

INDIAN LEGISLATION ON THE USE AND OWNERSHIP OF BIOTECHNOLOGY*

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1 INTRODUCTION

India has played a crucial role in discussions and negotiations concerning the intellectual property of biotechnology. The country is not only rich in biological resources and biodiversity, with more than 45.000 plants identified, but also in associated traditional knowledge, as manifested in the traditional medicine *Ayurveda* and its unique and distinguished cuisine. India is also the “pharmacy of the world”, occupying the position of fourth largest producer of pharmaceuticals in the world and the largest exporter of generic medicines to developing countries. The country also has a large rural population, composed mostly of small farmers. Moreover, perhaps more than any other country, India has innovated in laws regarding the use and ownership of biotechnology, especially with regard to requirements of innovation in drugs, access to essential medicines and protection of farmers’ rights and restrictions to the access to biological resources and associated traditional knowledge.

Brazil shares many of the concerns of India regarding the need for flexibilities in the protection of intellectual property rights and has cooperated with the country, especially in the exchange of information on the patenting of medicines – the antiretroviral Tenofovir is a case in point. Brazil has also a high degree of biodiversity, and can certainly benefit from the Indian experience in regulating the biotechnology sector. Moreover, Brazil still depends on the supply of active ingredients of various drugs from India, including antiretrovirals used to treat AIDS. Finally, India has also undertaken, along with Brazil, a leading role in discussions on the global governance of intellectual property.

Because the Indian laws of biotechnology have entered into force recently, many of their provisions are being challenged in court, and thus the creation of jurisprudence on the use and ownership of biotechnology in the country is a process that still has a high degree uncertainty and imprecision. In particular, the Indian law on the protection of plant varieties and farmers’ rights was only enacted in 2001 and India only changed its legislation in conformity with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 2005, unlike Brazil, which did so nine years earlier, in 1996.

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This study examines the various laws relating to the ownership and use of biotechnology in India. The second section presents a brief history of Indian patent laws. The third section highlights the changes set out in the most recent decrees and amendments to such patent laws. This section also discusses the lawsuits filed by the local branch of Swiss pharmaceutical multinational Novartis against the Indian government, which will help create jurisprudence of the latest version of the country's patent law. In addition, the section discusses the protection afforded by the new patent law to biological resources. The fourth section discusses the law on the protection of plant varieties and farmers' rights. Finally, the last section presents the regulation of GMOs, the legal regime for access and use of Indian biological resources, the regulation of stem cell research and the implications of the geographical indications law to the protection of traditional products in India.

2 THE EVOLUTION OF PATENT LAWS IN INDIA

The protection of inventions began in colonial India under imposition of England. In 1856 the Law VI was created, based on the British Patents Act of 1852, through which were guaranteed certain exclusive privileges to inventors for a period of 14 years. In 1859, that law was amended, creating the Act XV, in which patents asserted exclusive rights over the manufacture, sale and use of inventions in India as well as over third party authorization for a period of 14 years from the filing date of the patent application. In 1872 was created the Law of Patents and Designs Protection and, in 1883, the Law on Protection of Inventions. In 1888, the Inventions and Designs Act was consolidated. In 1911, the Indian Patents and Drawings Act was created, which was amended in 1920, 1930 and 1945. This law was drafted with the aim of favoring the business interests of the metropolis, ensuring its control of the Indian market. Consequently, 85% of the drugs sold in India were supplied by multinationals and prices for antibiotics in the country were among the highest in the world (Inpi, 2007, p. 63-63).

Immediately after independence in 1947, concerns about industrial development and public health led the Indian government to set up committees to prepare reports and discuss proposals for a new patent law. However, the National Patent Act only came into force in 1970. This law restricts patent rights for biotechnology, seeking to encourage the production of generics by:

- abolishing product patents for pharmaceuticals, chemicals and food, recognizing only patents for processes in these sectors;
- establishing a patent term of only seven years since the application or five years from the concession, whichever was shorter;
- requiring the patent holder to produce the patented good in the country, under penalty of revocation of its patent; and
- stipulating a ceiling for the payment of royalties of 4% of the net sale price in wholesale.

Largely as result of changes in its patent law, and relying on a relatively large market potential, which favors economies of scale in production, India became the fourth largest producer of pharmaceuticals in the world and the largest exporter of generics for developing countries; and the prices of medicines in the country became the lowest in the world.

As a developing country, India could benefit from a transition period of ten years (until 2005) to comply with the TRIPS Agreement. Unlike Brazil, which did not make use of this transition period, the adjustment of the Indian patent law in conformance with TRIPS was only completed in 2005. Among the major changes in such law required by the Agreement are the granting of patents for pharmaceuticals and food products and the extension of the patent term to 20 years.

Amendments in 1999 and 2002 and a 2004 decree sought to bring the Indian patent law in compliance with TRIPS, but became the target of criticism from affected groups for ignoring flexibilities permitted by the Agreement as well as the Doha Declaration on TRIPS and Public Health. After the approval of several amendments to the Decree of 2004, the Indian Parliament adopted the Patents Amendment Bill on March 2005 (Keayla, 2005, p. 3-4).

