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**PATENTS LEGISLATION AND INTERNATIONAL OBLIGATIONS: INDIA**

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## **Foreword**

As a proprietary right fostering innovation, patents play a role in a competitive economy. Patents rights are statutory intellectual property rights granted by the government to an inventor to manufacture, use or market an invention which in turn benefits consumers through the development of new and improved products and processes.

The 2005 Patents [Amendment] Act marks a distinct evolution in Indian Patent Law. With the inauguration of the product patents regime, India is fully compliant with Article 65(4). The contours of the Law and Rules are yet to be defined but it is clear that the Amendment builds on the Ordinance of March 2004 taking into consideration objections raised both by the public and political parties alike. The paper attempts a comparison of Indian legislative provisions vis-à-vis the minimum standards of protection required under the TRIPS Agreement and broader standards as defined in the Paris Convention. It attempts further to plot an evolution in the law as first promulgated in 1970 to that of its successive amendments.

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**Arvind Virmani**  
Director & Chief Executive  
ICRIER

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## 1. Introduction

The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement was the result of seven years of negotiations, from September 1986 to December 1993, as part of the Uruguay Round of Multilateral Trade Negotiations of the General Agreement on Tariffs and Trade. It was promulgated on the 1<sup>st</sup> of January 2005 thus forming a part of the legal obligations of the World Trade Organization and its member countries. It dramatically increased the minimum standards of protection for intellectual property rights,<sup>1</sup> including patents. The TRIPS Agreement, broadly, prescribed the following time line for compliance:

1. All World Trade Organization member countries had 1 year (up to the 1<sup>st</sup> of January, 1996) to phase in the minimum standards of protection.
2. Developing Countries were given an additional period of 4 years (up to January 2000) and Least Developed Countries an additional period of 10 years (up to January 2006) to phase in these minimum standards of protection.
3. A further period of 5 years (up to January 2005) was given to developing countries to introduce a product patents regime. Meanwhile, a 'mailbox' facility starting from the 1<sup>st</sup> of January 1995 to receive product patent applications in the field of pharmaceuticals and agricultural-chemicals till the 31<sup>st</sup> of December 2004 was required for along with the provision of Exclusive Marketing Rights in lieu of product patents during the transition period.
4. Product Patents in Least Developed Countries were to be introduced by 2006, however the transition period was extended to the 1<sup>st</sup> of January, 2016 by the Doha Declaration, paragraph 7

The Indian Government has promulgated changes in its Intellectual Property Law, especially patents, to meet its commitments under the Trade Related Aspects of Intellectual Property Rights Agreement. The Patents Act, 1970 (20<sup>th</sup> April, 1972) read

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<sup>1</sup> Trade Marks, Copyrights, Geographical Indications, Designs, Industrial Designs, Layout Designs of Integrated Circuits

with the Patents Rules, 1972 (20<sup>th</sup> April, 1972), which *revoked* the Patents and Designs Act 1911, has been amended thrice to bring India in compliance with its international obligations under the TRIPS Agreement:

1. Patents Amendment Act, 1999 (26<sup>th</sup> March 1999, *enforced retrospectively from* 1<sup>st</sup> January 1995) read with the Patents Rules, 1972 (20<sup>th</sup> April, 1972)
2. Patents Amendment Act, 2002 (25<sup>th</sup> June 2002, *enforced on* 20<sup>th</sup> May 2003) read with the Patents Amendment Rules (*enforced on* 20<sup>th</sup> May 2003)
3. The Patents Amendment Ordinance, 2004 was promulgated into the Patents [Amendment] Act 2005 on the 23<sup>rd</sup> of March 2005. It is to be read with the Patents Amendment Rules, 2005. The Patents Amendment Ordinance (a temporary executive decree not debated in the Parliament) 2004 was promulgated on the 26<sup>th</sup> of December 2004 under Article 123(1) of the Constitution of India after receiving Presidential assent<sup>2</sup>. The Ordinance had the same force as an Act of Parliament<sup>3</sup> and was to terminate at the expiration of six weeks from the re-assembly of the Parliament, or before, if resolutions disapproving it were passed by both Houses,<sup>4</sup> else it could have been withdrawn by the President of India at any time.<sup>5</sup> The Ordinance took effect as soon as it was promulgated by the President, subject to retrospective reversal, had the Legislature passed an Act to the same effect.<sup>6</sup> The Ordinance could have been challenged on the ground of *mala fides*<sup>7</sup> (in bad faith).

This paper attempts to catalog the successive amendments made to the Patents regime in India, with a view to fulfilling its international obligations under the Trade

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<sup>2</sup> Chapter III, *Legislative Powers of the President of India, The Constitution of India*, Section. 123(1): “If at any time, except when both houses of the parliament are in session, the president is satisfied that *circumstances exist which render it necessary for him to take immediate action*, he may promulgate such ordinance as the circumstances appear to him to require” (emphasis added)

<sup>3</sup> s. 123(2), The Constitution of India

<sup>4</sup> s. 123(2)(a), The constitution of India

<sup>5</sup> s. 123(2)(b), The constitution of India

<sup>6</sup> *The Shorter Constitution of India (Eleventh Edition)* by DD. Basu, Page 380

<sup>7</sup> Air 1982 SC paragraph 27 and 29

Related Aspects of Intellectual Property Rights and the Paris Convention. The first half deals with the substantive aspects and the second with the procedural aspects of patents law in India.

## **2. Patents Legislation and International Obligations: India**

### **2.1. Rights granted by the Patent:**

A Patent gives a monopoly right to a person who has invented a new and useful product or a new process of making a product or an improvement or modification of an existing product or process<sup>8</sup>. It is a statutory grant conferring exclusive right to manufacture the patented product or manufacture a product according to the patented process for a limited period of time, *that is*, a period of 20 years.<sup>9</sup> As provided for in the 2002 amendment and in keeping with the TRIPS Agreement, a patent confers on the owner the exclusive right by himself, his agents, assignees or licensees to prevent any third party, without explicit authorization, from making, using, offering for sale, selling or importing for *these* purposes the patented product.<sup>10</sup> In the case of the grant of a patent for a method or process of manufacture, this right extends to the ‘product obtained directly by the patented process,’<sup>11</sup> subject to prescribed exceptions.<sup>12</sup>

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<sup>8</sup> See P.Narayanan, *Patents Law, 3<sup>rd</sup> Edition*, in respect of any “improvement in or modification of” previous invention called the main invention *as described or disclosed* in the complete specification (not limited to the invention as claimed) for which a patent has been granted or an application has been made, Section 55(2), Patents Act (1970), Page 69-71

<sup>9</sup> Section 53(1), Patents Act, 1970: “Subject to the provisions of this act, the term of every patent granted, after the commencement of the Patents (Amendment) Act, 2002, and the term for every patent which has not expired and has not ceased to have effect, on the date of such commencement, under this Act, shall be *twenty years from the date of filing of the application for the patent*” (emphasis added). This provision was introduced by the 2002 Amendment in conformity with Article 33, the Trade Related Aspects of the Intellectual Property Rights Agreement (1995).

<sup>10</sup> Section 48(a), the Patents Act, 1970 as amended in 2002. This is in conformity with Article 28(1)(a) the Trade Related Aspects of Intellectual Property Rights Agreement (1995) and **goes** further than the rights conferred under the Paris Convention, Article 5<sup>quarter</sup>.

<sup>11</sup> Section 48(b), the Patents act, 1970 as amended in 2002. This is in conformity with Article 28(1)(b), the Trade Related Aspects of Intellectual Property Rights Agreement (1995).

<sup>12</sup> Rights of co-owners (Section 50), Use of patents by the Government (Section 47), Powers of the Central Government to use of inventions for the purposes of the Government (Section 100; ), Acquisitions of inventions and Patents by the Central Government (Section 102), Compulsory Licenses (Sections 83 to 94), *etc*

## **2.2. Time Frame for complying with the Trade related aspects of Intellectual property Rights Agreement:**

The Trade Related Aspects of Intellectual Property Rights Agreement provides for a three stage time frame for *developing countries* to comply with their international obligations:

1. The introduction of a ‘mailbox’ facility from the 1<sup>st</sup> of January 1995 to receive pharmaceutical and agricultural-chemical patent applications until the 31<sup>st</sup> of December 2004 along with the grant of Exclusive Marketing Rights in countries which did not provide for product patents in pharmaceuticals and agricultural-chemicals in their national patents legislation, was required, *Articles* 65(4),<sup>13</sup> 70(8),<sup>14</sup> 70(9).<sup>15</sup> The mailbox provision allowed applicants to file for patents, thereby establish a filing date while at the same time deferring to grant pharmaceutical and agricultural-chemical patents. The date of filing is important as it is used to assess whether the patent application at the time of filing, given the prior art, meets the necessary conditions for establishing patentability, which are, novelty, utility and inventive step.<sup>16</sup>

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<sup>13</sup> To the extent that developing country member is obliged by this agreement to extend product patent protection, it may delay the application for an additional period of 5 years.

<sup>14</sup> Article 70(8) Trade Related Aspects of the Intellectual Property Rights Agreement, established, that a contracting state which does not make Patent protection available from the 1<sup>st</sup> of January 1995, for pharmaceuticals and agricultural chemicals, will have to: (i) provide a means by which applications for patents for such inventions can be filed (ii) apply to these applications the criteria of patentability as established by Trade Related Aspects of the Intellectual Property Rights Agreement as if those criteria were applied on the date of filing or priority, (iii) provide patent protection counted from the filing date for patents which meet the criteria under (ii).

<sup>15</sup> Under article 70(9) an Exclusive Marketing Rights to sell or distribute the article or substance for the applicant, his agents or licensees, on and from the date of approval by the controller for a period of 5 years or till the date of the grant of the patent or the date of rejection of the application, whichever is earlier. Before the Exclusive Marketing Right is so available, it has to be established that the applicant has, (i) filed a patent application in a World Trade Organization member country on or after the 1<sup>st</sup> January, 1995 or thereafter, (ii) a patent application has been filed for the grant in another World Trade Organization member country after the afore date stated, (iii) marketing approval has been obtained for such a product in the said other World Trade Organization member, and (iv) marketing approval has been obtained in the host country

<sup>16</sup> *The effects of the 2005 TRIPS implementation deadline on access to medicines: Médecins Sans Frontières Campaign for Access to Essential Medicines*, February 2005



2. All other provisions under the Agreement pertaining to patents were to be complied with by 1<sup>st</sup> January 2000, *Article 65(2)*,<sup>17</sup> including, the reversal of burden of proof to strengthen ‘process patent’ protection,<sup>18</sup> the provisions of compulsory licensing (license to implement a patent against the will of the patent owner), a twenty year term of patent protection, *and*
3. The introduction of product patents in all fields of technology was required from the 1<sup>st</sup> of January 2005, *Article 65(4)*.

India chose to take advantage of the ten year transition period, provided under Article 65(4) of the Agreement.

