

Abstract

Robyn Ott is a third-year law student at the University of Oklahoma College of Law. She is also the Managing Editor of the Oklahoma Journal of Law and Technology for the 2004-2005 academic year. Ms. Ott wrote this eBrief under the direction of Professor Drew Kershen while working on the Project on Intellectual Property Rights in Living Matter. Below, Ms. Ott discusses the legal effect of India's Patents Act and the general requirements for determining the patentability of living matter under the Act.

Edited by Greg Milstead and Robyn Ott

APPLYING THE PATENTS ACT TO LIVING MATERIALS IN INDIA

© 2004 Robyn Ott

I. Introduction

India is a member of the Trade Related Aspects of the Intellectual Property Systems (TRIPS) agreement, and is therefore required to meet minimum intellectual property right standards.¹ Specifically, Article 27(1) requires TRIPS member states to grant patents for any invention in all fields of technology.² However, TRIPS does allow states to exempt certain substances and processes from patentability.³

The Patents Act of 1970 (Patents Act) regulates India's patent system. The Patents Act has fulfilled all of the temporary TRIPS requirements⁴ and details what is not patentable in India.⁵ This eBrief provides specific application of the Patents Act to inventions involving living materials in India, including plants, animals, microorganisms and other biological material, by outlining the inventions explicitly patentable under the

¹ *Patents*, INDIAIP.COM, at http://www.indiaip.com/patents_article.htm (last visited Mar. 19, 2004).

² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments--Results of the Uruguay Round vol. 31, art. 27(1), 33 I.L.M. 81 (1994) [hereinafter TRIPS] at http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5 (last visited Mar. 6, 2004). Patents are to be granted if they are new, involve an inventive step, and are capable of industrial application. *Id.*

³ *Id.* art. 27(3)(b).

⁴ Press, Information, and Culture Wing, Embassy of India, *US and European Commission Commend India's Initiatives on Patents*, INDIA NEWS ONLINE (May 1999), at http://www.indianembassy.org/inews/May_1999/foreign.html (last visited Mar. 6, 2004).

⁵ Patents Act § 3 (1970) (Act 39 of 1970) (India).

act and then detailing the potential obstacles for intellectual property rights in living material and processes creating living material that are not *per se* patentable.

II. Patentable Living Material in India

Article 27(3)(b) of TRIPS allows member states to deny patents for “plants and animals, other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.”⁶ As a result, TRIPS requires patents of microorganisms, non-biological, and microbiological processes.⁷ Further, animal and plant parts, and altered plants and animals are not explicitly included in the exemption, which means TRIPS may also require patenting of biological organisms.⁸ Some commentators have determined, however, that “since plants and animals are excluded, parts would also be excluded.”⁹

Complying with TRIPS, the Patents Act, as amended in June 2002, gives patent rights for new microorganisms.¹⁰ Other areas involving microorganisms are also patentable in India. For example, a synergistic composition containing the microorganism, which is either new or known, and a process using microorganisms to

⁶ TRIPS, *supra* note 2, art. 27(3)(b). States are allowed to provide for plant patents with an effective sui generis system. *Id.*; see Robyn Ott, *Protection of Plant Varieties and Farmers Rights Act*, 2 OKLA. J.L. & TECH. 14 (2004), available at <http://www.okjolt.org/published/2004okjoltrev14.html> [hereinafter Ott, *Protection*].

⁷ Someshwar Singh, *Patents on Life Forms Should Be Re-Examined, says India*, SUNS SOUTH-NORTH DEVELOPMENT MONITOR, Oct. 27, 1999, at http://www.gefoodalert.org/News/news.cfm?News_ID=1147 (last visited Mar. 19, 2004).

⁸ Vandana Shiva, *Ecologists Should Worry About the Dunkel Draft*, SUNS SOUTH-NORTH DEVELOPMENT MONITOR, Sept. 23, 1993, at <http://www.sunsonline.org/trade/areas/environm/09230193.htm> (last visited Mar. 28, 2004).

