

Abstract

Robyn Ott is the 2004-2005 Managing Editor for the Oklahoma Journal of Law and Technology. She wrote this eBrief while working under the direction of Professor Drew Kershen on the Project on Intellectual Property Rights in Living Matter. Below, Ms. Ott gives an overview of patentability requirements in India for plants, animals, and microorganisms. India is a signatory country to the Trade Related Aspects of the Intellectual Property Systems (TRIPS) agreement and has recently come into full compliance with the terms of that agreement.

Edited by Greg Milstead and Robyn Ott

PATENTABILITY OF PLANTS, ANIMALS AND MICROORGANISMS IN INDIA

© 2004 Robyn Ott

I. Introduction

India became a member of the World Trade Organization on January 1, 1995.¹ As a member, it was required to comply with the Trade Related Aspects of the Intellectual Property Systems (TRIPS) agreement.² TRIPS requires member countries “to provide adequate standards and principles concerning the availability, scope and use of intellectual property rights and effective means for the enforcement of these rights.”³

Prior to TRIPS, India’s patent system had been regulated by the country’s Patents Act of 1970 (Patents Act). To begin making India’s law consistent with TRIPS, the Patents Act was amended in 1999 and 2002.⁴ In addition, India is required to make further changes by January 1, 2005 in order to become fully TRIPS compliant.⁵

¹ *Understanding the WTO: The Organization*, at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (Apr. 4, 2003).

² Stephen Barnes, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 917 (2003).

³ Carole De Gaulle, *Intellectual Property and Patent in India*, NEWS TIME, Oct. 2000, at <http://www.foxmandal.com/publication/oct2000/oct2kca.html>.

⁴ See Patents (Amendment) Act (June 25, 2002) (No. 38 of 2002) (India) [hereinafter Patents (Amendment) Act of 2002]; Patents (Amendment) Act, 1999 (Mar. 26, 1999) (No. 17 of 1999) (India) [hereinafter Patents (Amendment) Act of 1999].

⁵ De Gaulle, *supra* note 3.

This eBrief explains India's current laws concerning patents for the areas of plants, animals, and microorganisms by describing what is and is not patentable. This eBrief further details how the Patents Act complies with the TRIPS agreement, and shows the temporary adjustments India has made in order to fulfill the TRIPS requirements.

II. The Patents Act

The Patents Act gives the patentee, and those to whom the patentee consents, the exclusive right for "commercial exploitation of his patent" for a limited time, in exchange for disclosure of the patentee's invention.⁶

Under the Patents Act, a patent is merely defined as "a patent granted under this Act."⁷ Indian commentaries, however, give a clearer definition of a patent. These commentaries claim a patent is a statutory right given to an inventor once the invention is registered with the Patents Office, excluding all others from using or benefiting from the invention for a limited time.⁸ The Patents Act grants the same patent rights to both domestic and foreign inventions.⁹ However, patent protection is "territorial in nature," and therefore, patents granted in India are only valid in India.¹⁰

The "fundamental principle" of the Patents Act is that subject matter can only be patentable if it is an invention.¹¹ An invention under the Act is "a new product or process

⁶ Singhanian & Co. LLP, *India Business Law Guide*, 16.03.1, at <http://www.singhanian.com/lawguide/content.htm> [hereinafter Singhanian]

⁷ Patents Act § 2(m) (1970) (Act 39 of 1970) (India).

⁸ See Society for Research and Initiatives for Sustainable Technologies and Institutions, *Patent*, at <http://www.sristi.org/material/1.3PATENT%20basics.doc> (last visited Mar. 6, 2004) [hereinafter Society]; Singhanian, *supra* note 6, at 16.03.2.

⁹ Embassy of India, *Intellectual Property Rights in India*, at http://www.indianembassy.org/policy/ipr/ipr_2000.htm (last visited Mar. 12, 2004).

¹⁰ Society, *supra* note 8.