### **2.3. Provisions under the Trade Related Aspects of Intellectual property Rights Agreement and Consequent Amendments in Indian Patents Law:**

#### *2.3.1. Objectives and principles:*

The Trade Related Aspects of Intellectual Property Rights Agreement adopted a ‘Paris *plus*’ approach under Article 2(1)<sup>19</sup> and provides the minimum standards for patent protection in Section V of the Agreement (Articles 27-34). The ‘objectives’ and ‘principles,’ provided for in the Agreement, offer an important framework for the interpretation and application of the provisions of the Agreement. The specific *objectives* of the Agreement are stated in Article 7,<sup>20</sup> which provides that national governments ‘should’ grant protection and enforcement to intellectual property rights, that is, the promotion of technological innovation and the transfer and dissemination of technology

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<sup>17</sup> A developing country is entitled to delay for a further period of 4 years the date of application [(in addition to Article 64(1), no member shall be obliged to apply the provisions of Trade Related Aspects of Intellectual Property Rights before the expiry of a general period of 1 year following the date of entry into force of the World Trade Organization]

<sup>18</sup> Inserted under the 2002 Amendment, Section 104A

<sup>19</sup> Members shall comply with Articles 1-12, and Article 19 of the Paris Convention 1967 (*last revised on September 28, 1979*). Nothing in parts I to IV of this Agreement shall derogate from existing obligations that members have to each other under the Paris Convention

<sup>20</sup> “The protection and enforcement of Intellectual Property Rights should contribute to the promotion of technological innovations and to the transfer and dissemination of technology and 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”

*and* that these objectives have to be pursued to the mutual advantage of the producers and users of technological knowledge, be conducive to social and economic welfare and must result in a balance of rights and obligations.

The *principles* of the Agreement are vested in Article 8, which contains two general provisions. The first, where the member states in either formulating or amending their laws or regulations, ‘may’ adopt measures ‘to protect’ public health and nutrition and to promote public interest in sectors of vital importance to their socio-economic and technological developments and the second to ‘prevent’ the abuse of intellectual property rights or resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. While Article 8(1)<sup>21</sup> empowers the member countries to undertake public interest benefaction, Article 8(2)<sup>22</sup> enunciates the adoption of measures to prevent the ‘abuse of intellectual property rights.’ The principle articulated in 8(2) is further substantiated in the mechanisms of Articles 31(k)<sup>23</sup> and 40,<sup>24</sup> more specifically, which together, give domestic legislation an opportunity to control abuses *or* anti-competitive practices associated with the exercise of intellectual property rights. Article 8 facilitates legislating limitations to exclusive patent rights along with the enactment of legislative provisions concerning compulsory licensing.

### 2.3.2. *Patentable Subject Matter:*

Article 27(1) of the Agreement provides that patents are to be available for:

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<sup>21</sup> “Members may, in formulating or amending their laws and regulations, adopt measures necessary to the protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement” Article 8(1)

<sup>22</sup> “Appropriate measures, provided that they are consistent with the provisions of the Agreement, may be needed to prevent the abuse of Intellectual property rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology, Article 8(2)

<sup>23</sup> Given the conditions for the grant of a compulsory license, a member is not required to “[] make efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time” *and* compulsory licenses granted are not required “[to] be authorized predominantly for the supply of the domestic market of the member authorizing such use.” Further, the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such case.

<sup>24</sup> Control of Anti-Competitive Practices in Contractual Licenses

- (i) *both* product and process inventions,
- (ii) in *all* fields of technology,
- (iii) *provided* they are new, involve an inventive step and capable of industrial application.
- (iv) *footnote 5* of the agreement provides that for these purposes the term ‘inventive step’ and ‘capable of industrial application’ may be deemed to be synonymous with the terms ‘non-obvious’ and ‘useful’ respectively.
- (v) patent are to be made available and patent rights enjoyable without discrimination<sup>25</sup> as to (a) place of invention, the (b) field of technology and (c) whether products are imported<sup>26</sup> or locally produced.

*Exclusions to Article 27(1):*

- (i) Article 27(2) provides for exclusions from patentability of inventions which are ‘necessary’ to protect *ordre public or morality*<sup>27</sup>

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<sup>25</sup> In *Canada – Patent Protection of pharmaceutical patents* (WT/DS114/R: 17 March 2000), it was established that “discrimination may arise from explicitly different treatment, sometimes called ‘*de jure* discrimination’, but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produce differentially disadvantageous effects, sometimes called ‘*de facto* discrimination’ [which] is a general term describing the legal conclusion that an ostensibly neutral measure transgresses a non-discrimination norm because its (i) actual effect is to impose differentially disadvantageous consequences on certain parties, and (ii) because those differential effects are found to be wrong or unjustifiable”

<sup>26</sup> Article 5A (1) of the Paris Convention prohibits the mere act of *importation* of patented articles by the patentee from any other member country as constituting the basis for forfeiture of the patent. However, Article 5A(2) further lays down that each Paris member is free to provide for the grant of compulsory license to prevent patent abuse, such as failure to work the patent in the country of grant. Given this, in *Intellectual Property Rights and International Trade*, edited by Carlos Correa and A.Yusuf, it is held that, “The relationship between 5A of the Paris Convention and Article 27(1) is not clear, as the former authorizes the granting of compulsory licenses on the basis of failure to work, while article 27(1) is intended, at least in principle, to restrict compulsory licenses on such grounds,” Page 191

<sup>27</sup> *Patent Rights* by Carlos Correa in *Intellectual Property and International Trade* edited by Carlos Correa and A.Yusuf, “[] the concept of *ordre public* [] may be interpreted as being narrower than ‘public order’ or ‘public interest.’ [There is] no generally accepted notion of *ordre public*: member countries have therefore a certain degree of flexibility to define which hypotheses are covered, depending on their own conception of the protection of public values. Article 27(2), itself indicates that the concept is not limited to ‘security’ reasons; it also relates to the protection of ‘human, animals or plant life or health’ and may be applied to inventions that may lead to ‘serious prejudice to the environment.’” Also see *India, IP/C/M/28*, para. 127

- (ii) *including* to protect human, animal or plant life or health or to avoid serious prejudice to the environment, *provided* that such exclusions are not made merely because the exploitation is prohibited under domestic law<sup>28</sup>.
- (iii) Article 27(3) further *excludes* from patentability
  - (a) diagnostic, therapeutic and surgical methods for the treatment of humans and 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 micro-biological processes.

Members are also required to provide for the protection of plant varieties either by patents or by an *effective sui generis* system or any combination thereof (Protection of Plant Varieties and Farmers Rights Act, 2001).

The TRIPs Agreement does not define what constitutes an invention: it only specifies the requirements to be satisfied in order to obtain protection for an invention. *Novelty*, *non-obviousness* (inventive step) and *utility* (industrial applicability) determine the criteria of patentability. Novelty provides a proper incentive for innovation, rewarding that which is new and not imitative.<sup>29</sup> Non-obviousness establishes a patentability step, a level of development beyond the prior art that must be accomplished, before a patent can be issued, it is a ‘non-triviality’ requirement.<sup>30</sup> The requirement that a claim be ‘capable of industrial application’ tends to exclude areas of basic research from patentability. A disclosure requirement is provided for under Article 29 of the Agreement which requires a patent applicant to disclose the invention in a manner sufficiently clear and complete for it to be executed by a person skilled in the art. It may also require the applicant to indicate the ‘best mode’ required for carrying out the invention known to the inventor at the date of filing of the patent application or the date of priority. The

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<sup>28</sup> Article 4 quarter of the Paris Convention, lays down the principle that the grant of a patent cannot be refused or invalidated on the ground that the sale of the patented product (or of a product resulting from the patented process) is restricted or limited by domestic law

<sup>29</sup> Report by the USPTO (2003), *To promote innovation: The proper balance of competition and patent law and policy*, Chapter 4, page 2

<sup>30</sup> *id*

disclosure requirement guarantees a relatively swift dissemination of technical information from which others in the art can learn.

As patents are granted under national laws and have territorial application the specific ‘scope’ of patentability has not been negotiated at the TRIPS Council.<sup>31</sup> The ‘level’ of protection is crafted in the national domain.<sup>32</sup> India expressed the view that the lack of clear definitions for the ‘criteria’ of patentability has left grey areas, in particular with respect to the [*threshold*] definition of the term ‘invention’ and the ‘scope’ of patentable micro-organisms and microbiological and non-biological processes.<sup>33</sup> This may result in poor quality or questionable patents which are likely invalid or contain claims that are overly broad.<sup>34</sup> Another concern that has plagued India with respect to the TRIPS Agreement is the patenting of products based on India’s bio-diversity and traditional knowledge (*bio-piracy*)<sup>35</sup> without recognizing and *rewarding* the traditional contribution of rural communities to the conservation of biological diversity. This brings into purview the issue of compatibility between the TRIPS Agreement and the principles of Convention on Biological Diversity which reaffirms the sovereign rights of the States

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<sup>31</sup> India, IP/C/M/28

<sup>32</sup> *id*

<sup>33</sup> India, IP/C/W/161; IP/C/M/28 para. 128

<sup>34</sup> Report by the USPTO (2003), *To promote innovation: The proper balance of competition and patent law and policy*, Introduction, page 5

<sup>35</sup> As the Trade Related Aspects of Intellectual Property Rights Agreement contains no provisions allowing a members claim to enforce ‘fair and equitable sharing of benefits’ from the patenting of its own genetic resources abroad, in IP/C/W/429/Rev.1, on 27<sup>th</sup> September, 2004 Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela proposed to implement a *legally binding obligation* to (i) disclose the source and country of origin of biological resources and/or traditional knowledge used in the invention, (ii) provide evidence of prior informed consent through approval of authorities under the relevant national regimes, and (iii) provide evidence of fair and equitable benefit sharing under the relevant national regimes. This will serve the following purposes: (i) helping patent examines determine whether the claimed invention constitutes an invention that is excluded from patentability under Articles 27(2) and (3) of the Trade Relate Aspects of Intellectual property Agreement, (ii) enhancing the ability of countries to track bad patents and in the instances where they are granted and challenge the same, (iii) reducing instances of bad patents and (iv) improving compliance with their national laws on Prior Informed Consent and fair and equitable benefit sharing prior to accessing a biological resource/associated traditional knowledge. Article 29 already obliges members to require that patent applicants 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 to carry out the invention known to the inventor. An obligation to disclose source and country of origin of biological resources and/or traditional knowledge used in an invention would play a crucial role in ensuring patent quality.

over their biological resources with the main objective of the conservation of biological diversity, sustainable use of its components and fair and equitable sharing of benefits arising out of utilization of genetic resources.<sup>36</sup>

A few WTO members maintain that by incorporating the patenting of micro-organisms<sup>37</sup> and micro-biological processes, the TRIPS Agreement, has violated the basic tenet of patent law, that while discoveries are not patentable, inventions are.<sup>38</sup> Literally translated, discovery is new insight into a product or process that already exists in nature while an invention involves the production a new product/process hitherto unknown. There is immediate need for a clearer understanding of which stages of research into genetic resources, including genetic parts and components, constitute ‘discovery’ and which fulfill the requirement of an invention.<sup>39</sup> It is questionable whether the mere act of ‘isolation’ of genetic material from its natural source, as legally established in many developed countries, would satisfy the test of non-obviousness or inventive step.<sup>40</sup> In this background, developing countries, including India, face a dilemma with defining the contours of biotechnological inventions, the patenting of micro-organisms and non-

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<sup>36</sup> See, Article 1, 3, 15, 16(5) and 8(j) of the Convention on Biological Diversity

<sup>37</sup> With regard to what action should be taken in the World Trade organization on the treatment of micro-organisms, the following view has been expressed: (i) There is no scientific or other rationale for distinguishing between plants and animals on the one hand and micro-organisms on the other (Kenya on behalf of the African Group, IP/C/W/163) and micro-organisms, like other biological and living organisms, should be excluded from patentability, Kenya, IP/C/M/28, para. 152), (ii) the coverage of the term ‘micro-organism’ should be clarified, in particular so as to exclude cell lines, enzymes, plasmids, cosmids and genes (Kenya, IP/C/M/28, para. 152), (iii) individual members should determine and apply the term in their national jurisdiction in accordance with Article 1.1 of the Budapest Treaty and not seek to define the term. Patent experts have a fairly clear idea of the term but the issue is complex and therefore it is better left to each members patent offices and experts to determine (Korea, IP/C/M/35, para. 225), (iv) it should be left to national policy to decide what are patentable micro-organisms (India, IP/C/W/161), given that micro-organisms could be excluded from patentability under Article 27(2) (IP/C/W/161)