⁹ Singh, *supra* note 7. If the biological areas are excluded, the biological material can still receive a patent if that material is also chemical, like artificial enzymes for example. The material would be patented as chemicals. *Id.*

¹⁰ Patents (Amendment) Act § 4(e) (June 25, 2002) (No. 28 of 2002) (India) [hereinafter Patents (Amendment) Act].

produce a substance can both be patented.¹¹ Also, the process of biosynthesis of a new microorganism is patentable.¹² Microorganisms that are lyophilized as an end product are patentable.¹³

The Calcutta High Court in India has addressed the issue of whether a process involving microorganisms that are living as an end product can be patented in a 2002 case.¹⁴ It should be noted here that the definition of invention, which was litigated in the case, has been amended since this case was decided.¹⁵ Prior to the case, the applicant had requested a patent for the process of creating a vaccine to protect poultry from infectious bursitis.¹⁶ The Controller of Patents determined the process was not an invention because the end product produced by the process contained a living organism, and thus was not patentable.¹⁷ The applicant appealed the Controller's decision to the Calcutta High Court. The Controller claimed a patent is given only for a process that results either in an

¹¹ N.R. Subbaram, *Protection of Biotech Inventions*, HINDU, Dec. 29, 2003, at <http://www.hindu.com/biz/2003/12/29/stories/2003122900321600.htm> (last visited Mar. 19, 2004). These processes are patentable subject to the requirements for patentability under the patents act, which specifically requires a new process that involves an inventive step; see Robyn Ott, *Patentability of Plants, Animals and Microorganisms in India*, 2 OKLA. J.L. & TECH. 16 (2004), available at <http://www.okjolt.org/published/2004okjoltrev16.html> [hereinafter Ott, *Patentability*].

¹² Subbaram, *supra* note 11.

¹³ *Dimminaco A. G. v. Controller of Patents Designs and Ors.*, AID No. 1 of 2001, Jan. 15, 2002. Lyophilization (or freeze drying) is "the process of removing water from a frozen biomaterial via application of a vacuum." KIMBALL R. NILL, GLOSSARY OF BIOTECHNOLOGY TERMS 148 (2d ed. 1998).

¹⁴ *Id.* This case, however, held a living end product was an invention based on the old Patents Act definition of invention. *Id.*

¹⁵ The definition of invention was amended six months after this case was decided; see Ott, *Patentability*, *supra* note 11.

¹⁶ *Dimminaco*, AID No. 1 of 2001.

¹⁷ The Controller of Patents argued that the process could not be considered a manufacture or substance, under the old definition, meaning the process could not be an invention. *Id.* Under the old definition, an invention was "any new and useful (i) art, process, method or manner of manufacture; (ii) machine, apparatus or other article; [or] (iii) substance produce by manufacture, and includes any new and useful improvement of any of them, and an alleged invention." Under the new definition, these specific classifications are not required, see Patents (Amendment) Act § 3(f).

article, substance, or manufacture and a vaccine with a living organism is not an article,¹⁸ substance,¹⁹ or manufacture. The court used the normal dictionary meaning of manufacture, because it was not defined in the Patents Act, and determined manufacture is where “the material in question after going through the process of manufacture has under-gone any change by the inventive process and it becomes a material which is different from the starting material.” The court determined this meaning does not exclude the process of preparing a product that contains a living substance from patentability. The court found that no statute precluded a living end product from the definition of manufacture. Also, the court decided that “since the claim process for patent leads to a vendible product,²⁰ it is certainly a substance after going through the process of manufacture.”²¹ The court ultimately concluded that “a new and useful art or process is an invention,” and because the process is new and useful, it “is apparently patentable under section 5²² read with section 2(j)(i)”²³ of the Patents Act. The court determined that “where the end product is a new article, the process leading to its manufacture is an invention.”²⁴ Although the definition of invention has been amended, this change may actually enhance the court’s invention argument, because now the elements of manufacture, article, or substance are no longer required. Rather, the new

¹⁸ The Controller claimed the dictionary meaning of article is a “material thing, item, a thing of a particular class or kind as distinguished from a thing of any class of kind.” The Controller said the definition does not cover living things. *Dimminaco*, AID No. 1 of 2001.