¹¹ Patent Office, India, *MANUAL OF PATENT PRACTICE & PROCEDURE* (July 2001) at <http://www.patentoffice.nic.in/ipr/patent/manual.htm> (last visited Mar. 6, 2004).

involving an inventive step and capable of industrial application.”¹² This definition was added in the 2002 amendment¹³ and is TRIPS compliant.¹⁴ The terms “inventive step” and “capable of industrial application” are defined under the 2002 amendment. An inventive step is “a feature that makes the invention not obvious to a person skilled in the art.”¹⁵ The definition given for “capable of industrial application” does not provide additional meaning;¹⁶ however, commentators have said the term is synonymous with “useful.”¹⁷

Prior to the amendment, the Supreme Court of India determined the requirements for a patentable invention.¹⁸ Under the previous law, an invention was “any new and useful art, process, method of manufacture, machine, apparatus or other article, [or any] substance produced by manufacture.”¹⁹ Under this definition, the Supreme Court held that an invention was required 1) to meet the test of “new” and “useful,” meaning “novel” and “utility,”²⁰ and 2) to be the inventor’s own invention, rather than a “mere verification of what was already known before the date of the patent.”²¹ These requirements present a mixed question of law and fact contingent on

¹² Patents Act § 2(j).

¹³ Patents (Amendment) Act of 2002, *supra* note 4, § 3(f).

¹⁴ **N.S. Gopalakrishnan, Patents (Second Amendment) Bill, 1999 - An Analysis**, 1 *Supreme Court Cases Weekly* 14, (2001) at <http://www.ebc-india.com/lawyer/articles/2001v1a2.htm> (last visited Mar. 6, 2004). TRIPS has not defined invention, but has provided a test, which requires an invention to be “new,” having an “inventive step,” and be “capable of industrial application.” 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). None of these terms are defined in TRIPS. Gopalakrishnan, *supra*. It seems that India’s definition was changed to comply with TRIPS. *Id.*

¹⁵ Patents (Amendment) Act of 2002, *supra* note 4, § 3(f).

¹⁶ The term is defined as an invention that “is capable of being made or used in an industry.”

¹⁷ Srividhya Ragavan, *Patent Amendments in India in the Wake of TRIPS*, CASRIP NEWSLETTER, Winter 2001, at <http://www.law.washington.edu/Casrip/newsletter/newsv8i1Ragavan.pdf> (last visited Mar. 6, 2004);

Gopalakrishnan, *supra* note 14.

¹⁸ *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries* 10 (1979) 2 SCC 511.

¹⁹ Patents Act § 2(j).

²⁰ The Supreme Court determined that a “new and useful” invention is required to have “novelty” and “utility.” Gopalakrishnan, *supra* note 14.

²¹ *Id.*

each case's circumstances.²² Commentators have differing predictions of whether the new definition will change the Supreme Court's patentability requirements.²³

III. What is Not Patentable?

The Patents Act has explicitly excluded certain items and processes from the definition of invention, thus making them unpatentable.²⁴ Under the Act, no frivolous or obvious invention is patentable.²⁵ Also, the mere discovery of "any living thing or non-living substance occurring in nature" is not an invention.²⁶ Further, if the intended use of an invention causes conflict with public order or morality, or causes "serious prejudice" to humans, animals, plant life, health, or the environment, the invention is unpatentable.²⁷ This includes "method[s] of adulteration of food."²⁸

Under the Act, any "method of agriculture or horticulture" is not an invention.²⁹ For example, inventing a method to produce "a new form of a known plant," which involves modifying the "conditions under which natural phenomena would pursue their inevitable course" is unpatentable.³⁰ Moreover, one Indian Court³¹ held unpatentable a "method of producing improved soil from soil with nematodes by treating the soil with a preparation containing

²² CASRIP Newsletter . Winter 2001, Supreme Court case of *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries*.