<sup>38</sup> Kenya on behalf of the African Group, IP/C/W/163

<sup>39</sup> Malaysia, IP/C/M/32, para. 143

<sup>40</sup> India, IP/C/M/29, para. 161. Mere discoveries, not involving human intervention, are not considered patentable subject-matter (Japan, IP/C/M/29 para. 151, Switzerland, IP/C/M/30, para. 164). It has been elaborated that if, however, naturally occurring things, such as chemical substances or micro-organisms, have been first isolated artificially from their surroundings in nature they are capable of constituting an invention. It has also been said that if the subject-matter of a patent has involved sufficient human intervention, such as isolation or purification, and if the isolated or purified subject-matter is not of a previously recognized existence, then it is considered an invention (EC, IP/C/W/254, Japan, IP/C/M/29 para. 151, United States, IP/C/M/29 para. 186)

biological processes in their national legislation.<sup>41</sup> At the outset, India excludes the discovery of any living or non living thing or non living substance occurring in nature,<sup>42</sup> plants and animals in whole or any part *including* seeds, varieties and species and essentially biological processes for production or propagation of plants and animals *other than* micro-organisms from the ambit of patentability.<sup>43</sup>

The most important criteria for judging patent eligibility is that of ‘non-obviousness’ or ‘inventive step,’ this involves a question of fact and degree and is to be answered in accordance with the general policy of the Patents Act to reward and encourage invention without inhibiting improvements of existing technology by others.<sup>44</sup> The question to be asked is: “Was it for practical purposes obvious to the skilled worker, in the field [of technology] concerned, in the state of knowledge existing at the date of the patent to be found [] then available to him, that he would or should make the

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<sup>41</sup> In *Diamond v. Chakrabarty*, the Supreme Court in the United States held that a live, human made micro-organism was patentable under 35 USC Article 101 (“whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements or this title”). The test set down by the court of patentable subject matter in this area is whether the living matter is the result of human intervention, “his claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name, manufacture or use”. The Supreme Court chose an expansive definition of the term ‘manufacture’<sup>41</sup> the court further held that the congress intended statutory subject matter to ‘include anything under the sun that is made by man, 447 US at 309, *citing* S.Rep.No.82-1979, at 5 (1952); H.R.rep.No. 82-1923, at 6(1952). Non-obviousness under 35 USC 103 requires an invention to be beyond the ordinary abilities of a skilled artisan knowledgeable in the appropriate field. In *Graham v John Deere Co*, 383 US 1, 11 (1966) the Supreme Court held that non-obviousness requires a three part inquiry: (i) the scope and content of the prior art are to be determined, (ii) differences between the prior art and the claims at issue are to be ascertained, and (iii) the level of ordinary skill in the pertinent art resolved. The federal court has filled the gap in part through its “suggestions test”, which focuses on the extent to which “the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success (*brown and Williamson Tobacco Corp v Philip Morris, Inc.*, 229 F. 3d 1120, 1124 (*Fed. Cir* 2000)). The Supreme Court also identified a number of “secondary considerations,” including ‘commercial success, long felt but unsolved needs, and failure of others,’ that “may have relevancy” as “indicia of obviousness (*Graham*, 383 US at 17-18). The Federal Circuit has required considerations of any evidence of these secondary characteristics and, at times, has given them considerable weight as means for overcoming that might otherwise be *prima facie* case of obviousness under the primary *Graham* test.

<sup>42</sup> Section 3©, Patents [Amendment] Act, 2002.

<sup>43</sup> Section 3(j), Patents [Amendment] Act, 2002

<sup>44</sup> *See, Societe Technique De Pulverisation Step v. Emson Europe (1993) RPC 513 (CA)*

invention the subject of the claim concerned?”<sup>45</sup> The requirement that an invention be non-obvious preserves the public domain by creating a patent free zone around the existing state of art. Usefulness<sup>46</sup> was recognized as one of three pre-requisites in establishing patentability, even in *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries*<sup>47</sup> it was held that “[] that Section 26(1)(f) of the 1911 Act recognized the lack of utility as one of the grounds on which a patent could be revoked.” Thus, there must be an invention applied to produce a practical result<sup>48</sup> that is, it must be capable of industrial applicability; an invention must be a ‘new and useful’ ‘method or manner’ of manufacture.

The definition of ‘invention’ was amended in 2002<sup>49</sup> in accordance with the TRIPS Agreement to mean a new product or process involving an inventive step (a feature that makes the invention not obvious to a person skilled in the art)<sup>50</sup> and capable of industrial application<sup>51</sup> (capable of being made or used in an industry).<sup>52</sup> The combined effect of these definitions was to provide a progressive meaning to the term *invention*, one which would encompass just about every new creation in any field of scientific endeavor, provided it was not prohibited under Section 3 of the Act.<sup>53</sup> Under the 2004 Ordinance, the scope of patentable inventions has been expanded, beyond the purview of process, to mean a patent for ‘any invention,’<sup>54</sup> that is *either* product or process. The

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<sup>45</sup> See, *Halsbury 3<sup>rd</sup> Edition, Vol. 29, p. 42* referred to by Vimadalal, J at the Bombay High Court in *Erbwerke Hoechst and B Coproration v. Unichem Laboratories* AIR 1969 Bom. 225.

<sup>46</sup> Under 35 USC 101, it means that the invention must be minimally operable towards some practical purpose. “The claimed invention as a whole must accomplish a practical application. That is, it must produce ‘a useful, concrete and tangible result’.” *State Street 149 F. 3d at 1373, 47 USPQ2d at 1601-2*

<sup>47</sup> AIR 1982 SC 144

<sup>48</sup> *Harwood v. Great Northern Railway Company*, (1864-65) 11 HLC 654

<sup>49</sup> Section 2(1)(j) of the Patents Act, 1970 defined an invention as follows: “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>50</sup> Section 2(1)(ja)

<sup>51</sup> Section 2(1)(j)

<sup>52</sup> Section 2(1)(j)

<sup>53</sup> Asian Patent Attorneys Association Newsletter, June 2003, p. 169

<sup>54</sup> Section 2(1)(m)



definition of an inventive step has been qualified to “a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both [emphasis added] and that makes the invention not obvious to a person skilled in the art.” ‘Technical advance as compared to the existing knowledge’ and ‘economic significance’ are terms of art subject to judicial interpretation.

With the introduction of product patents the regime for Exclusive Marketing Rights has been revoked. Section 5 as amended in 1999 provided patents for *methods or processes of manufacture*. It provided that inventions, (a) claiming substances intended for use, or capable of being used, as food<sup>55</sup> or as medicine or drug<sup>56</sup>, or (b) relating to substances prepared or produced by chemical processes which includes ‘biochemical, biotechnological and microbiological processes’<sup>57</sup> (including alloys, optical glass, semi-conductors, inter-metallic compounds), were to be denied a patent in respect of the claims for the substances themselves.<sup>58</sup> The claim for patenting a substance itself intended for use, or capable of being used, as medicine or drug (*except* all chemical substances that are ordinarily used as intermediaries in the preparation and manufacture of any of medicines or substances, Section 2(1)(v)), could be made under Chapter IV of the Act dealing with Exclusive Marketing Rights.<sup>59</sup> Exclusive Marketing Rights provided a means for accepting patent applications for pharmaceutical and agricultural-chemical products, which were not to be referred to the examiner for making a report until 31<sup>st</sup>

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<sup>55</sup> Omitted under 2004 Ordinance, “Food means any article of nourishment for human consumption and also includes any substance intended for the use of infants, invalids or convalescents as an article of food or drink (Section 2(g))”

<sup>56</sup> Omitted under the 2004 Ordinance, Section 2(1): “Medicines and drugs, include, (i) all medicines for external and internal use of human beings or animals, (ii) all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals, (iii) all substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals, (iv) insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants, (v) all chemicals substances which are ordinarily used as intermediates in the preparation or manufacture of the medicines or substances above referred to.”

<sup>57</sup> 2002 Amendment

<sup>58</sup> Section 5(1), Patents Act 1970, subject to the 1999 Amendment

<sup>59</sup> Section 5(2) Patents Act 1970, subject to the 1999 Amendment

December, 2004.<sup>60</sup> Only the application for grant of exclusive rights to sell or distribute the article or the substance could be referred for an examiner's report. An Exclusive Marketing Right would grant the patent owner the exclusive right by himself, his agents or licensees to sell or distribute in India the article or the substance on or from the date of approval granted by the Controller until a period of five years or until the date of grant of patent or the date of rejection of application for the grant of patent, whichever is earlier.

Under the 2004 Ordinance every application for the grant of Exclusive Marketing Right's filed before January 1<sup>st</sup> 2005, in respect of a claim for a patent covered under S. 5(2) shall be deemed to be treated as a request for examination for grant of patent under 11B(3).<sup>61</sup> The application in respect of which exclusive rights have been granted before the 1<sup>st</sup> of January 2005 shall be examined for the grant of patents immediately on the commencement of the Ordinance.<sup>62</sup> Every exclusive right to sell or distribute an article or substance in India granted before 1<sup>st</sup> January 2005 will continue to be effective with the same terms and conditions of the grant.<sup>63</sup> Although the 20-year term will be counted from the date of the patent application, the protection will be effective from the date of grant of patent, that is, the protection based on patents granted to mailbox applications will be effective only prospectively from the date of grant of the patent and not retrospectively from the date of application. Infringement proceedings will not be allowed retrospectively and patent owners (for patent rights granted under Section 5(2)) shall be entitled to receive only a reasonable royalty from enterprises which were producing and marketing the patent product prior to the 1<sup>st</sup> of January 2005 and which continue to so do.<sup>64</sup>

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<sup>60</sup> Section 5(2)

<sup>61</sup> Section 77(1)

<sup>62</sup> Section 77(3), *See* "All suits relating to infringement of the exclusive right granted before the 1<sup>st</sup> of January 2005 shall be dealt with in the same manner as if they were suits concerning infringement of patents", Section 77(4). "The examination and investigation required as carried out for the grant of exclusive right shall not be deemed in any way to warrant the validity of any grant of exclusive right to sell or distribute, and no liability shall be incurred by the central government or any officer for the same", Section 77(5).