¹⁹ The Controller showed “substance” is not defined in the Patents Act, and thus the dictionary meaning of “species of matter of a definite chemical composition or a solid or real thing as opposed to appearance or shadow” or “the muscular tissue or fleshy art of any animal body” also did not describe a living thing. *Id.*

²⁰ The court details the requirements of a vendible product, see discussion of vendible products *infra*.

²¹ *Dimminaco*, AID No. 1 of 2001.

²² Section 5 says a product intended for use, or capable of being used, as food or medicine or drug, or which is created by a chemical process is not patented.

²³ Section 2(j)(i) is the definition of invention under the old Patents Act.

²⁴ *Dimminaco*, AID No. 1 of 2001.

definition merely calls for a new, non-obvious and useful product or process.²⁵ As noted above, the court determined the vaccine was new and useful and made no discussion about the end product containing living material in reaching this conclusion. However, other changes to the act may change the case's outcome. For example, section 3(j) was added to the Patents Act after this case and now excludes essentially biological processes for production or propagation of plants and animals from the definition of invention. In that case, the court cautioned that claims for patentability should "be considered by the controller on the principle of section 3" of the Patents Act.

In secondary arguments, the Controller of Patents also claimed the process was not patentable because it was a substance prepared by a process that is capable of being used as food or drug. This second argument was quickly disregarded because the applicant had applied for a patent on the process for the preparation of the vaccine instead of applying for a patent on the product.²⁶ The case also found that administrative policies, such as those of the Patents Office, cannot override statutory provisions like the Patents Act.²⁷ As a result, this decision may "caution the Patent Office from further use of obscure administrative policies to override statutory provisions."²⁸ Although the court found the end product containing a living organism was patentable, the court did explain

²⁵ See discussion *infra*.

²⁶ Section 5 of the Patents Act prohibits the product from patentability where the product is intended for use or capable of being used as, among other things, medicine or drug. The applicant, however, was only patenting the process, which is allowed under the Patents Act. This portion of Section 5 is from the original Patents Act and was not changed in the subsequent amendments, see Ott, *Patentability*, *supra* note 11.

²⁷ *Dimminaco*, AID No. 1 of 2001.

²⁸ *Manufacture Applies to Living Organism*, BUSINESS LINE, at <http://www.patentmatics.com/news2002/news25.htm> (last visited Mar. 28, 2004) (citing Samarash Chakraborty, attorney for the applicant).

that a claim that a product or process is patentable, because it fits the definition of invention, must be decided on the facts of each case.²⁹

In addition to microorganisms, India has provided guidance for the patentability of other living materials. However, the Patents Act differs significantly from TRIPS by explicitly denying patent rights for any part of plants or animals including seeds, varieties, and species.³⁰ Moreover, the Patents Act has elected to place chemical processes, including biochemical, biotechnological and microbiological processes in a specific section of the act that only grants patent rights to the chemical process but not the substance.³¹ For example, the process of creating a biochemical substance is patentable, but the substance itself cannot be patented. TRIPS has given India, and other developing countries until January 1, 2005 to achieve full compliance with TRIPS,³² which includes providing product patents for life forms of non-biological, microbiological³³ and biological processes.³⁴

India has also placed substances intended for or capable of being used as food or medicine in the section that provides only for process patents.³⁵ As a result, substances for use in diagnostic kits and drug delivery systems that were developed by the use of

²⁹ *Dimminaco*, AID No. 1 of 2001.

³⁰ Patents (Amendment) Act § 4(e).

³¹ Patents Act § 5(1)(b).

³² Comments to the Patents (Amendment) Act indicate that “it is unlikely that the Act will be amended before [January 2005] to allow product patent[s]” Ministry of Law, Justice and Company Affairs, *Extraordinary*, (No. 42, June 25, 2002) at

<http://www.dpahuja.com/newpatentsact/Patent%20Act%202002%20and%20Comments.pdf> (last visited Mar. 28, 2004).