²³ **N.S. Gopalakrishnan says the case-law meets the TRIPS requirements. Gopalakrishnan, *supra* note 14. Gopalakrishnan has also said the new amendment will not change the requirements. Srividhya Ragavan says a "different treatment" will be needed for the second of the Supreme Courts requirements. Ragavan, *supra* note 17.**

²⁴ Patents Act § 3; *see* Gopalakrishnan, *supra* note 14.

²⁵ Patents Act § 3(a).

²⁶ Patents (Amendment) Act of 2002, *supra* note 4, § 4(b).

²⁷ Patents Act § 3(b).

²⁸ Patent Office, *supra* note 11.

²⁹ Patents Act § 3(h). This section is limited to an amendment change that removes "plants" from non-patentability when the patent sought is for any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of plants. In this circumstance only, the process for treating the plant is patentable; *see* Patents (Amendment) Act of 2002, *supra* note 4, § 4(d)(ii).

³⁰ N.V. Philips, Gloeiammpenfabrieken's Application 71 RPC 192; Patent Office, *supra* note 11.

³¹ Patent Office, *supra* note 11 (citing Virginia Carolina Chemical Corporation application 1958 RPC 38).

specified phosphorothioates.”³² Courts have found that a method for producing algae and mushrooms is analogous to agriculture because mushrooms and algae belong to the plant kingdom and, therefore, are not inventions for purposes of the Patents Act.³³

Any treatment³⁴ of animals “to render them free of disease or to increase their economic value or that of their products” is not an invention.³⁵ Therefore, methods of treatment or diagnosis to an animal body by means of surgery are excluded from the definition of invention.³⁶ For example, an Indian Court³⁷ found a method of implanting an embryo transplant from a donor mammal into the uterus of a recipient mammal unpatentable because the method would “have to be carried out by a surgeon or veterinary surgeon.”³⁸ Treatment and diagnosis methods performed on “tissues or fluids, which have been permanently removed from the body,” however, may be patentable.³⁹ Courts have clarified this distinction by holding that a method of therapy performed on materials temporarily removed from the body, but that remain in living communication with the body (for example blood circulating through the materials and the body) is unpatentable.⁴⁰ Also, a method of controlling parasitic worms, which can be found in the intestinal tracts of animals, was found to be unpatentable.⁴¹ The applicants contended that the composition was not therapy because it would prevent the reproduction of the worms and kill

³² Id.

³³ Id. (citing 264/Cal/79 and 445/Del/93).

³⁴ This includes “any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic, or other treatment . . .” Patents Act § 3(i).

³⁵ Patent Office, *supra* note 11. Treatments to plants are no longer excluded from the invention definition after the 2002 amendment omitted “and plants” from this section. Patents Act § 3(i)(ii).

³⁶ Patent Office, *supra* note 11.

³⁷ Occidental Petroleum Corporation’s Application (not reported); Patent Office, *supra* note 10.

³⁸ Patent Office, *supra* note 11

³⁹ Id.

⁴⁰ Id. (citing Calmic Eng’g Co Ltd’s Application, [1973] RPC 684).

⁴¹ Patent Office, *supra* note 11 (citing Ciba-Geigy AG’s Application (not reported) (where a patent application was denied for a method of using an anthelmintic composition to control parasitic helminthes, which are worms that may develop in the animal body).

them if they infested the animal, without affecting the animal's body. The court held, however, that because the infestation of the worms can result in restricted growth, damage to the animal, and even death if not properly treated, and since the application did not mention controlling the worms by the use of the composition in any environment other than the animal body, the infestation was a disease requiring medical treatment of the animal. Therefore the Court disallowed the process to be patented since the treatment, "whether curative or preventative, constituted therapy practiced on the animal body."⁴² To further clarify this section, "body" means a living body; therefore, a method practiced on a dead body, for example a process that determines the cause of death, is patentable.⁴³

