

## What's 'New'? - Isn't it Obvious?

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A new approach to Section 3(d) of Indian patent law using common principles of statutory construction suggests that Section 3(d) should be viewed as a proviso to the general definition of an invention in the Indian Patents Act. As such Section 3(d) should be strictly construed. The term 'mere discovery' should encompass only natural things merely observed and not non-natural substances that result from human endeavour. The term 'efficacy' used as an exception to the proviso should be broadly construed to include more than 'therapeutic efficacy'. Construed in this traditional manner Section 3(d) may well comply with TRIPS.

**Keywords:** Therapeutic efficacy, novel, patentable subject matter, newness, novelty, inventive step

In 2005, in an effort to become a Member of the World Trade Organization, Indian Parliament adopted significant changes to its patent statutes.<sup>1</sup> While seeking to harmonize its patent laws with developing international norms, India refined its unique approach<sup>2</sup> by drawing a statutory boundary as a distinction between 'invention'<sup>3</sup> and what is 'mere discovery'<sup>2</sup> by classifying certain subjects beyond the reach of patentability.<sup>4</sup>

What is 'new' or 'novel' is still a subject to debate. In plain English, something 'new' is anything 'not existing before,' anything 'made, introduced, or discovered recently or now for the first time.'<sup>5</sup> What is 'new' or 'novel' in the language of intellectual property, and what is 'mere discovery,' is not so simple and, perhaps, not so 'obvious.'<sup>3</sup>

Whether India's amendments to its Patent Act comport with developing international norms has been the subject of famous litigation,<sup>6</sup> scholarly comment and political attention. In an effort to

contribute to the debate, this article considers whether, from the perspective of a hypothetical United States Federal Judge, the 2005 amendments to the India Patent Act, 1970<sup>1</sup> would be deemed compliant with India's obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>7</sup>

It does not focus on the litigation that has thus far transpired, but endeavours to examine, independently, the substantive argument that Section 3(d) of India's 2005 Patent Act is not in conformity with TRIPS, as if that question had been presented to a US Court.<sup>8</sup>

### Indian Patent Act

The construction of a statute must always begin with the words of the statute itself.<sup>9</sup> Ordinary rules of statutory construction,<sup>10</sup> The Supreme Court of United States said, hold that the 'plain meaning of the statute's words, enlightened by their context and the contemporaneous legislative history, can control the determination of legislative purpose.'<sup>11</sup> The first task, then, is to look to the plain words of India's Patent Act. If the language of a statute is plain, if there is no ambiguity, 'the duty of interpretation does not arise, and the rules which are to aid doubtful meanings need no discussion.'<sup>12</sup>

The United States statute defining patentable subject matter, Section 101 of the United States Patent Act, is 'cast in broad terms to fulfill the constitutional and statutory goal of promoting 'the progress of science and the useful arts' with all that means for the

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social and economic benefits.' Notwithstanding its breadth, the Supreme Court has found the statute free of ambiguity. 'Broad general language,' the Court said, 'is not necessarily ambiguous when congressional objectives require broad terms.'<sup>13</sup>

The Supreme Court has emphasized that its 'individual appraisal of the wisdom or unwisdom of a particular [legislative] course . . . is to be put aside in the process of interpreting a statute,' and that the Court's task 'is the narrow one of determining what Congress meant by the words it used in the statute.' Once that is done, the Court said, 'our powers are exhausted.'<sup>14</sup>

#### **Broad Statutory Definition of Patentable Subject Matter**

It is within these parameters of judicial restraint that a US Court would consider the unique statutory approach to the problem of 'newness' and 'novelty' that India has adopted in its 2005 amendments to the Patents Act, 1970.<sup>1,2</sup> Prior to its amendment in 2005, the Patent Act of 1970, as amended by the Patents (Amendment) Act of 1999, provided that an 'invention' means 'any new and useful (i) art, process, method or manner of manufacture; (ii) machine, apparatus or other article; (iii) substance produced by manufacture, and includes any new and useful improvement of any of them, and an alleged invention.'<sup>15</sup> In 2002, the Act was amended to define an 'invention' as 'a new product or process involving an inventive step and capable of industrial application,' and to define an 'inventive step' as 'a feature that makes the invention not obvious to a person skilled in the art.'<sup>1</sup>