<sup>63</sup> Section 77(2)

<sup>64</sup> Section 11A(7), Patents [Amendment] Act 2005

The Act enumerated what are ‘not’ inventions and those inventions that are not patentable.<sup>65</sup> Inventions, the primary or intended use or commercial exploitation of which could be contrary to ‘public order<sup>66</sup> or morality’ or which cause serious prejudice to human, animal or plant life or health or to the environment are not patentable.<sup>67</sup> India has incorporated the qualifier of ‘serious prejudice’ to human, animal and plant life or health and has not adopted the standard of ‘necessity’ to protect ‘*ordre public* or morality’ in comparison with Article 27.2.<sup>68</sup> While the TRIPS agreement is silent on the issue of the patentability of ‘new uses’ of known substances, including second or subsequent therapeutic uses for known pharmaceutical products,<sup>69</sup> the 2004 Patents Ordinance qualified ‘new use of a known substance’ with the threshold requirement of ‘mere.’<sup>70</sup> This widened the scope of patentability by narrowing the exception to it. It allowed patents to be granted for second use or new formulations of existing molecules.<sup>71</sup> In response to this concern the Patents [Amendment] Act (2005) has re-formulated the exception, to the stricter standard of a “*mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance* [emphasis added] 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 is also excluded from patentability unless such known processes result in a new product or employ at least one new reactant.” “Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other

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<sup>65</sup> *WTO-TRIPS Obligations and Patents Amendment in India*, K.D. Raju, Page, 228

<sup>66</sup> “[*Ordre Public*] may be interpreted as being narrower than ‘public order’ or ‘public interest,’” *Patents Rights, Intellectual Property and International Trade*, page 192

<sup>67</sup> Section 3(b), 2002 Amendment

<sup>68</sup> Prior to its substitution, clause (b) read as under: (b) an invention the primary or intended use of which would be contrary to law or morality or injurious to public health

<sup>69</sup> A potential weapon in lengthening patent protection past the 20 year minimum

<sup>70</sup> The mere discovery of any new property or ‘mere’ new use for a known substance or of the mere use of a known process, machine or apparatus is also excluded from patentability unless such known processes result in a new product or employ at least one new reactant (Section 3(d))

<sup>71</sup> [http://www.ip-watch.org/weblog/index.php?p=33&res=800\\_ff&print=0](http://www.ip-watch.org/weblog/index.php?p=33&res=800_ff&print=0): “Companies invest heavily in ‘evergreening,’ that is, making some small change to a medicine and seeking a new patent.” Tight definition of patentability allows affordable generic versions of drugs to be produced on the expiry of the 20 year term

derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”<sup>72</sup> The term ‘efficacy’ or the variables to interpret or evaluate it remain un-defined. The Act excludes any process for the medicinal, surgical, curative, prophylactic, diagnostic<sup>73</sup>, therapeutic<sup>74</sup> or other treatment of human beings or any process for the similar treatment of animals *excluding* plants<sup>75</sup> to render them free of disease or to increase their economic value or that of their products<sup>76</sup> from the realm of patentability, in consonance with Article 27(3)(a). The forms of treatment are exponentially defined. Under the 2004 Ordinance a computer programme *per se* (excluding its technical application to industry *or* a combination with hardware) along with mathematical method or business method or algorithm were excluded from patentability.<sup>77</sup> An argument against the provisions of Section 3(k) stipulated that since commercial software has ‘some’ industrial application and that all such applications can be construed as technical applications it opens up software, in general, to patenting.<sup>78</sup> It posed to give rise to multinational monopoly by protecting the ‘idea’ on which the software is developed, further (cost of developing software multiplies, patent thickets form, practice of defensive patenting commences, royalty stack-up’s occur).<sup>79</sup> This is distinct from copyright protection (Section 14 (b), Copyright Act, 1957), which apart from being automatically guaranteed, protects the expression of a ‘function or an idea in the computer code’.<sup>80</sup> It is emphasized that the Indian software industry would be much better served by taking the Free or Open Source route.<sup>81</sup> As per

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<sup>72</sup> Patents Amendment Act (2005), *Explanation* to Section 3(d)

<sup>73</sup> Inserted, 2002 Amendment

<sup>74</sup> *id*

<sup>75</sup> Omitted, 2002 Amendment

<sup>76</sup> Section 3(i)

<sup>77</sup> Sections 3(k) and (ka) respectively

<sup>78</sup> <http://www.smh.com.au/news/Soapbox/Software-patents-a-blow-to-India/2005/02/17/1108609336187.html?oneclick=true>

<sup>79</sup> a dense web of overlapping patents intellectual property rights

<sup>80</sup> <http://www.linux-india.org/index.pl?id=3651&isa=Newsitem&op=show>

<sup>81</sup> <http://www.smh.com.au/news/Soapbox/Software-patents-a-blow-to-India/2005/02/17/1108609336187.html?oneclick=true>

the new Act, the clarification relating to the patenting of software related inventions has been deleted.

In keeping with the issue of ‘biopiracy’ the Indian Government under the 2002 Amendment also excluded an invention which, in effect, is traditional knowledge or which is an aggregation of duplication of known properties of traditionally known component(s), Section 3 (p).<sup>82</sup> India’s initiative in fighting ‘bio-piracy’ was further fortified under the 2004 Ordinance with the inclusion of two new provisions for opposition at the pre and post grant levels. These are, failure to disclose or the incorrect mention of the source of geographical origin of biological material used for the invention in question *and* the invention claimed is anticipated by knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere in the world.

### 2.3.3. *Rights conferred and exceptions to rights conferred:*

Article 28 guarantees exclusive rights to patent owners, defined in a *negative* manner as the faculty to *prevent* certain acts relating to the invention. Exceptions counter-balance the monopoly rights granted by the patent. The *preamble, principles* and *objectives* of the Agreement may be drawn on to carve out exceptions and grant compulsory licenses. Article 30<sup>83</sup> enunciates *limited exceptions*,<sup>84</sup> given that such

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<sup>82</sup> Also excluded under Section 3 are: an invention which is frivolous or which claims anything obvious contrary to well established natural laws (3(a)), a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance (3(e)), the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way (3(f)), a method of agriculture or horticulture (3(h)), literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions (3(l)) [2002 Amendment], a mere scheme or rule or method of performing mental act or method of playing game (3(m)) [2002 Amendment], a presentation of information (3(n)) [2002 Amendment], topography of integrated circuits (3(o)) [2002 Amendment]

<sup>83</sup> In *Canada – Patent Protection of Pharmaceutical Patents* (WT/DS114/R: 17 March 2000-Panel Report), the panel found that the conditions for the application of Article 30 apply *cumulatively* (emphasis added), each being a separate and independent requirement that must be satisfied. Both the goals and the limitations stated in articles 7 and 8.1 must obviously be borne in mind when interpreting the limiting provisions of the Trade Related Aspects of Intellectual Property Rights Agreement.

<sup>84</sup> In *Canada – Patent Protection of Pharmaceutical Patents* (WT/DS114/R: 17 March 2000-Panel Report), ‘limited’ is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact

exceptions (i) do not *unreasonably conflict with a normal exploitation* of the patent<sup>85</sup> and (ii) do not *unreasonable prejudice the legitimate interests* of the patent owner taking into account the legitimate interests<sup>86</sup> of the third parties. Article 31 enumerates *refusal to deal, emergency and extreme urgency, anti-competitive practices, non-commercial use and dependent patents*’ as possible grounds for the concession of patents rights without the authorization of a patent holder for “other use” barring the exceptions provided for under Article 30. It provides a detailed set of conditions<sup>87</sup> to be met for the grant of a compulsory license. These exceptions once interpreted together, ‘may even expand’<sup>88</sup> the

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<sup>85</sup> In *Canada – Patent Protection of Pharmaceutical Patents* (WT/DS114/R: 17 March 2000-Panel Report), the normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity

<sup>86</sup> In *Canada – Patent Protection of Pharmaceutical Patents* (WT/DS114/R: 17 March 2000-Panel Report), ‘legitimate interests’ in this context, must be defined in the way that it is often used in legal discourse - as a normative claim calling for protection of interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms.

<sup>87</sup> The requirement of a proposed user to made efforts within a reasonable period of time to obtain authorization from the right holder on reasonable commercial terms and conditions for a licenses may be waived by a member country in the event of a national emergency, circumstances of extreme urgency or in the case of public non-commercial use (Article 31(b)), the scope and duration of such use shall be limited to the purpose for which it was authorized (Article 31(c)), such use shall be non-exclusive (Article 31(d)), such use shall be non-assignable, *except* with that part of the enterprise or goodwill which enjoys such use (Article 31(e)), such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use (Article 31(f)), subject to the adequate protection of the legitimate interests of the person so authorized, such use will be terminated if circumstances which led to it cease to exist and are unlikely to reoccur (Article 31(g)), the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization and under Article 31(k) the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration (Article 31(h)) *and* members are not obliged to apply Articles 31(b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive (Article 31(k))

<sup>88</sup> *Intellectual Property Rights and International Trade-the TRIPS Agreement, ‘Universal minimum standards of intellectual property protection under the TRIPS component of the WTO Agreement’* Carlos Correa and A.Yusuf, Page 34

pre-existing grounds for limiting a patentee's exclusive right under Article 5A (2-4)<sup>89</sup> of the Paris Convention.

The general purpose for granting a Compulsory License, in India, is to ensure that a patented invention is worked on a commercial scale without undue delay to the fullest extent that is reasonably practicable, while not unfairly prejudicing the interest of the person (for the time being) working or developing a patent.<sup>90</sup> Compulsory licenses also act as an essential tool for governments in facilitating their public health policies. Under Section 83(d) India recognizes that patents should *not* impede the protection of public health and nutrition and should act as an instrument to promote public interest, especially, in sectors of vital importance for socio-economic and technological development. India also recognizes that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public, Section 83(g) reiterated in Section 90(1)(iii).

The Ministerial Declaration on 'The TRIPS Agreement and Public Health' (14<sup>th</sup> of November, 2001) acknowledged the gravity of the health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.<sup>91</sup> Many developing countries and least developed countries cannot manufacture either active ingredients or formulations, due to the lack of technology, equipment, human resources or for want of economic viability of domestic production. Paragraph 6 of the Declaration recognized that WTO members with insufficient or no manufacturing capacity could face difficulties in making effective use

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<sup>89</sup> *Article 5A(3)*- Prohibits forfeiture on grounds of abuse without first trying the remedy of compulsory licensing, even specifying that members have to allow for two years from the grant of the first compulsory license before proceedings for forfeiture can be instituted. *Article 5A(4)*- Requires another time restriction namely, no compulsory license, on grounds of failure to work or insufficient working can effectively be applied for prior to three years from the grant of the patent or four years from the date of filing of the patent application, whichever is longer. The time restriction applies only to the particular case of the application for compulsory licenses on grounds of non-working or insufficient working. An application for compulsory licenses on such grounds is to be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license is to be non-exclusive and non-transferable except in the case of the business entity itself.

<sup>90</sup> Section 89

<sup>91</sup> Paragraph 1

of compulsory licenses under Article 31(f) of the TRIPS Agreement, given that compulsory licensing “shall be authorized *predominantly* for the supply of the domestic market.” The Article forbids producer countries from exporting a ‘predominant’ amount or more of their generic pharmaceutical products to importing countries. Under paragraph 6 the Declaration instructed the TRIPS Council to find an ‘expeditious’ solution to this problem. The Decision adopted by the General Council on the 30<sup>th</sup> of August 2003, chose the mechanism of an ‘interim waiver’<sup>92</sup> of Article 31(h) and Article 31(f) to “an extent necessary for the purposes of the production of pharmaceutical product and its concurrent export to an eligible importing country.”<sup>93</sup> Article 31(b) requiring the grant of a compulsory license to follow an “authorization” from the patent owner on “reasonable commercial terms” within a “reasonable period of time” (*except* in the event of a ‘national emergency, extreme urgency *or* public non-commercial use’<sup>94</sup> or to remedy an anti-competitive practice under Article 31(k)) and Article 31 (h) requiring the payment of compensation taking into account the economic value of the authorization, have not been waived.<sup>95</sup> Where Article 31(b) cannot be waived the “reasonable period of time” must be reduced to expedite the access to pharmaceutical products.<sup>96</sup> The 2005 Act, provides a period of *not exceeding* 6 months.<sup>97</sup> The waiver of Article 31(h) needs to be implemented, domestically, to prevent a claim for compensation in accord with national law. Where a compulsory license is granted in the exporting country, the Decision warrants that ‘adequate remuneration’ taking into account the economic value of the authorization under Article 31(h), may be paid in that member taking into account the

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<sup>92</sup> Temporarily suspends Treaty Obligations under the Trade Related Aspects of intellectual Property Rights, (Article 57 of the Vienna Conventions on the law of treaties)

<sup>93</sup> Paragraph 2

<sup>94</sup> Declaration (5C), “Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”

<sup>95</sup> “The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.” Further, under Article 31(k) anti-competitive practices may be taken into account in determining the remuneration

<sup>96</sup> Also provided for in the Preamble to the Decision, “Where eligible importing members seek to obtain supplies under the system set out in this decision, the importance of a rapid response to those needs...”