The 2002 amendment adds a section specifying that plants and animals and any part of a plant or animal, excluding microorganisms but including seeds, are not patentable.⁴⁴ Likewise, varieties, species, and essentially biological processes used for production or propagation of plants and animals are unpatentable.⁴⁵

A mere admixture or a process for producing the admixture, where the end product is only an "aggregation of the properties," is not patentable.⁴⁶ For example, a mixture of sugar, water, and colorants to produce a soft drink is a mere admixture that results in an aggregation of the properties.⁴⁷ If, however, the admixture transforms the basic ingredients "into synergistic properties of a mixture," like soap or detergent, then the invention is patentable.⁴⁸

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Patents (Amendment) Act of 2002, *supra* note 4, § 4(d).

⁴⁵ *Id.* These areas are protected, however, under the Protection of Plant Varieties and Farmers Rights Act (Act 53 of 2001) (India), which complies with TRIPS by protecting plant varieties through a *sui generis* system of protection. See Robyn Ott, Protection of Plant Varieties and Farmer's Rights Act, 2 OKLA. J.L. & TECH. 14 (2004), available at <http://www.okjolt.org/published/2004okjoltrev14.html>.

⁴⁶ Patents Act § 3(e).

⁴⁷ Patent Office, *supra* note 11.

⁴⁸ *Id.*

Even if the subject matter is an invention, the Patents Act may still exclude the invention from patentability. Certain substances are excluded from patent rights, and only the process to create the substance is patentable.⁴⁹ This limitation applies to any substance where the use is intended for, or capable of being used as, food, medicine, or drug.⁵⁰ Under the Act, food is “any article of nourishment for human consumption,” which includes all food or drink intended for the use of infants, invalids, or convalescents.⁵¹

Finally, any substance that is prepared or produced by a chemical process cannot be patented--only the process itself is patentable.⁵² A chemical process includes biochemical, biotechnological, and microbiological processes.⁵³

IV. What is Patentable?

The Patents Act does not describe, in an inclusive manner, what is patentable; rather, omissions of subject matter from the non-patentable sections clarify what subject matter can be patented. As indicated in the above section, the process of creating biochemical, biotechnological, and microbiological processes is patentable.⁵⁴ Therefore, patents are available for “processes or methods of production of tangible and nonliving substances” like enzymes, hormones, and vaccines.⁵⁵ Furthermore, processes using bioconversion, microorganisms, biologically active substances, biotechnology, microbiology, and/or chemical substances produced by using genetically engineered organisms are patentable.⁵⁶ Moreover, the Patents Act

⁴⁹ See Patents Act § 5.

⁵⁰ *Id.* § 5(1)(a).

⁵¹ Patents (Amendment) Act of 2002, *supra* note 4, § 3(c).

⁵² *Id.* § 5(1)(b).

⁵³ *Id.* § 5.

⁵⁴ *Id.* § 5(1)(b).

⁵⁵ Patent Office, *supra* note 11.

⁵⁶ *Id.*

explicitly excludes microorganisms from the invention exemption, making them patentable.⁵⁷

The mere discovery of organisms, however, is not patentable.⁵⁸

Finally, although the Act does not allow patents for a method of horticulture,⁵⁹ as noted above, the Act does explicitly specify that any method relating to the *treatment* of plants is patentable.⁶⁰ Therefore, the Act allows an invention to be patented that is merely a method of making plants free of disease.⁶¹ Also, a process for improving the plant's value or increasing the value of the plant's products is patentable.⁶²

Upon being issued a product patent, the patentee has the exclusive right to prevent third parties, who do not have the patentee's consent, from "making, using, offering for sale, selling, or importing" the product in India.⁶³ If the patent is for a process, however, the patentee has an additional right to prevent third parties, who do not have the patentee's consent, from using the process.⁶⁴ The exclusive right to prevent third parties from using, selling, importing, or offering for sale a product that was directly obtained by the patented process in India is still applicable.⁶⁵ The Act, as amended, now specifically allows any "person who is duly authorized by the

⁵⁷ Patents (Amendment) Act of 2002, *supra* note 4, § 4(e). This meets the requirement under Article 27(3) of TRIPS. *Id.*

⁵⁸ Suman Sahai, *India's Plant Variety Protection and Farmers' Rights Act, 2001*, CURRENT SCI., Feb. 10, 2003, at 411, available at <http://www.iisc.ernet.in/~currsci/feb102003/407.pdf> (last visited Mar. 6, 2004).