The 2005 amendments added another definition of a 'new invention' to the extant definition of 'invention,' which continues in effect after the 2005 amendments.<sup>1</sup> A 'new invention' is defined as 'any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art.'<sup>1</sup> The 2005 amendments define a 'pharmaceutical substance' as 'any new entity involving one or more inventive steps.'<sup>1</sup> And they define the term 'inventive step' to mean '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 a person skilled in the art.'<sup>1</sup>

The terms 'new invention' and 'pharmaceutical substance' are not used in the Indian Patent Act outside their definitions, in Section 2.<sup>16</sup>

As of 2005, therefore, it would appear that the Indian Patent Act would, in its plain language, broadly declare an 'invention' as any 'new product or process involving an inventive step and capable of industrial application.' Since the word 'new invention' is not employed by the Indian Patent Act in any place other than its definition, a US Court would have no occasion to apply the definition it provides. Nevertheless, that Court might well look to the definition of a 'new invention' provided by the 2005 amendments, as evidence of the purpose and intention of the Indian Parliament when enacting the amendments, especially when looking at issues of anticipation and obviousness.

#### **Narrow Exceptions**

As of 1999, Indian patent law already contained exceptions to patent eligibility, describing matters that 'are not inventions' within the meaning of the Indian Patent Act.<sup>1</sup> A number of these exclusions, though codified in statute in a manner unknown in United States, at least, were and remain unremarkable. For example, the Act declares unpatentable 'an invention which is frivolous or which claims anything obvious contrary to well established natural laws;' as well as 'an invention the primary or intended use of which would be contrary to law or morality or injurious to public health;' and 'the mere discovery of a scientific principle or the formulation of an abstract theory.'<sup>17</sup>

Other statutory exclusions in the Indian Patent Act, though statutory, appear to codify certain principles of 'obviousness,' declaring 'mere' combinations or rearrangements of other elements as unpatentable.<sup>18</sup> Hence, the Indian Patent Act declares 'not an invention' any 'substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance,' and 'the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way.'<sup>19</sup>

The remaining exclusions from what might be considered an 'invention' under the Indian Patent Act, have proven to be more controversial. As of 1999, the Indian Patent Act described matters that 'are not inventions,' as:

- (a) the mere discovery of any new property or new use for a known substance or of the mere use of

a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;

- (b) a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture;
- (c) a method of agriculture or horticulture;
- (d) any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.<sup>20</sup>

In 2002, the Indian Parliament added a number of items to its compendium of matters deemed 'not an invention.'<sup>21</sup> The 2005 amendments altered the text of Section 3(d) of the Patent Act, 1970, in a manner that has engendered the greatest controversy:

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

*Explanation*—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.<sup>22</sup>

Neither Section 3(d) of the Indian Patent Act, nor any other Section apart from the definition introduced in the 2005 Patent Act, refers to a 'pharmaceutical substance.'<sup>23</sup> From the text of Section 3(d) itself, however, it would appear that its main body applies to more than 'pharmaceutical substances' or 'pharmaceutical products.'<sup>2</sup> The 'Explanation,' like the body, only refers to 'substances' and not 'products,' and neither uses the word 'pharmaceutical.' On the other hand, unlike the body of Section 3(d), the 'Explanation' seems to be directed at pharmaceutical 'substances,' although it curiously omits using the term 'pharmaceutical

substances' that was added to the Indian Patent Act at the same time as Section 3(d).<sup>6</sup>

#### **The Explanation in Section 3(d)**

Such statutorily engrossed explanations are unknown to American statutory law. In Indian law, the 'role of an Explanation of a statute is well known.' According to Indian courts, by 'inserting an Explanation in the Schedule of the Act, the main provisions of the Act cannot be defeated ... the scope and effect of a provision cannot be enlarged.'<sup>24</sup>

In the United States, legislative direction about the intended meaning or coverage of a particular statutory phrase is included either in the language of a statute itself, usually as a preamble<sup>25</sup>, policy statement<sup>26</sup> or simple legislative history. A preamble to a statute is a 'prefatory explanation or statement, which purports to state the reason or occasion for making a law or to explain in general terms the policy of the enactment.'<sup>25</sup> It is predatory and imposes no substantive restrictions. For the purposes of this article, the 'Explanation' that is now included in Section 3(d), and that was apparently added at the last minute before consideration of the Act,<sup>27</sup> will be regarded as if it were a preamble or a policy statement since, according to Indian law, an 'explanation,' like a preamble or policy statement, is not meant to enlarge the scope or effect of the statutory provision.<sup>28</sup>