³³ TRIPS, *supra* note 2, art. 65(4), see Ott, *Patentability*, *supra* note 11.

³⁴ Shiva, *supra* note 8. If TRIPS does not allow for plant and animal parts, and altered plants and animals, then these biological process exclusions must be removed from the Patents Act in order for India to become TRIPS compliant, meaning the Patents Act will be required to allow patents for biological organisms.

³⁵ Patents Act § 5(1)(a).

plasmids and DNA, are not patentable in India.³⁶ Only the process for preparing the substances is patentable.

Both TRIPS and the Patents Act exclude plants, animals, and essentially biological processes for the production of plants and animals from patentability.³⁷ Although plants do not have to be patented, TRIPS does require member states either to provide patent rights or an effective *sui generis* system to protect plant varieties.³⁸ India has elected to provide a *sui generis* system through the Protection of Plant Varieties and Farmers Rights Act.³⁹

III. Requirements for Patentability

Although TRIPS and the Patents Act have provided explicit areas of patentability, some areas are still uncertain, particularly the patentability of living materials.⁴⁰ TRIPS has not given guidance for patentability of life forms, except those mentioned above. Instead, TRIPS has allowed member states to determine the patent rights for these remaining life forms.⁴¹

In India, living materials are patentable if they satisfy the Patents Act requirements.⁴² India's patent law requires the material or process to meet the definition

³⁶ Subbaram, *supra* note 11. India has been given until January 1, 2005 to provide product patents for these substances. If India does not change its law, India will no longer be TRIPS compliant. Carole De Gaulle, *Intellectual Property and Patent in India*, NEWS TIME, Oct. 2000, at <http://www.foxmandal.com/publication/oct2000/oct2kca.html> (last visited Mar. 28, 2004).

³⁷ See TRIPS, *supra* note 2, art. 27(3)(b); Patents (Amendment) Act § 4(e).

³⁸ TRIPS, *supra* note 2, art. 27(3)(b); see Ott, *Protection*, *supra* note 6.

³⁹ B.J. Krishnan, *Move to Join UPOV*, HINDU BUSINESS LINE, Oct. 2, 2002, at <http://www.mindfully.org/WTO/UPOV-Farmers-Rights10oct02.htm> (last visited Mar. 28, 2004); see Ott, *Protection*, *supra* note 6.

⁴⁰ Subbaram, *supra* note 11.

⁴¹ *Patents*, *supra* note 1.

⁴² Subbaram, *supra* note 11.

of invention, which includes a distinction from a discovery. Further, the invention must be sufficiently disclosed, meet the vendibility test, and be within the public interest.⁴³

In the Patents Act, invention is defined as a new product or process involving an inventive step and capable of industrial application.⁴⁴ Although the terms “inventive step” and “capable of industrial application” are individually defined in the Patents Act, the meanings are taken from Article 27(1) of TRIPS, which defines the terms as non-obvious and useful.⁴⁵

Under the act, a patent must be an invention, and not a discovery, meaning it must meet the required criteria of new, non-obvious, useful, and repeatable. The Patents Act excludes the discovery of “any living thing or non-living substance occurring in nature,” from patentability.⁴⁶ To meet this initial criteria, the product or process must be “isolated from nature by the application of human intellect” in order to be an invention, and not discovery.⁴⁷ For an invention to be considered new, it must not have been “disclosed to the public either in writing or orally, by use or otherwise” in India or elsewhere before the date of filing.⁴⁸ To meet the non-obviousness requirement, the invention, as described in the Patent Act, must involve anything beyond the ability of someone skilled in the art.⁴⁹ In order for the invention to be useful, it must be an invention that

⁴³ See Ott, *Patentability*, *supra* note 11.

⁴⁴ Patents (Amendment) Act § 4(e). For a discussion on the old and new definition of invention, see Ott, *Patentability*, *supra* note 11.