⁵⁹ A process patent is not allowed for methods and processes of horticulture and agriculture, including food. Patents Act § 3(h); *see also* Sahai, *supra* note 57. Also, cells, cell lines, and cell organelles can not be patented. *Id.*

⁶⁰ Patents (Amendment) Act of 2002, *supra* note 4, § 4(d)(ii). This is in compliance with Article 27(3)(a) of TRIPS. *Id.*

⁶¹ Sahai, *supra* note 57.

⁶² *Id.* A process patent is not allowed for methods and processes of horticulture and agriculture, including food. Patents Act § 3(h); *see also* Sahai, *supra* note 57. Also, cells, cell lines, and cell organelles can not be patented. *Id.*

⁶³ Patents (Amendment) Act of 2002, *supra* note 4, § 25.

⁶⁴ *Id.*

⁶⁵ *Id.*

patentee to sell or distribute the product,” to import the product into India.⁶⁶ Thus, importation will no longer be an infringing use.⁶⁷

The patentee’s exclusive rights, however, are limited to the conditions in Section 47 of the Patents Act.⁶⁸ This section provides that the Government of India may import, make⁶⁹ or use “any article made by using a process in respect of which the patent is granted.”⁷⁰ Further any patented substance or process may be made or used by any person for experiment or research, including the instruction of pupils.⁷¹

When any of these rights are violated, the patentee has a right to sue.⁷² Relief available to the patentee includes an injunction and the patentee’s choice of damages or an accounting of profits.⁷³ Further, the court may seize, without compensation, “goods which are found to be infringing” and other materials that are predominantly used to create infringing goods.⁷⁴

To comply with TRIPS,⁷⁵ the Patents Act was amended to provide patent protection for twenty years.⁷⁶ During the patent’s protection term, the patent must be renewed by paying a “prescribed renewal fee.”⁷⁷ If the renewal fee is not paid within the required period, the patentee loses all patent rights for the patented substance or process.⁷⁸ The Patents Act has also explicitly

⁶⁶ Patents (Amendment) Act of 2002, *supra* note 4, § 44.

⁶⁷ Ragavan, *supra* note 17.

⁶⁸ **De Gaulle, *supra* note 3.**

⁶⁹ The product may be made by or on behalf of the Government. Patents Act § 47(1).

⁷⁰ Patents Act § 47(1), (2).

⁷¹ *Id.* § 47(3).

⁷² Society, *supra* note 8. The proceedings cannot be brought in any court inferior to the district court. Patents Act § 104.

⁷³ Patents Act § 108.

⁷⁴ Patents (Amendment) Act of 2002, *supra* note 4, § 45; *see also* Gopalakrishnan, *supra* note 14.

⁷⁵ TRIPS, *supra* note 14, art. 33.

⁷⁶ Patents (Amendment) Act of 2002, *supra* note 4, § 27.