If the Explanation appended to Section 3(d) of the 2005 Indian Patent Act is simply 'the legislature's view on some aspect of the operation of effect of the bill,'<sup>25</sup> and not binding on the courts that must interpret Section 3(d), it may 'aid the construction of doubtful clauses, but ... cannot control the substantive provisions of the statute,' especially if 'if no doubt exists as to a statute's meaning.'<sup>25</sup> It may state 'the general objectives of the act so that administrators and courts may know its purposes,'<sup>26</sup> but cannot alter the meaning or scope of the Section it explains.<sup>29</sup>

Viewed as such, there is no need for a Court to directly construe meaning of the words of 'Explanation', as such. Instead, it is necessary for a Court to construe the words of the statutory provision itself, having regard to the Explanation solely as a means of construing the principal section. Hence, it is essential for a Court to determine the general meaning of the phrase 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance' that is at the core of Section 3(d).

### Statutory Construction

In the ordinary case, whether an appeal from the determination of an Examiner or the United States Board of Patent Appeals (or any Indian equivalent), a US Court would note the general rules of statutory construction that have been applied when construing provisions of patent laws:

... the key to interpreting a patent statute still remains the ascertainment of the legislative intent as expressed in the statute. The statute's language is the best and most reliable index of the statute's meaning and must be consulted first. The language of the statute is construed in view of the statute's purpose. The language used in the statute is given its natural, plain, ordinary, and commonly understood meaning, unless a term has acquired a peculiar meaning as a result of statutory definition or judicial construction. Where the statutory wording is clear, a court should neither add to nor alter it to accomplish a purpose that does not appear on the face of the statute. Where terms are not defined in a statute, courts turn to their ordinary dictionary meaning. ...<sup>30</sup>

A US Court, considering the structure of the Indian Patent Act would note that the general definition of an 'invention' is set forth in Section 2 of the Act, and that Section 3, in a separate section, in a new chapter, entitled 'Inventions Not Patentable,' begins with the phrase 'The following are not inventions within the meaning of this Act ...' It would note that Section 5 of the Act, in the same chapter, was repealed by the 2005 amendments, and that the only other remaining section in the same chapter of the Indian Patent Act precludes granting of patents for 'inventions' relating to atomic energy falling within India's Atomic Energy Act.<sup>31</sup>

A Court in the United States would note that the word 'invention' is frequently used in the Indian Patent Act, and that it is only sometimes in conjunction with the phrase 'not patentable' or a reference to 'an invention [relating to atomic energy] for which no patent can be granted.'<sup>32</sup> Even Section 3, itself, uses the word 'invention.' From this alone, it might well find that the definition of 'invention' found in Section 2 of the Indian Patent Act to have greater importance. It would have to be construed, in every place it appears in the Act, in the light of Section 3, but the word 'invention' would be the 'controlling' term, not the specific exceptions enumerated in Section 3.

### Section 3(d) as an 'Exception'

Considering the structure of the Indian Patent Act, as well as the 'natural, plain, ordinary, and commonly

understood meaning' of the words used in Sections 2 and 3(d) of the Indian Patent Act, a US Court would probably consider the main body of Section 3(d) to be an 'exception,'<sup>33</sup> or something in the nature of a 'proviso,'<sup>34</sup> to the general definition of the term 'invention' set forth in Section 2, instead of a separate and independent statutory prescription or proscription. Indeed, Section 3(d) cannot stand on its own; a legislative declaration of what is 'not an invention,' is essentially meaningless, without a corresponding definition of what is an 'invention.' So viewing Section 3(d), such a hypothetical US Court would probably strictly construe the language of Section 3(d).<sup>30</sup> In any event, even if such a Court gave the limiting language of Section 3(d) weight equal to that of the definition of an 'invention' found in Section 2, would likely resolve any doubts about patentability in favour of the general provision in Section 2 rather than the exceptions created by Section 3,<sup>35</sup> whether or not it presumed that the qualifying language in Section 3(d) should be strictly construed.<sup>36</sup>