<sup>97</sup> Explanation to Section 84(6)(iv)



economic value to the importing country of the use authorized in the exporting country (paragraph 3).

Section 92A(1) of the Ordinance provided that compulsory licenses should be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector “provided [the] compulsory license has been granted in such country”. The Decision provides two alternative ways to establish ‘insufficient or no manufacturing’ capacity (not applicable to Least Developed Countries), *that is* (a) the member has established that it has no manufacturing capacity in the pharmaceutical sector *or* (b) the member has some pharmaceutical manufacturing capacity, has examined its capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. What manufacturing capacity means in either of the options is open to interpretation. It does not include the requirement that an importing country must face a genuine public health problem or that the country lack the resources to purchase needed medicines from the manufacturer.

The latter half of the Section, it appeared, called for an examination by the Indian authorities of whether an importing country had complied with the TRIPS obligation. It was widely argued that it was not for the exporting country to lay down conditions as to how the importing country should comply with the TRIPS provisions. The Ordinance did not establish a system which “as a matter of ‘right’”<sup>98</sup> could provide the Indian pharmaceutical manufacturer with a compulsory license for manufacture and export. So hence, an amendment to the Ordinance has been introduced by the Patents [Amendment] Act 2005 Act. Now, compulsory licenses are available for the manufacture and export of patented pharmaceutical products to any country having ‘insufficient or no manufacturing capacity’ in the pharmaceutical sector for the concerned product to address public health problems, provided that compulsory licenses have been granted by the importing country “*or such country has by notification or otherwise allowed importation of the patented pharmaceutical product from India.*”

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<sup>98</sup> *id*

In general, the TRIPS Agreement should be interpreted and implemented in a manner supportive of the WTO member's rights to protect public health, and in particular to promote access to medicines for all.<sup>99</sup> Each provision of the Agreement should be read in light of the objectives and principles set forth in Article 7 and 8. Such an interpretation finds support in the Vienna Convention on the Law on Treaties which establishes that "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 objects and purpose."<sup>100</sup>

#### **2.4. Conclusion: Important changes proposed in the Patents [Amendment] Act, 2005**

India has amended its Patents legislation successively to bring it in accord with the TRIPS Agreement, the latest of the three amendments being the Patents [Amendment] Act (2005). The final deadline of the 1<sup>st</sup> of January 2005 imposed under the TRIPS Agreement has been met with the introduction of a product patents regime. While the new Act has been hailed as a step towards facilitating greater 'innovation' it has also been criticized as culminating the supply of cheap medicines to the poor.

The 2005 Act has sought to amend the 2004 Ordinance (26<sup>th</sup> December, 2004). Sections 3(k) and 92(1)(A) of the Ordinance pertaining to software patenting and the requirement of 'authorization' respectively, which purported to impose a 'TRIPS plus' requirement have been omitted. The Act has restricted the scope of patentability by modifying the definition of 'inventive step,' it has attempted to curb "evergreening" patents. Through the Act, the government has attempted to preserve a larger public domain or 'patent free zone' around the existing state of art from that provided for under the Ordinance. Parallel imports, to facilitate access to cheaper drugs have been provided for bereft of the earlier required "duly authorized by the patentee" under Section 107A(b). Procedural changes have been incorporated with a period of 6 months

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<sup>99</sup> Declaration on the TRIPS Agreement and Public Health, Paragraph 4

<sup>100</sup> Article 31

quantifying 'reasonable period' in relation to compulsory licenses under. Reasonable royalty has been recognized at 5% for the production of 'on patent' generic drug. A right to representation has been provided for at the pre grant opposition level and the grounds to invoke pre-grant opposition have been expanded.

## 2.5. Procedure

### 2.5.1. Compulsory Licenses

KEY	
Italics Underlined	2005 Act ( <i>tentative</i> )
Bold and Italics	2004 Ordinance + 2005 Rules
Underlined	2002 Act as Omitted+ 2002 Rules

Where, (a) by reason of the refusal of the patentee to grant a license on reasonable terms (i) an existing trade or industry or the development of and establishment of any trade or industry in India is prejudiced []; (ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms ('From manufacture in India', **1970 Act, Omitted under the 2002 Amendment**); (iii) a market for export of the patented article manufactured in India is not being supplied or developed; (iv) the establishment or development of commercial activity in India is prejudiced; (b) if by reason of conditions imposed upon the grant of licenses, or upon the purchase, hire or use of the patented article/process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India is prejudiced; (c) "if the patentee imposes a condition upon the grant of licenses under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing "[**2002 Amendment**]; (d) ('If the demand for the patented article in India if being met to a substantial extent by importation from abroad by,' **1970 Act, Omitted under the 2002 Amendment**) if the patented invention is not worked in India on a commercial scale to an adequate extent or the fullest extent that is reasonably practicable; (e) "if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by the patentee or person claiming under him, persons directly or indirectly purchasing from him, or other persons against whom the patentee is not taking or has not taken proceedings for infringement" [**2002 Amendment**] S. 84(7)

GROUNDS FOR GRANT OF A PATENT: After expiration of 3 years from the date of **sealing of a patent**, any person interested may apply to the controller for the grant of CL, on any of the following grounds: (i) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (ii) that the patented invention is not available to the public at a reasonably affordable price, or (iii) "that the patented invention is not worked in the territory of India" [**2002 Amendment**], S. 84(1). APPLICANT: any person, notwithstanding that he is already a licensee, S. 84(2).

CONSIDERING THE APPLICATION: the controller shall take into account, the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make the full use of the invention, the ability of the applicant to work the invention to the public advantage, the capacity of the applicant to undertake the risk in providing capital and working the invention if the application were granted, "whether the applicant has made efforts to obtain a license on reasonable terms and conditions and such efforts have been unsuccessful in a reasonable period as the Controller deems fit", *shall not ordinarily exceed 6 months* [**2002 Amendment**], determined by controller (*except*, the last requirement shall not apply in cases of a national emergency, circumstances of extreme urgency, or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee prior to the application), S. 84(6). The controller, if satisfied, may grant a license on such terms as he may deem fit, S. 84(4).

If, upon consideration of the evidence, the Controller is satisfied that a *prima facie* case has **not** been made out for the making of an order under Sections 84 he shall notify the applicant accordingly, and unless the applicant requests to be heard in the matter, within **1 month** from the date of such notification, the Controller shall refuse the application [**Rule 97(1)**]. (2) If the applicant requests for a hearing within **1 month**, the Controller shall, after giving the applicant an opportunity of being heard, determine whether the application may be proceeded with or whether it shall be refused [**Rule 97(2)**].

Where the controller is satisfied that the time which has elapsed since the sealing of the patent has for any reason been *insufficient* to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable, he may, *adjourn the further hearing of the applicant* for such period **not exceeding 12 months** as appears to him to be sufficient for the invention to be so worked, *subject to proviso*, S. 86(1)

If the controller is satisfied that a *prima facie* case has been made out under Section 84 the controller shall direct the applicant to serve copies of the application to the patentee and any other person interested in the patent and shall **publish the application in the official journal** [**2004 Ordinance**], S. 87(1). A notice of opposition shall be sent to the Controller within **2 months** from the date of the **publication** [**2004 Ordinance**] of the application [**Rule 98(1)**]. The notice of opposition shall include the terms and conditions of the license, if any, the opponent is prepared to grant to the applicant and shall be accompanied by evidence in support of the opposition [**Rule 98(2)**]. The opponent shall serve a copy of his notice of opposition and evidence on the applicant and notify the Controller when such service has been effected [**Rule 98(3)**]. The Controller shall forthwith fix a date and time for the hearing of the case and shall give the parties no less than 10 days notice of such hearing [**Rule 98(5)**]. The procedure specified in *Rule 62(2)-(5)*, shall apply to the procedure for hearing [**Rule 98(6)**].

If the Controller is satisfied that the manufacture/use/sale of materials *not* protected by the patent is prejudiced by conditions imposed by patentee on the grant of license under the patent/the purchase/hire/use of the patented articles/process, then he *may* order the grant of licenses under the patent as he thinks fit, S. 88(1). After the sealing of the patent, any person who has the right to work any other patented invention either as patentee or licensee (exclusive or not), may apply to the controller for the grant of a license this patent on the ground that he is hindered or prevented without such license from working the other invention *efficiently* or to the *best advantage* possible [cannot work patent without infringing the other or this patent involves important technological advancements or considerable economic significance in relation to the other patent, S. 88(3)], S. 91(1). No such order shall be made, unless the controller is satisfied, that (i) that the applicant is able and willing to grant, or procure the grant to the patentee or his licensees, of a license in respect of the other invention on reasonable terms, (ii) that the other invention has made a substantial contribution to the establishment or development of commercial/industrial activities in the territory of India. Controller may order on the terms he thinks fit the license, "further the license granted by the controller shall be non-assignable except with the assignment of the respective rights" [**2002 Amendment**], S. 91(3). The provisions of Sections 87, 88, 89 and 90 shall apply to licenses granted under this section, S. 91(4).

In setting the terms and conditions of the CL, the controller shall endeavour to secure: royalty and other remuneration reserved to the patentee /other person beneficially entitled to the patent, is *reasonable*, having regard to the nature of the invention/expenditure incurred in making the invention and obtaining a patent/keeping it in force/relevant factors; patented invention is worked to the fullest extent by the person to whom the license is granted, and with reasonable profit to him; patented articles are made available to the public at reasonably affordable prices; license is non-exclusive; right of the licensee is non-assignable; license is for the balance term of the patent unless a shorter term is consistent with public interest; (that the license is granted with a predominant purpose of supplying in the Indian market-*omitted under the 2005 Act*), *provided, that the licensee may also export the patented product in accordance with S. 92A, provided further that in case the license is granted to remedy a practice determined after judicial and administrative process to be anti-competitive, the licensee shall be permitted to export the patented product-omitted under the 2005 Act* [**2004 Ordinance**] *that the license is granted with the predominant purpose of supply in the Indian market and that the licensee may also export the patented product if need be, that in case the license is granted to remedy a practice determined after judicial/administrative process to be anti-competitive, the licensee shall be permitted to export the patented product*, S. 90(1). No license granted by the controller shall authorize the licensee to import the patented article/ article or substance made by a patented process where such importation would constitute an infringement of the rights of the patentee, S. 90(2), *however*, the central government may, if it is necessary in its opinion for the public interest, direct the controller, to authorize, any licensee to import the patented article/article or substance made by a patented process, S. 90(3).

Where the terms and conditions of a license have been settled by the controller, the licensee may, at any time after he has worked the invention on a commercial scale for a period not less than **12 months**, make an application to the controller for the revisions of the terms and condition on the grounds that the terms and conditions have proved more onerous and that the licensee is unable to work the invention, except at a loss, S. 88(4).



