sup>196</sup> Given the market disruption and costs low or non-inventive development patents may cause, India as the World Bank suggested, may opt for high standards of inventiveness thereby preventing routine discoveries from being patented.<sup>197</sup> In fact, the Patent (Amendment) Act, 2005 has headed in this direction by introducing more rigorous requirements for 'inventive step' and the expansive 'new use' exclusion.<sup>198</sup> These higher standards could certainly help in curbing new grants of patents for incremental pharmaceutical innovations.

India should make every effort to prevent the grant of frivolous patents and 'ever-greening.' The Indian Patent Office should formulate and implement detailed Guidelines for examining the patent applications in the pharmaceutical sector in order to eliminate the remotest possibility of granting frivolous patents. Similarly, India must formulate strict standards and detailed Guidelines for examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility. Alternatively,

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<sup>196</sup> See, e.g., CARLOS CORREA, TRENDS IN DRUG PATENTING, CASE STUDIES (2001).

<sup>197</sup> World Bank, *Global Economic Prospects and the Developing Countries* 143 (2001).

<sup>198</sup> See Basheer *supra* note 2, at 34.

India could adopt related forms of IP in order to promote and reward minor innovations, such as utility models.<sup>199</sup>

The discussions in this article clearly establish that the Doha Declaration and flexible provisions of the TRIPS Agreement give us adequate opportunity to frame law to protect our national interest without amending the Patent Act, which would be contrary to the provisions of the TRIPS Agreement.

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<sup>199</sup> Utility models protect the functional aspect of models and designs, generally in the mechanical field. See Uma Suthersanen, *Utility Models and Innovation in Developing Countries*, UNCTAD-ICTSD Project on IPRs and Sustainable Development, (2006) available at [http://www.unctad.org/en/docs/iteipc20066\\_en.pdf](http://www.unctad.org/en/docs/iteipc20066_en.pdf). Though novelty and inventiveness are required, the criteria for conferring protection are generally less strict than for patents. *Id.* The term of protection also is shorter. *Id.* Utility models are concerned with the way in which a particular configuration of an article works, unlike industrial designs, which are only concerned with its ornamental aspect. *Id.*