### Mere Discovery

The word 'mere discovery' is, perhaps, the least complicated to interpret in Section 3(d) and in many ways the most critical. Section 3(d) begins with, and is entirely confined to, that which is 'mere discovery.' If 'discovery' is the act of finding a new form of a known substance in the course of a search, or imply becoming aware of, observing that form for the first time,<sup>5</sup> then location or finding of a specific polymorph, metabolite or isomer of that substance, or simple purification of that substance or alteration of its particle size, in the course of research and development would seem to fall within the words 'mere discovery' within the meaning of the statute, especially when strictly construed in accordance with its plain meaning, unless the isolation or purification results in the enhancement of the known efficacy of that substance.<sup>37</sup>

On the other hand, creation of a salt, ester, or ether, or production of a previously unknown, non-natural polymorph, would not seem to be 'mere discovery' since human intervention or ingenuity, rather than mere observation, is required.<sup>3,5</sup> Such substances are 'new' or 'novel' because they 'recently c[a]me into existence,' and do not 'resemble[e] something formerly known or used.'<sup>4</sup> Of course, any of these substances will not be a patentable invention unless they also meet the test for 'invention' or 'new invention,' set forth in Section 2 of the Act. It must be

shown that such substances are 'a new product ... involving an inventive step,' that is 'a feature that makes the invention not obvious to a person skilled in the art,' and that such product 'is capable of industrial application.'

#### **Known Substance**

Others have argued that the words 'known substance' in Section 3(d) are ambiguous or create ambiguity.<sup>38</sup> Though arguments can be made about the specific substance against which a comparison should be made, under Section 3(d), the explanation to Section 3(d) declares that salts, esters, polymorphs, metabolites, isomers, and the other varieties of matter therein listed must be regarded by the courts and administrators as the 'same' as the 'known substance,' unless they 'differ significantly in properties with regard to efficacy.' These types of materials cannot, by this definition, be regarded as a 'new' substance or a 'new form' of a substance, within the meaning of Section 3(d), unless they differ significantly in properties with regard to efficacy. If these types of materials are 'merely discovered,' rather than 'invented,' they are not patentable unless their isolation or purification results in the enhancement of the known efficacy of that substance. On the other hand, if these types of materials are formed by human creative endeavour, as a product that is not otherwise observable, because not found as an observable, natural form of material, then these types of materials would not have been 'merely discovered.' They would have been 'invented.'

#### **Efficacy**

The most complex words in Section 3(d) are the qualifying phrases in the preceding sentences: 'unless they differ significantly in properties with regard to efficacy,' and 'results in the enhancement of the known efficacy of that substance.' In each of these phrases, the term 'efficacy' is key. 'Efficacy' is simply 'the ability to produce a desired or intended result 'as per Compact Oxford Dictionary.'<sup>39</sup> It is 'the power to produce an effect' as per Merriam Webster Online Dictionary'. According to Dorland's Medical Dictionary, efficacy is 'the ability of a drug to achieve the desired effect,' or 'the ability of an intervention to produce the desired beneficial effect in expert hands and under ideal circumstances,' or 'the ability of a drug to produce the desired therapeutic effect.'<sup>39</sup> Something is 'significant' if it is 'extensive or important enough to merit attention,'<sup>39</sup> or if it has or is likely to have 'influence or effect,' or if it is 'of a

noticeably or measurably large amount,' or if it 'probably caused by something other than mere chance.'<sup>40</sup> An 'enhancement' is a 'rise,' 'increase,' or 'augmentation.'<sup>41</sup>

Strictly construing Section 3(d) in accordance with its plain meaning, a 'new form of a known substance which does not result in the enhancement of the known efficacy of that substance,' therefore, is one that does not result in a rise or increase in, or augment, the power of the known substance to produce an effect. Using a medical definition, a substance excluded by Section 3(d) from the ability to garner a patent is one that does not result in a rise or increase in, or augment, 'the ability of a drug to achieve the desired effect,' or 'the ability of an intervention to produce the desired beneficial effect in expert hands and under ideal circumstances,' or 'the ability of a drug to produce the desired therapeutic effect.'<sup>42</sup> Section 3(d) does not, as suggested by recent decisions, allow patent consideration only for 'new form[s] of a known substance,' that result in an in a rise or increase in, or augment, 'the ability of a drug to produce the desired therapeutic effect.'<sup>43</sup> Indeed, the plain language of Section 3(d) does not include the word 'therapeutic.' It would be inappropriate to 'read into the patent laws limitations and conditions which the legislature has not expressed.'<sup>44</sup>