⁴⁵ Section 2(ja) of the Patents Act defines inventive step as “a feature that makes the invention not obvious to a person skilled in the art.” Capable of industrial application is defined in section 2(ac) as an invention that “is capable of being made or used in an industry.”

⁴⁶ Patents (Amendment) Act § 4(b).

⁴⁷ Subbaram, *supra* note 11.

⁴⁸ *Id.*; see Patents Act § 13.

⁴⁹ SME Network, *What Is a Patent?*, at <http://www.smenetwork.net/patents/Patentsbasic.htm> (last visited Mar. 19, 2004); see Patents (Amendment) Act § 3(f).

functions.⁵⁰ Under the old definition of invention, the Patents Office manual said an element of commercial or pecuniary success has no relation to usefulness for purposes of patentability.⁵¹ The manual also said usefulness merely depends on whether the result as promised by the applicant in the application actually occurs.⁵² Finally, the Patents Act also requires an invention to be repeatable, thus enabling others to repeat the invention.⁵³

In order for an applicant to patent living material, the applicant must also prove sufficient disclosure.⁵⁴ The Patents Act requires that every patent application “fully and particularly describe the invention and its operation or use and the method by which it is performed,” including a “title sufficiently indicating the subject-matter to which the invention relates.”⁵⁵ The application must also define the scope of the invention. All these claims must be “as clear and concise as the nature of the subject will admit.”⁵⁶ The sufficient disclosure requirement is mandatory, and is difficult when describing living materials.⁵⁷ The requirement can be satisfied, however, by depositing a sample of the living material with the International Depository Authority if the material is not available to the public.⁵⁸ The applicant must also provide the Authority with all the available characteristics of the biological material required for it to be correctly identified.⁵⁹ Also, the applicant must disclose the source and geographical origin of the biological

⁵⁰ Patents (Amendment) Act § 3(f). This requirement is intended to avoid patenting perpetual motion machines. *Id.*

⁵¹ PATENT OFFICE, INDIA, MANUAL OF PATENT PRACTICE & PROCEDURE 1.3.6 (July 2001) at <http://www.patentoffice.nic.in/ipr/patent/manual.htm> (last visited Mar. 6, 2004).

⁵² *Id.*

⁵³ Subbaram, *supra* note 11.

⁵⁴ Patents Act § 10.

⁵⁵ *Id.*

⁵⁶ Patent Office, *supra* note 51, at 3.5.0; *see also* Patents Act § 10(5).

⁵⁷ Subbaram, *supra* note 11.

⁵⁸ Patents Act § 10(a)(4)(d)(ii)(A); *see also* Subbaram, *supra* note 11.

⁵⁹ Patents Act § 10(a)(4)(d)(ii)(B),

material.⁶⁰ If the application fails to disclose or inaccurately describes the source or geographical origin of the biological material used for the invention, the patent may be revoked by the High Court.⁶¹ Once the deposits are made, the Authority provides an accession number, which is considered as an equivalent description of the living material.⁶² After going through this process, the invention is deemed to have satisfied the sufficient disclosure requirement.⁶³

The depository system was implemented to “provide a mechanism to verify compliance with national laws and contracts concerning access to genetic resources and benefit sharing.”⁶⁴ The regulations India has followed in adopting the depository system, though, are not pursuant to TRIPS requirements. As noted above, TRIPS provides minimum requirements for member states, and TRIPS has not required a depository system for providing information on the geographic origin of genetic resources. Rather, India has implemented the depository system to meet the provisions of the Convention on Biological Diversity (CBD), which India adopted in 1992.⁶⁵ CBD has the purpose of conserving biological diversity, providing for “sustainable use” of the elements of biological diversity, and allowing for the “fair and equitable sharing of benefits” arising from using genetic resources and appropriate transfers of relevant technology.⁶⁶ Relating to the depository system, CBD requires parties to “respect, preserve and maintain” the

⁶⁰ *Id.* § 10(a)(4)(d)(ii)(D). TRIPS does not require disclosure of the source of origin of the biological material used in the invention. *Patents, supra* note 1.