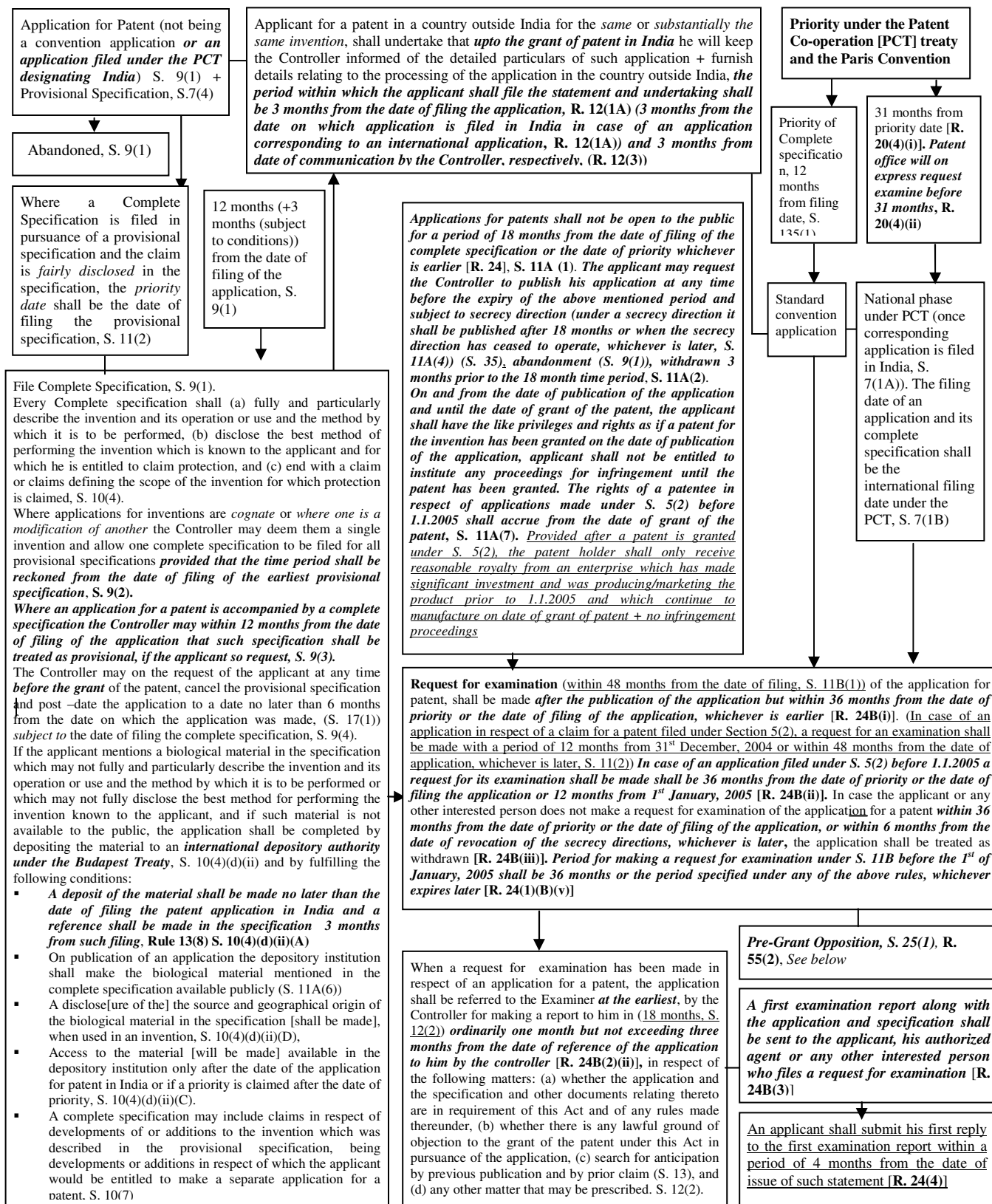
If the Controller is satisfied that a *prima facie* case has **not** been made out for the revision of the terms and condition of the license, he may notify the applicant accordingly and unless within **a month** of the applicant requests to be heard in the matter, the Controller may refuse the application. If the Controller allows the application to be proceed with, he shall direct the applicant to serve copies of the application and of the evidence in support thereof upon the patentee or any other person appearing in the register to be interested in the patent or upon any other person on whom, in his opinion such copies should be served [**Rule 101(1)**]. The patentee or any other person on whom copies of the application and of the evidence has been served, may give to the Controller notice of the opposition within **1 month** from the date of such service. Such notice shall contain the grounds relied upon by the opponent and shall be accompanied by evidence in support of the opposition [**Rule 100(3)**]. On completion of the above proceedings, the Controller shall forthwith fix a date and the time for the hearing of the case and shall give the parties not less than 10 days notice of such hearing [**Rule 100(6)**]. The procedure in *Rule 62(2)-(5)* shall, so far as may apply to the procedure for hearing under this rule as they apply to the hearing of opposition to the grant of patent [**Rule 100(7)**]

On an application by the patentee or any other person deriving an interest/title in the patent, a CL may be terminated by the controller [The application shall be accompanied by the evidence in support of the application [**Rule 102(1)**]], if and when circumstances that gave rise to the grant no longer exist and such circumstances are unlikely to reoccur, S. 94. The applicant shall serve a copy of the application and evidence on the holder of the compulsory license and shall inform the Controller the date on which the service has been effected [**Rule 102(2)**]. The holder of the Compulsory License may file his objection along with the evidence, if any, to the application within **1 month** from the date of receipt of the application and evidence by him to the Controller and serve a copy thereof to the applicant [**Rule 102(3)**]. On completion of the above proceedings, the Controller shall forthwith fix a date and the time for the hearing of the case and shall give the parties not less than 10 days notice of such hearing [**Rule 100(5)**]. The procedure specified in sub-rules *Rule 62 (2)-(5)* so far as may be, apply to the procedure for hearing under this rule as they apply to the hearing of opposition to the grant of patent [**Rule 100(6)**]. "The controller shall take into account that the interest of the person granted the CL is not unduly prejudiced" [**2002 amendment**], S. 94. In the Controller decides to terminate the Compulsory License he shall forthwith issue an order giving terms and conditions, if any, of such termination and serve copies of the order to both the parties [**Rule 100 (7)**]

**SPECIAL PROVISIONS FOR CL ON NOTIFICATIONS BY THE CENTRAL GOVERNMENT:** If the Central Government is satisfied, in respect of a patent in force in circumstances of national emergency, extreme urgency or public non-commercial use, that it is necessary that CL should be granted after the sealing to *work* the invention, then Controller shall grant license to a person interested on terms and conditions as he thinks fit [here, "notwithstanding Section 90(2), where the Controller is satisfied that it is necessary in a circumstance of national emergency/extreme urgency/public non-commercial use including public health crisis, related to AIDS, human immuno deficiency virus, tuberculosis, malaria or other epidemics",[**2002 Amendment**], S. 87 will not apply, S. 92(3)], endeavouring to secure that the articles manufactured under the patent be available to the public at the lowest price consistent with the patentees deriving a reasonable advantage from their patent rights, S. 92(1). Sections 83, 87, 88, 89 and 90 shall apply, S. 90(2). ***Section 92A-(1) CL should be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided CL's have been granted by such countries or such country has by notification or otherwise allowed importation of the patented pharmaceutical product from India, (2) the controller shall, on receipt of an application in the prescribed manner, grant a CL solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him, (3) (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a CL can be exported under any provisions of this Act. For the purpose of this section, 'pharma products' means any patented product, or product manufactured through a patented process, of the pharma sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use [2004 Ordinance]***

## 2.5.2. Patenting Procedure

### 2.5.2.1. Application for Patent to Formal Request for Examination:



## 2.5.2.2.Pre-Grant Opposition

*Opposition to grant of patent: (at any time within 4 months from the date of advertisement of acceptance of complete specification (+1 month)) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of the patent on the ground of: (a) patentability including novelty, inventive step and industrial applicability, or (b) non-disclosure or wrongful mentioning in complete specification, source and geographical origin of biological material used in the invention and anticipation of invention by the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere, or (c) that the patentee or the person under/through whom he claims wrongfully obtained the invention or any part thereof from him or from a person under/through whom he claims, (d) that the invention so far as claimed in any claim of complete specification has been published before the priority date of the claim in any specification filed in pursuance of an application for a patent made in India on or after 1<sup>st</sup> January, 1912, in India or elsewhere in any document, (e) that the invention is claimed in a complete specification published on or after the priority date of the claim of the patentee and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the claim of the patentee, (f) that the invention claimed in the complete specification was publicly known or used in India before the priority date of that claim (here, an invention relating to a process for which a patent is granted shall be deemed to have been publicly known or publicly used in India before the priority date of a claim if the product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only), (g) that the invention claimed is obvious and does not involve an inventive step, having regard to (b) or having regard to what was used in India before the priority date of the claim, (h) that the subject of any claim of complete specification is not an invention or not patentable, (i) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed, (j) that the patentee has failed to disclose to the Controller the information required by S. 8 or has furnished information which in any material particular was false to his knowledge, (k) that in the case of a patent granted on convention application, the application for the patent was not made within 12 months from the date of the first application for protection for the invention made in a convention country or in India, (l) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention, (m) that the invention so far claimed in any claim of complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, S. 25(1). The Controller shall if requested by such persons for being heard, hear him and dispose of the representation in such manner and within such period as may be prescribed. (A person making a representation shall not be made party to any proceeding under this Act only for the reason that he has made such representation, S. 25(2))*

*Opposition by representation: Representation for opposition shall be filed within a period not exceeding (within 4 months from the date of advertisement of the acceptance of the complete specification, R. 56(1) six three months from the date of publication of the application under 11A, or before the grant of patent, whichever is later, and shall include a statement and evidence, if any, in support of the representation and a request for hearing if so desired [Rule 55 (1)]*

*On receipt of the notice of opposition, the controller shall by order constitute an opposition board and it shall submit a report with recommendations three months from the date on which the documents were forwarded to them [Rule 56]*

*On receiving the notice, the applicant shall, if he so desires, files his statement and evidence, if any in support of his application within one month from the date of notice [Rule 55(4)]*

*On consideration of the statement and evidence filed by the applicant, the controller may refuse to grant a patent on the application or require the complete specification to be amended to his satisfaction before the grant of the patent [Rule 55(5)]*

*After considering the representation and submission made during the hearing if so requested, the controller shall proceed further simultaneously either rejecting the representation and granting the patent or accepting the representation and refusing the grant of the patent on that application, ordinarily within one month from the completion of the above proceedings [Rule 55(6)]*

*Filing of written statement of opposition and evidence: The opponent shall send a written statement setting out the nature of the opponent's interest, the facts upon which he bases his case and relief which he seeks and evidence, if any, along with notice of opposition (or within 2 months from the date of the notice of opposition) and shall deliver to the applicant a copy of the statement and the evidenced [Rule 57]*

*If the (applicant) patentee desires to contest the opposition, he shall leave at the appropriate office a reply statement setting out fully the grounds upon which the opposition is contested and evidence, if any by him under Rule 57 and delivery to the opponent a copy thereof [Rule 58(1)]. If the applicant does not desire to contest or leave his reply and evidence within the period as specified in sub-rule (1), the shall be deemed to have been revoked [Rule 58(2)]*

*The opponent may, within 1 month from the date of delivery to him of a copy of the (applicant's) patentees reply statement and evidence under Rule 58, leave at the appropriate office evidence in reply strictly confined to matters in the applicants evidence and shall deliver to the applicant a copy of such evidence [Rule 59]*