#### **Section 3(d) in Context**

Since, in effect, by its placement in the Patent Act as an exception to the more general rules of patentability and patent eligibility provided in the definitions of 'invention,' 'new invention' and 'inventive step' set forth in Section 2 of the Act, a hypothetical Court in the United States might well construe Section 3(d) to be, in effect, an 'exception' or something in the nature of a 'proviso' to the more general rule, that removes 'special cases from the general enactment and provide[s] for them specially.'<sup>45</sup> Combining these plain language definitions, a US Court would, in the view of this author, narrowly construe the restrictive scope of the 'exception' or 'proviso' and it would find 'only those subjects expressly restricted' to be 'freed from the operation of the [general provisions of the] statute.'<sup>46</sup> Moreover, if such a Court construed Section 3(d) as an 'exception' or 'proviso,' rather than a wholly independent statutory term, a US Court might well place the burden on anyone relying upon the exception created by Section 3(d) to demonstrate that a particular pharmaceutical substance falls within its provision and is not otherwise patentable.<sup>47</sup>

In the light of these principles of statutory construction, a US Court might construe Section 3(d) to declare 'not an invention' only those new forms of a known substance, including the variety listed in the explanation to Section 3(d), that were 'merely discovered,' that is observed in that form, in their natural state, for the first time in the course of a search, and not produced or created by human effort. It would likely further restrict the operation of Section 3(d) to those 'merely discovered' new forms of a substance that do not result in a rise or increase in, or augment, 'the ability of a drug to achieve the desired effect,' or 'the ability of an intervention to produce the desired beneficial effect in expert hands and under ideal circumstances,' or 'the ability of a drug to produce the desired therapeutic effect.'

A US Court, applying well-recognized rules of statutory construction, might also narrowly construe the interpretive guidance expressed in the explanation to Section 3(d), and give it limited weight. It would likely find that the Indian Parliament stated its intention, in that 'Explanation', to find salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives to be the same as an otherwise 'known substance' unless they differ significantly in properties with regard to efficacy.<sup>48</sup> Such a Court would be prone to define the latter phrase broadly, thus giving the entire 'Explanation' a narrow effect, and it would likely find, considering the plain language of the statute, that the Parliament meant to limit the excluded varieties described in the 'Explanation' only to those which do not result in a rise or increase extensive or important enough to merit attention in 'the ability of a drug to achieve the desired effect,' or 'the ability of an intervention to produce the desired beneficial effect in expert hands and under ideal circumstances,' or 'the ability of a drug to produce the desired therapeutic effect.' If one of the varieties of products listed in the 'Explanation' demonstrated a rise, increase or augmentation of 'the ability of a drug to achieve the desired effect,' that was 'probably caused by something other than mere chance,' a US Court would likely deem the explanation to Section 3(d) to provide no guidance to the Court. Such a Court would then be left with a narrow construction of the language of Section 3(d) itself.

#### **Section 3(d) and Patent Eligibility**

If a US Court considered issues under Section 3(d) as concerns with patent eligibility, rather than an issue

of legislatively determined 'obviousness,' it would likely start with the presumption that even though the Section 2 of the Indian Patent Act is only 'definitional' it will, like Section 101 of the United States Patent Act, 'include anything under the sun that is made by man.'<sup>49</sup> It would likely place the burden on anyone challenging patent eligibility of a 'new form of a known substance' under Section 3(d), such as a patent examiner or a litigant challenging validity of an issued patent during infringement litigation, to demonstrate that the substance sought to be patented was 'merely discovered,' that is merely observed in that form, in its natural state, for the first time in the course of a search, and not produced or created by human effort. It would place on such a person the burden to demonstrate that, even if the substance was 'merely discovered,' that the substance did not result, in the case of a pharmaceutical product, in a rise, increase, or augmentation of 'the ability of a drug to achieve the desired effect,' or 'the ability of an intervention to produce the desired beneficial effect in expert hands and under ideal circumstances,' or 'the ability of a drug to produce the desired therapeutic effect.' Failing such proof by clear and convincing evidence, the standard usually applied in US courts to challenges to validity of patents, such a Court would reject the challenge and consider whether the claimed invention met the other requirements for patentability, that is, priority, novelty and utility.