⁶¹ Patents (Amendment) Act § 31; *see* S.K.Verma, *Access to Plant Genetic Resources and Intellectual Property Rights: The Case of India*, CASRIP NEWSLETTER, Spring/Summer 2001, at <http://www.law.washington.edu/casrip/newsletter/newsv8i2Verma.pdf> (last visited Mar. 19, 2004).

⁶² Subbaram, *supra* note 11.

⁶³ *Id.*

⁶⁴ Verma, *supra* note 61.

⁶⁵ *Id.*

⁶⁶ *Patents, supra* note 1.

traditional knowledge, innovations, and practices of indigenous people and local communities “relevant for the conservation and sustainable use of biological diversity.”⁶⁷

TRIPS, in contrast, does not require protection of traditional knowledge.⁶⁸

TRIPS and CBD both address the protection of and access to biological and genetic resources, but the two agreements differ on the traditional knowledge requirements.⁶⁹ However, some say the two agreements also have conflicting provisions for technology holders and holders of genetic resources.⁷⁰ The United States disagrees, claiming the US has not been provided with proof that “a single inconsistency between the two agreements” exists.⁷¹ The World Trade Organization and World Intellectual Property Organization have addressed concerns of inconsistency and have instructed TRIPS to “examine, *inter alia*, the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore, and other relevant new developments raised by members”⁷²

In addition to the requirements outlined above, patent applications must also pass a vendibility test to determine if the living matter should be patented. A vendible product is something that “can be passed on from one man to another upon the transactions of

⁶⁷ Convention on Biological Diversity § 8(j), 31 I.L.M. 818 (1992).

⁶⁸ Genetic Resources, Traditional Knowledge and Intellectual Property Rights, *Issue brief for the World Summit on Sustainable Development by the Center for International Environmental Law*, (2002), at <http://www.ciel.org/Publications/iprights.pdf> (last visited Mar. 28, 2004).

⁶⁹ Verma, *supra* note 61.

⁷⁰ *Id.*

⁷¹ Singh, *supra* note 7. The United States of America, in a paper submitted to the TRIPS Council, says “[i]t is time, therefore, to lay to rest the allegation that the obligations of the two agreements are inconsistent and concentrate on addressing any specific concerns that [TRIPS] members that are also members states of the CBD might have about the manner in which they might implement particular obligations of either agreement so that they avoid any question of conflict with obligations under the other agreement.” *Id.*

⁷² Genetic Resources, *supra* note 68.

purchase and sale.”⁷³ To satisfy the test, an invention must result in the production of a vendible item, improve or restore former conditions of a vendible item, or preserve and prevent a vendible item from being produced.⁷⁴ This test may not pose a high threat to living organisms, as one Indian court has held that the process for creating a vaccine leads to a vendible product even if the end product contains live material.⁷⁵

A final requirement of importance when seeking patents for living materials in India is satisfying the public interest requirement. The Patents Act, as allowed under TRIPS,⁷⁶ excludes inventions from patentability if their primary or intended use or commercial exploitation is contrary to public order, morality, or causes serious prejudice to the environment, health, or human, animal or plant life.⁷⁷ At least one commentator has questioned whether living materials are patentable under this section due to their environmental impact.⁷⁸

IV. Conclusion

Although the Patents Act is not clear on every area involving patentability of living material, the Act has given guidelines for what is and is not allowed to be patented. Through these guidelines, the Patents Act has provided a general framework that allows “ample scope” for protecting areas involving living materials.⁷⁹

⁷³ *Dimminaco A. G. v. Controller of Patents Designs and Ors.*, AID No. 1 of 2001, Jan. 15, 2002.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ Article 27(2) of TRIPS allows members to “exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

⁷⁷ See Patents (Amendment) Act § 4(a); TRIPS, *supra* note 2, art. 27(2).

⁷⁸ Verma, *supra* note 61.

⁷⁹ Subbaram, *supra* note 11.