⁷⁷ Singhania, *supra* note 6, at 16.03.7. The first renewal fee is due the second year after the patent has been sealed. All subsequent payments are due each succeeding year. The payment period can, however, be extended to six months if requested. *Id.*

⁷⁸ Patents Act § 53(2).

clarified that inventions will not be protected after the patent term has expired, and is not available if the renewal payment is not paid.⁷⁹

V. Temporary Adjustments

India has not fully complied with Article 27(1) of TRIPS, which requires protection of all inventions of both products and processes,⁸⁰ except plants and animals.⁸¹ India has only fully provided patent protection for processes or methods for chemical processes, excluding the resulting product from patentability.⁸² Furthermore, processes intended for or capable of use as food, medicine, or drug are patentable, but the product itself is unpatentable.⁸³ India has been granted an extension, however, for agricultural chemical products⁸⁴ and all products intended for use or capable of being used as food, medicine, or drug,⁸⁵ meaning that India does not have to provide full patent rights for these categories of inventions until January 1, 2005.⁸⁶ Until then, India has temporarily set up a system to provide Exclusive Marketing Rights (EMRs)⁸⁷ for food,

⁷⁹ Patents (Amendment) Act of 2002, *supra* note 4, § 27; *see also* Gopalakrishnan, *supra* note 14.

⁸⁰ “Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.” TRIPS, *supra* note 14, art. 27(1).

⁸¹ Members may also exclude from patentability . . . plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. However, Members shall provide for a protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of the subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.” *Id.* art. 27(3).

⁸² Patents Act § 5(1)(b).

⁸³ *Id.* § 5(1)(a).

⁸⁴ TRIPS, *supra* note 14, art. 70(8). In addition to agricultural chemical products, India has also provided a mailbox system and EMRs for pharmaceutical products.

⁸⁵ Email from Srividhya Ragavan, Professor, University of Oklahoma College of Law, to Robyn Ott (Mar. 6, 2004, 2:54PM) (on file with author).

⁸⁶ De Gaulle, *supra* note 3; *see* TRIPS, *supra* note 14, art. 65(4).

⁸⁷ EMRs were created in Section 3 of the Patents (Amendment) Act of 1999, *supra* note 4.

medicine, drug, and agricultural chemical products.⁸⁸ This system of granting EMRs provides TRIPS member states with a transition period⁸⁹ before fully extending protection to products.⁹⁰

EMRs give inventors limited protection, by providing exclusive rights only for the sale of the product, rather than for both the sale and manufacture of the product.⁹¹ Inventors can file EMR applications for food, medicine, drug, and agricultural chemical products under a mailbox system.⁹² If the inventor has filed a mailbox application, and the product has received a patent and marketing approval by another World Trade Organization member state, the inventor applicant will receive an EMR.⁹³ The EMR will be valid for five years or, if earlier, validity will end at the date the patent is granted or rejected.⁹⁴

The mailbox system further allows the inventor to “establish priority dates that serve as evidence of the novelty of their inventions.”⁹⁵ By 2005, India must review the mailbox applications that have been received and provide patents for products that have met the TRIPS criteria for patentability.⁹⁶

VI. Conclusion

The Patents Act sets forth the requirements for patents, specifically detailing patent rights and terms, and describes that subject matter which cannot be patented. Although the Act was not always TRIPS compliant, the Dispute Settlement Body of the World Trade Organization

⁸⁸ 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) [hereinafter Press].

⁸⁹ The transition period is from January 1, 1995, to January 1, 2005. Gopalakrishnan, *supra* note 14.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² Article 70(8) of TRIPS allows developing countries to establish a mailbox system. Eric Brown, *TRIPS: India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, European Journal of International Law, 1998, at <http://www.ejil.org/journal/Vol9/No1/sr1f-01.html> (last visited Mar. 6, 2004).

⁹³ TRIPS, *supra* note 14. art. 70(9).

⁹⁴ Patent Office, India, *Exclusive Marketing Rights*, at <http://www.patentoffice.nic.in/ipr/patent/emr.htm> (last visited Mar. 6, 2004).

⁹⁵ Brown, *supra* note 91.

⁹⁶ *Id.*

2 OKLA. J. L. & TECH. 16 (2004)

www.okjolt.org

declared in May 1999 that India is now in full compliance with its “international obligations” to the WTO, including TRIPS.⁹⁷

⁹⁷ Press, *supra* note 87.