#### **Section 3(d) and 'Deemed' Obviousness**

If, as suggested above, a US Court would consider Section 3(d) to be a legislative description of what it 'deemed' to be 'obvious' in the light of prior art,<sup>25</sup> instead of a legislative declaration of 'eligibility,' the Court would likely first determine whether a patented substance otherwise complied with the general requirements for patent eligibility and patentability. It would thus look to the provisions of Section 2 of the Patent Act and determine whether the product is an 'invention,' that is, a 'new product or process involving an inventive step and capable of industrial application.' It might also consider, tangentially, whether it is a 'new invention,' that is, an 'invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art.'<sup>50</sup> In the course of this determination, the Court would

consider whether the patent was the result of an 'inventive step,' that is, '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 a person skilled in the art.'<sup>51</sup>

In essence, in so doing, a US Court would likely first engage in a process, compelled by the language and structure of Section 2 of the Indian Patent Act, that would consider issues of anticipation, obviousness, priority and utility, before considering the application of Section 3(d). When it reached issues raised under Section 3(d), if any remained to be separately decided after more routine consideration of patent eligibility and patentability, it would, as noted above, place the burden on a patent challenger to demonstrate, likely by clear and convincing evidence, that Section 3(d) prohibited issuance of a patent. In sum, especially since such a construction of Section 3(d) would be more likely to withstand scrutiny under TRIPS,<sup>52</sup> a US Court would narrowly construe the limitations created by Section 3(d), as suggested above.<sup>53</sup>

## TRIPS

As a non-self-executing treaty,<sup>54</sup> Article 27 of the TRIPS Agreement requires that all members of the World Trade Organization adopt or maintain domestic laws<sup>55</sup> that shall provide for the issuance of patents '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>56</sup> Although none of these three terms is defined in the TRIPS Agreement, from other writings, it would appear that the term 'new' is meant solely to refer to 'absolute novelty' or 'relative novelty,'<sup>57</sup> that is, the choice made by member states to award patent priority to those deemed 'first-to-file' or 'first-to-invent.'<sup>58</sup> A note to Article 27 of the Agreement instructs that 'the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively.'<sup>59</sup>

Even these comments leave much to be defined. The diverse descriptions of 'novelty,' 'inventive step' and 'usefulness' that might be afforded by various national legal systems was seemingly recognized in TRIPS, which 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>56</sup>

The TRIPS Agreement, on its face, allows Members of the WTO to 'exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.'<sup>57</sup> It also permits Members to exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals,' and 'plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes...'<sup>57</sup> The Agreement contains no other permitted exclusions from the general rules of patent eligibility and patentability, set forth in Article 27 of the treaty.

The principal issue raised by the text of Article 27 of the TRIPS Agreement is whether the specific authorized exceptions to 'patentability' described in paragraphs 2 and 3 of that Article preclude adoption of measures, either by judicial determination or statutory enactment, of provisions of domestic law that have the effect of excluding other subject matter from patent eligibility or patentability. A US Court, considering whether the 2005 amendments to the Indian Patent Act, especially Section 3(d) comply with TRIPS, would probably look first to the language of the treaty itself.<sup>59</sup> Article 31 of that 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>60</sup>

Since the United States is not a party to the Vienna Convention on the Law of Treaties,<sup>61</sup> interpretation of TRIPS would, in a US Court, follow standard United States domestic law principles of treaty construction.<sup>62</sup> A US Court, applying domestic law on the interpretation of treaties, would likely interpret the language of TRIPS in 'good faith' and its plain meaning, that is, 'in accordance with the ordinary meaning ... given to the terms of the treaty in their context and in the light of its object and purpose.' The TRIPS Agreement recognizes the private nature of intellectual property rights (IPR), 'the underlying public policy objectives of national systems for the protection of intellectual property, including

developmental and technological objectives,' and the 'special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.'<sup>63</sup>