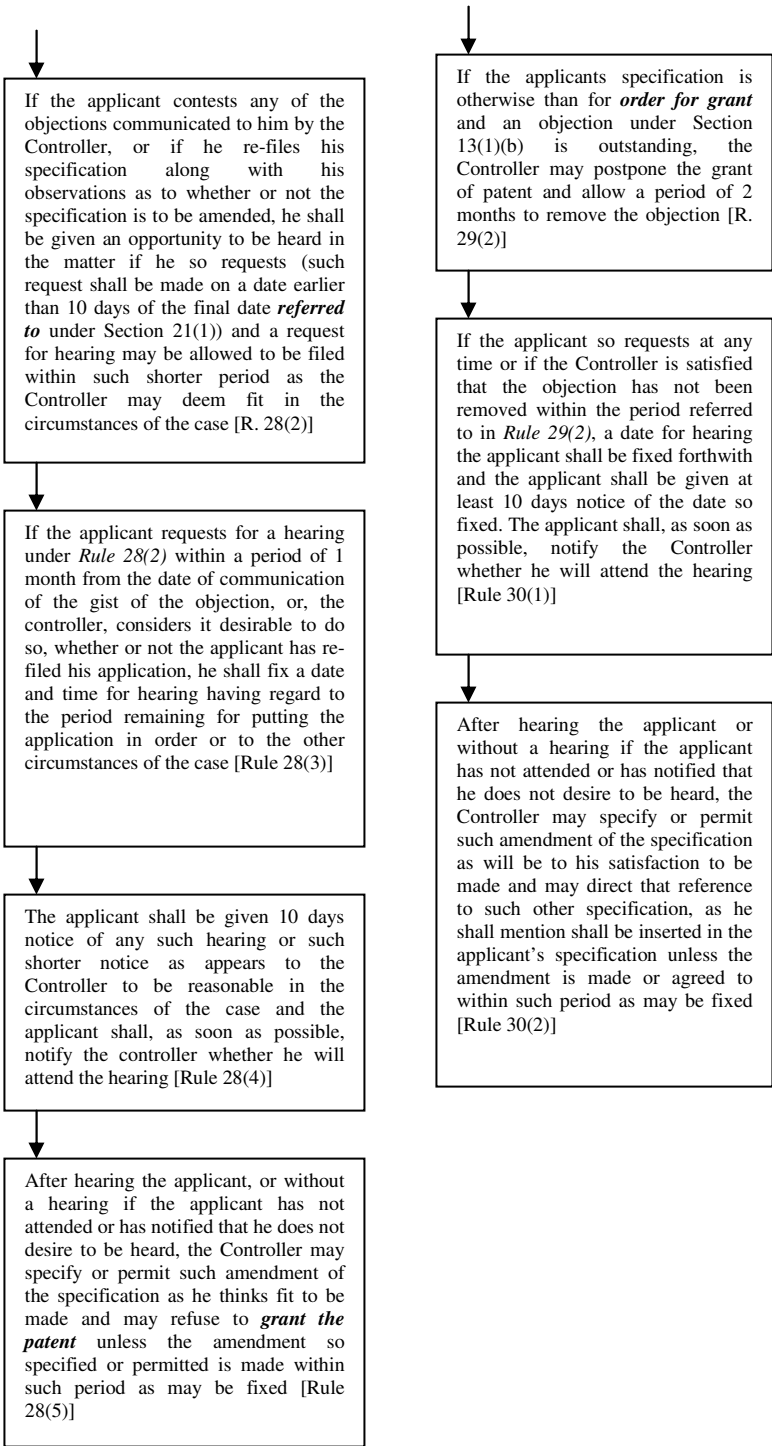
*No further evidence shall be delivered by either party except with the leave or the direction of the Controller, provided that such leave or direction is prayed before the controller has fixed the hearing under Rule 62 [Rule 60]*

*On the completion of the presentation of evidence or on receiving the recommendation of the Opposition Board or at any other time as the Controller may think fit, he shall forthwith fix a date and time for the hearing of the opposition and shall give the parties not less than 10 days notice of such hearing [Rule 62(1)] If either party to the proceeding desires to be heard, he shall inform the controller by notice [Rule 62(2)] The Controller may refuse to hear any party who has not given notice [Rule 62(3)]. After hearing the party or parties desirous of being heard, or if neither party desires to be heard, then without a hearing, and after taking into consideration the recommendation of the opposition board, the Controller shall forthwith decide the opposition and notify his decision to the parties giving reasons thereof [Rule 62(4)]*

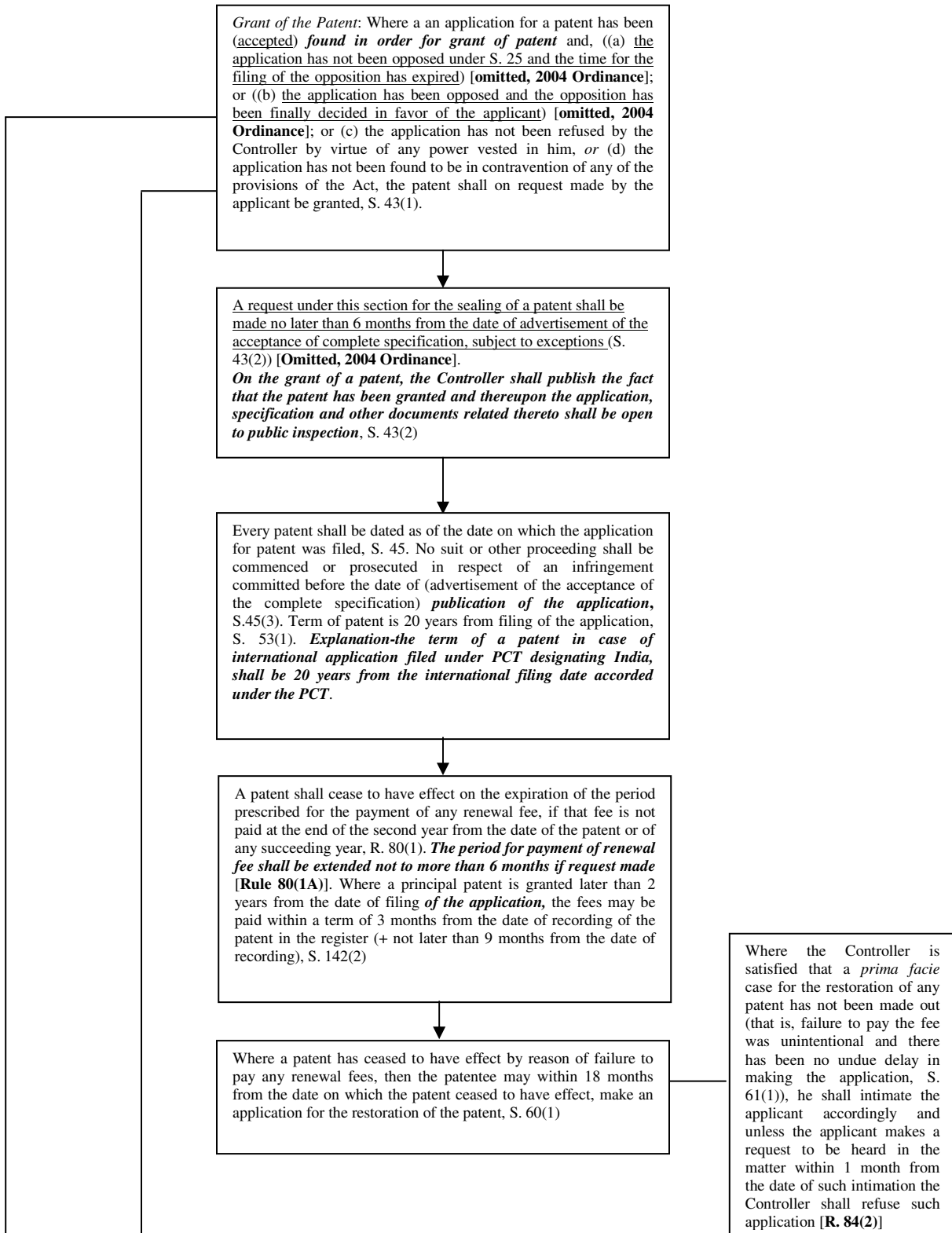
### 2.5.2.3. Formal Request for Examination to Acceptance







## 2.5.2.4. Grant of Patent to Renewal



*Opposition to grant of patent:*  
*At any time after the grant but before the expiry of a period of one year from the date of publication of grant of patent, any person interested may give notice of opposition to the Controller on the following grounds, S. 25(3):*

*(a) that the patentee or the person under/through whom he claims wrongfully obtained the invention or any part thereof from him or from a person under/through whom he claims,*

*(b) that the invention so far as claimed in any claim of complete specification has been published before the priority date of the claim in any specification filed in pursuance of an application for a patent made in India on or after 1<sup>st</sup> January, 1912, in India or elsewhere in any document,*

*(c) that the invention is claimed in a complete specification published on or after the priority date of the claim of the patentee and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the claim of the patentee,*

*(d) that the invention claimed in the complete specification was publicly known or used in India before the priority date of that claim (here, an invention relating to a process for which a patent is granted shall be deemed to have been publicly known or publicly used in India before the priority date of a claim if the product made by that process had already been imported into India before that date except where such importation has been for the purpose of reasonable trial or experiment only),*

*(e) that the invention claimed is obvious and does not involve an inventive step, having regard to (b) or having regard to what was used in India before the priority date of the claim,*

*(f) that the subject of any claim of complete specification is not an invention or not patentable,*

*(g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed,*

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

*(i) that in the case of a patent granted on convention application, the application for the patent was not made within 12 months from the date of the first application for protection for the invention made in a convention country or in India,*

*(j) that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention,*

*(k) that the invention so far claimed in any claim of complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.*

Where the applicant requests for a hearing within the time allowed and the Controller, after giving the applicant such a hearing, is *prima facie* satisfied that the failure to pay the renewal fees was unintentional, he shall (advertise) *publish* the application *in the Official Gazette* [R. 84(3)]

Opposition to restoration at any time within 2 months from the date of (advertisement) *publication* of the application *in the Official Gazette* [R. 85(1)]. The procedure specified in *Rules 57 to 62*, apply to the hearing of the opposition [R. 84(3)]

Where the Controller decides in favour of the applicant, the applicant shall pay the unpaid renewal fees and the additional fees, within 1 month from the date of the order of the Controller allowing the application for restoration [Rule 86(1)]

*Opposition by representation:* Representation for opposition shall be filed within a period not exceeding (within 4 months from the date of advertisement of the acceptance of the complete specification, R. 56(1)) six *three months from the date of publication of the application under IIA, or before the grant of patent, whichever is later, and shall include a statement and evidence, if any, in support of the representation and a request for hearing if so desired* [Rule 55 (1)].