In the light of these recognitions, the TRIPS Agreement sets forth its clear purpose to 'reduce distortions and impediments to international trade,' while 'taking into account the need to promote effective and adequate protection of IPR, and to ensure that measures and procedures to enforce IPR do not themselves become barriers to legitimate trade.'<sup>64</sup> TRIPS was thus designed, according to its own terms, at least in part, to provide 'adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights,' and 'effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems.'<sup>64</sup>

The TRIPS Agreement thus recognizes that there will be diversity, although it seeks to set basic, minimum standards for protection of intellectual property, including patent rights. The Agreement was crafted against a background of lengthy discussion among developed and developing nations, and against a long history of patent practice, especially in developed countries, such as the United States. The expectation, apparent in the TRIPS Agreement, appears to have been that customary norms, already accepted by the international community at large, require protection of 'inventions' that demonstrate 'newness,' that is, some form of 'priority;' some form of 'novelty' or 'non-obviousness;' and some form of 'usefulness' or 'industrial application' or 'utility.'

However, the specific definition of the process for determining priority, novelty and utility, as well as the details of standards that more specifically define those determinations, was left to national action.<sup>65</sup> It was at the time, and remains today, clear that different nations, however desirous of achieving a common international understanding of the substantive standards for 'invention,' priority, novelty and utility, apply different notions when considering specific applications for patents. A particular pharmaceutical product, like the commercial forms of 'atorvastatin' or 'esomeprazole', may be found patentable in some nations and not-patentable in others, even if they nominally apply the same general notions of priority, novelty and utility.

It was clear at the time TRIPS was adopted, as it is today, that the United States has judicially created exclusions from patent eligibility that go beyond those explicitly set forth in paragraphs 2 and 3 of Article 267 of the TRIPS Agreement. As noted above, the United States, by judicial decision, excludes from patentable subject matter the 'laws of nature, physical phenomena, and abstract ideas [that] have been held not patentable.' Similarly, United States law, by judicial decision, declares that 'a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter,' and that, 'likewise, Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity.' Such discoveries, the United States Supreme Court has said, are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'<sup>13</sup> These same notions are found in Section 3 of the Indian Patent Act. Neither Section 3 of the Indian Patent Act, nor the United States' judicial decisions to similar effect, violates the TRIPS Agreement. The treaty, on its face, does not define 'novelty' or 'inventive step' or what may be 'obvious' or 'useful,' and limits its scope to 'inventions' and not 'discoveries.'

Section 3(d), as noted above, is directed only to 'mere discovery' of certain substances. It does not preclude the allowance of patents for 'inventions' of pharmaceutical products. On its face, therefore, especially if construed narrowly, as suggested above, and consistent with the principle that it 'ought never to be construed to violate the law of nations, if any other possible construction remains,'<sup>66</sup> Section 3(d) may well comply with the TRIPS Agreement. The failure of the TRIPS Agreement to prescribe more rigorous, or at least more detailed standards, is one that may well deserve remedy. If faced with the precise question, however, a court in the United States would likely find that any such failing must be found in further international agreement, and not in the courts.<sup>67</sup>

## Conclusion

Others have suggested legislative reform to Section 3(d) to 'iron out' its 'creases.'<sup>68</sup> A close examination of Section 3(d), however, may well suggest that under amended Section 3(d) of the Indian Patent Act, a patent applicant should not be required, at least during the examination process, to bear the initial burden of showing that its claimed pharmaceutical invention has

‘enhanced efficacy.’ Such a close examination may also suggest that ‘efficacy’ was not limited in the statute to ‘therapeutic efficacy.’ The language of the statute itself, even considered in the light of the available legislative history, does not appear to compel such a limitation.

If Section 3(d) is construed as suggested in this article, it may well be that no substantial further legislative action is required, as has been suggested by other authors. It may well be that, if construed in the manner suggested in this article, Section 3(d) complies with the TRIPS Agreement and such legislation will not be necessary.

If, on the other hand, Section 3(d) is construed differently, especially in a manner that precludes patenting of a large number of pharmaceutical ‘inventions,’ instead of limiting the patent eligibility of ‘mere discoveries,’ further controversy will result, and the purposes of the TRIPS Agreement may well be defeated. This result will not be in the interests of any of the litigants in such cases, and it will not be in the interests of India or any of the developed or developing international community.

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