*On receipt of the notice of opposition, the controller shall by order constitute an opposition board and it shall submit a report with recommendations three months from the date on which the documents were forwarded to them* [Rule 56]

*On receiving the notice, the applicant shall, if he so desires, files his statement and evidence, if any in support of his application within one month from the date of notice* [Rule 55(4)]

*On consideration of the statement and evidence filed by the applicant, the controller may refuse to grant a patent on the application or require the complete specification to be amended to his satisfaction before the grant of the patent* [Rule 55(5)]

*After considering the representation and submission made during the hearing if so requested, the controller shall proceed further simultaneously either rejecting the representation and granting the patent or accepting the representation and refusing the grant of the patent on that application, ordinarily within one month from the completion of the above proceedings* [Rule 55(6)]

**Filing of written statement of opposition and evidence:** The opponent shall send a written statement setting out the nature of the opponent's interest, the facts upon which he bases his case and relief which he seeks and evidence, if any, along with notice of opposition (or within 2 months from the date of the notice of opposition) and shall deliver to the applicant a copy of the statement and the evidenced [Rule 57]

*Revocation of Patents:*

(1) A patent may be revoked on a petition of any person interested or of the Central Government *by the Appellate Board (S, 117D(1))* or on a counter claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say, S. 64(1):

(a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India;

(b) that the patent was granted on the application of a person not entitled under the provisions of this Act to apply therefore (an application for a patent may be made by any of the following persons, that is to say (a) by any person claiming to be the true and first inventor, (b) by any person being the assignee of the person claiming to be the true and first inventor, (c) by the legal representative of any deceased person who immediately before his death was entitled to make such an application, S. 6);

(c) that the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims;

(d) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;

(e) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in section 13 [no account shall be taken of personal document or secret trial or secret use and (ii) where the patent is for a process or for a product as made by a process, the importation of the product into India made abroad by the process shall constitute knowledge or use in India of the invention on the date of the importation, except where such importation has been for the purpose of reasonable trial or experiment only, S. 64(2)];

(f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim [no account shall be taken of personal document or secret trial or secret use and (ii) where the patent is for a process or for a product as made by a process, the importation of the product into India made abroad by the process shall constitute knowledge or use in India of the invention on the date of the importation, except where such importation has been for the purpose of reasonable trial or experiment only, S. 64(2)];

(g) that the invention, so far as claimed in any claim of the complete specification, is not useful;

(h) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;

(i) that the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification;

(j) that the patent was obtained on a false suggestion or representation;

(k) that the subject of any claim of the complete specification is not patentable under this Act;

(l) that the invention so far as claimed in any claim of the complete specification was secretly used in India, otherwise than as mentioned in sub-section (3), before the priority date of the claim [no account shall be taken of any use of the invention, (i) for the purposes of reasonable trial or experiment only, (ii) be the government/any person authorized by the government/government undertaking, in consequence of the applicant for the patent or any person from whom he derives title having communicated or disclosed the invention directly or indirectly to the government or person authorized or to the government undertaking, S. 64(3)];

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

(n) that the applicant contravenes any direction for secrecy passed under section 35 or made or caused to be made an application for the grant of a patent outside India in contravention of section 39 (2002Amendment));

(o) that leave to amend the complete specification under section 57 or section 58 was obtained by fraud;

(p) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(q) that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere..

A patent may be revoked by the High Court on the petition of the Central Government, if the High Court is satisfied that the patentee has without reasonable cause failed to comply with the request of the Central Government to make/use/exercise the patented invention for the purposes of the government within the meaning of section 99 (any machine, apparatus, article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made or on behalf of the government for the purpose merely of its own use; any process in respect of which the patent is granted may be used by or on behalf of the government for the purpose merely of its own use; any machine, apparatus or other article in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted or may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils and; in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution which the central government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette upon reasonable terms, S. 64(4).

Where the central government opines that a patent or the mode in which it is exercised is mischievous to the state or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect the official Gazette and then the patent shall be deemed revoked, S. 66

- These grounds shall also be available as a defence in any suit for infringement of a patent, S. 107(1)
- In any proceeding before the Appellate Court or the High Court for the revocation of a patent (where the application for an amendment is made after the *grant of a patent* and the nature of the proposed amendment is substantive, the application shall be *published*, R. 81(3)(a), any person interested in opposing the application shall give a notice of opposition within 3 months from the date of *publication*, R. 81(3)(b), Rules 57-63 shall apply), the Appellate Board or the High Court may, subject to S. 59 (amendment of an application, complete specification shall be made only by way of disclaimer, correction or amendment, amendment shall be allowed for the purpose of incorporating actual fact and no amendment of a complete specification shall be allowed where the amended specification would claim or describe matter not in substance disclosed or shown in the specification before amendment, or the claim of the specification as amended would not fall wholly in the scope of the claim of the specification before the amendment) allow the patentee to amend his complete specification in such manner and subject to such conditions as the court thinks fit, and if, in any proceeding for revocation, the Appellate Board or High Court decides that the patent is invalid, it may allow the specification to be amended instead of revoking the patent, S. 58(1).

If the (*applicant*) *patentee* desires to contest the opposition, he shall leave at the appropriate office a reply statement setting out fully the grounds upon which the opposition is contested and evidence, if any by him under Rule 57 and delivery to the opponent a copy thereof [Rule 58(1)]. *If the applicant does not desire to contest or leave his reply and evidence within the period as specified in sub-rule (1), the shall be deemed to have been revoked [Rule 58(2)]*

The opponent may, within 1 month from the date of delivery to him of a copy of the (*applicant's*) *patentees* reply statement and evidence under Rule 58, leave at the appropriate office evidence in reply strictly confined to matters in the applicants evidence and shall deliver to the applicant a copy of such evidence [Rule 59]

No further evidence shall be delivered by either party except with the leave or the direction of the Controller, provided that such leave or direction is prayed before the controller has fixed the hearing under Rule 62 [Rule 60]

On the completion of the presentation of evidence or *on receiving the recommendation of the Opposition Board* or at any other time as the Controller may think fit, he shall forthwith fix a date and time for the hearing of the opposition and shall give the parties not less than 10 days notice of such hearing [Rule 62(1)] If either party to the proceeding desires to be heard, he shall inform the controller by notice [Rule 62(2)] The Controller may refuse to hear any party who has not given notice [Rule 62(3)]. After hearing the party or parties desirous of being heard, or if neither party desires to be heard, then without a hearing, *and after taking into consideration the recommendation of the opposition board*, the Controller shall forthwith decide the opposition and notify his decision to the parties giving reasons thereof [Rule 62(4)]

## End Notes

Article 27(3) of the TRIPS Agreement provides a choice in protecting plant varieties. Member may choose from patents, a *sui generis* system or a combination of the two. The *sui generis* system (translating roughly into *self-generating*) means any system a country decides on, provided it grants effective plant breeders rights.<sup>101</sup> The Indian legislation has sought to balance plant breeder's rights with farmer's rights. The Indian Legislation is the first to grant formal rights to farmers in a way that their self-reliance not jeopardized.<sup>102</sup> The Indian Parliament enacted the *Protection of Plant Varieties and Farmer's Rights Act, 2001* on November 15, 2001.

The Act aims to establish "an effective system for the protection of plant varieties, the rights of farmers and plant breeders, to encourage the development of new varieties of plants." The three key aims of the Act are: (i) the protection of the rights of farmers for their contribution made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties, (ii) the protection of plant breeders rights to stimulate investment for research and development, both in the public and the private sector, for the development of new plant varieties,<sup>103</sup> and (iii) giving effect to Article 27.3(b) of the TRIPS Agreement on plant variety protection.<sup>104</sup>

**Application:** Application for registration must be confined to a single variety and variety should not contain any gene or gene sequence involving terminator technology (S. 18(1)(c)). The applicants must provide the complete passport data of the parental lines from which the variety has been derived along with the geographical location in India from where the genetic material has been taken (S. 18(1)(h)). Breeders are to submit an affidavit that their variety does not contain a Gene Use Restricting Technology. The applicants will also have to provide all information about the contribution, if any, of any farmer, village community, institution or organization in the breeding, evolution or development of the variety and also information on the use of genetic material conserved by any tribal or rural families in its breeding S. 40(1) (S. 18(1)(d)). The above conditions will not, however, apply to the registration of farmers varieties (S. 18(1)). Applications from the foreign nationals will be entertained provided the country grants the same rights to Indian citizens in respect of registration of plant varieties (*AAPA News, No.30, June 2003*).

**Advertisement of application:** After the variety has been registered, it is published in the gazette of India inviting claims of benefit sharing from those who have contributed genetic material for the development of the variety. Opposition to the registration may be made on the following grounds, (a) that the person opposing the application is entitled to the breeders right as against the applicant, *or* (b) the variety is not registrable under the act *or* (c) the grant of certificate of registration may not be in public interest *or* (d) that the variety may have adverse effect on the environment, S. 21(3)) (*AAPA News, No.30, June 2003*).

**Researcher's Rights:** Use of the variety for research/experimentation and for creating other varieties is permitted under the Act, S. 30. However, for repeated use as parental line for commercial production, permission from the breeder must be taken, S. 30 (*AAPA News, No.30, June 2003*).

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<sup>101</sup> 'India's Plant Variety Protection and Plant Breeders Act, 2001,' Suman Sahai

<sup>102</sup> *id*

<sup>103</sup> Rights recognized under the legislation extend, for seed and/or propagating material of the protected variety, to: (i) production, (ii) selling, (iii) marketing, (iv) distribution, (v) export, (vi) import, these rights are consistent with those that have been provided under UPOV '91

<sup>104</sup> (1) New varieties [any *new* plant variety that conforms to the criteria of *novelty, distinctiveness, uniformity and stability* can be registered, S.15(1). The 'distinctiveness, uniformity and stability' criteria are the same as in the UPOV (*AAPA News, No.30, June 2003*)]. (2) Essentially derived variety [having one of the following characteristics, (a) predominantly derived from an initial variety while retaining the expression of the essential characteristics that result from the genotype or combination of the genotype of such initial variety, (b) any variety that is clearly distinguishable from initial variety, or (c) conforms to such initial variety in the expression of the essential characteristics that result from the genotype or combination of genotype of such initial variety, S. 2(i) (Similar to that in UPOV 1991)] that differ from the patent variety by one or more characteristics can also be registered. (3) Extant variety [(i) varieties that have been notified under the Seeds Act, 1996, (ii) farmers varieties, and (iii) varieties about which there is common knowledge, and (iv) any other variety that is in the public domain], S. 2(j), and (4) Farmers Varieties [(i) varieties that have been traditionally cultivated and evolved by farmers in their fields and (ii) a wild relative or landacre of a variety about which farmers possess common knowledge], S. 2(l)

Farmer's Rights: a farmers who has bred or developed a new variety shall be entitled for registration and other protection in like manner as the breeder or a variety under this Act, S. 39(1)(i)

A farmer who is engaged in the conservation of genetic resources of land races and wild relatives of economic plants and their improvement through selection and preservation shall be entitled in the right prescribed manner for recognition and reward from the Gene Fund, provided that the material so selected and preserved has been used as donors of genes in varieties registrable under this Act, S. 39(1)(iii)

The provisions of the Act do not affect the right of a farmer to save, use, exchange, sell or share his farm produce, if the produce relates to a variety protected under the act. S. 39(1)(iv). This is different from farmers exemptions granted under the UPOV, which were in the norm of 'plant back rights,' that is, the right to save seeds from the harvest to sow the next crop. The farmer is not entitled to sell '*branded* seed [any seed put in a package or any other container and labeled in a manner indicating that such seed is of a variety protected under the act]of a variety protected under this act, S. 39(1).

Where any propagating material of a variety registered under this Act has been sold to farmers, the breeder shall disclose expected performance under given conditions if the seeds fail to provide the same the farmers may claim compensation, S. 39(2).

Benefit-Sharing: After registration of the variety, any person or group of persons may stake a claim of 'benefit sharing' in the claimed variety by notifying the authority. after due investigation, the authority may order that a compensation be paid to the claimant (person/group of persons/non-governmental organizations) based on (a) the extant and the nature of the use of genetic material of the claimant in the development of the variety relating to which the benefit sharing has been claimed, and (b) the commercial utility and the demand in the market of the variety relating to which the benefit sharing has been claimed, the compensation shall be deposited at the gene fund, S. 26 (AAPA News, No.30, June 2003).

Compulsory Licensing: after three years from the date of issue of a certificate of registration of a variety, any interested person may make an application alleging that reasonable requirements of the public for seeds or other propagating material of the variety have not been satisfied, or that seeds are not available to the public at a reasonable price, and may pray for grant of cl, S. 47.

Rights of communities: any person/group of persons (actively engaged in farming or not/non-governmental organizations), may on behalf of any village or community in India, file with the approval of the central government, any claim attributable to the contribution of the people of that village or local community, in the evolution of any variety for the purpose of staking a claim on behalf of such village or local community, compensation to be paid to gene fund, S. 41.

Protection of innocent infringement: Rightly assuming that farmers may unknowingly infringe breeders' rights since they will not be used to the new situation, the law provides for protection from prosecution for innocent infringement, S. 42