3 THE CURRENT INDIAN PATENT LAW

3.1 Compulsory licensing

Concerns about public health and access to medicines significantly restrict pharmaceutical patent rights in the new Indian law. In particular, compulsory licensing¹ is allowed in several cases, including:

- for public, noncommercial, governmental use;
- in situations of national emergency or extreme urgency; and
- for the local production of generics under many conditions.

It should be noted that the noncommercial use of the compulsory license does not mean that it must necessarily be granted to producers in the public sector; it may also be granted by the government to private producers who act as public sector suppliers. Crucially, in an situation of emergency or extreme urgency there is no impediment to the commercial use of the compulsory license, which means it can be used to supply the private sector. This distinction is important because in India more than 70% of medicines are sold through private retailers. Moreover, the provision of the Indian patent law that regulates situations of noncommercial public use as well as extreme urgencies and emergencies – section 92 (1) – allows for compulsory licensing immediately after the grant of the patent. The royalties

1. Compulsory licensing breaks the monopoly right of the patent, allowing its object to be used, produced or marketed by any agent in the country conditioned on the payment of royalties to the patent holder. According to the Doha Declaration on TRIPS and Public Health, each member country of the World Trade Organization (WTO) is free to determine the criteria, procedures and conditions for compulsory licensing that are most fit to ensure the protection of public health.

to be paid to the patent holder are freely determined by the Patents Controller, which can even be set to zero when deemed necessary for the public interest. Finally, there are no restrictions on the kinds of diseases for which this provision can be applied.

As for compulsory licensing for the local production of generics, sections 84-89 of the Indian patent law offer ample grounds for its issuance, which include:

- damage to existing business or industry, or that which may be developed or established in India;
- existence of demand for the patented good that is not supplied in adequate extent or on reasonable terms;
- lack of provision or development of export markets for the patented good produced in India;
- lack of local working of the patented invention on a commercial scale in the Indian territory in an adequate or feasible way; and
- lack of exploitation of the patented invention on a commercial scale in the Indian territory because of importation from abroad.

Moreover, the law does not restrict compulsory licensing to only one producer of generics; licenses can be issued to various producers in order to promote competition. Another advantage of these compulsory licensing provisions is that they can be used for all classes of drugs. However, the law causes delays in issuing compulsory licenses by determining a three-year grace period, starting from the grant of the patent, for issuing such licenses; and by not predetermining a deadline for them.

With respect to compulsory licensing, the 2005 patent law of India especially innovates by including, among the conditions for issuing such licenses, the failure to supply exportation markets with goods patented in the country. This provision is particularly important for the international community, given the dependence of developing countries, including Brazil, on medicines produced in India. For example, nearly 50% of all drugs used to treat AIDS globally are produced in India; and the country exports drugs to over 150 countries. Article 31 (f) of TRIPS restricts the export of compulsorily licensed medicines in member countries to an amount inferior than that destined for the domestic market; however, as the domestic market in India is relatively large, the country could still supply most export markets. Another option to export compulsorily licensed drugs would be to use the mechanism agreed on August 30, 2003 as a solution to Paragraph 6 of the Doha Declaration, also included in the Indian law, which allows the export of these drugs to countries that lack pharmaceutical production capabilities. This mechanism allows the issuance of a compulsory license immediately, but requires that *i*) each product be compulsorily licensed both in India and in the importing country, *ii*) a WTO authorization is obtained and that *iii*) the packaging of the product is differentiated in order to prevent smuggling (Society for Economic and Social Studies, 2007, p. 31-40).

India also allows parallel importation, with the aim of reducing the prices of foreign patented products sold in the country.

3.2 Restrictions and opposition to the concession of patents

A major concern associated with the patenting of drugs and food products refers to the granting of frivolous patents and the practice of *evergreening*, which consists of the extension of the term of the patent – set by TRIPS to 20 years – through the patenting of molecules that are similar to pre-existing ones and that represent relatively little innovation.

India's patent law amendments seek to prevent the granting of such frivolous patents by stipulating that “an inventive step involves technical advances as compared to the existing knowledge or having economic significance or both”, and that “a pharmaceutical substance is a new entity involving one or more inventive steps”. These amendments also stipulate in Section 3 (d) that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy is not patentable” and that “salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy”. Section 3 (d) is the most controversial and powerful instrument to prevent frivolous patents, banning patenting activity in the absence of an innovative or inventive step.

The Indian subsidiary of Swiss pharmaceutical multinational Novartis has filed a lawsuit against the rejection of its patent application for the leukemia drug Gleevec. This drug was originally patented abroad in 1993, and TRIPS allows countries such as India, that did not recognize patents on pharmaceutical products before complying with the Agreement, to render drugs patented before 1995 forever ineligible for patenting. However, Novartis applied for a patent in India for the beta crystalline form of Gleevec, arguing that such drug represented an improvement over its previous form, because it is less hygroscopic and therefore more stable. Nevertheless, the Indian patent office rejected such application arguing that, in its new version, Gleevec did not meet the requirements of inventive step and non-obviousness. This version did not constitute a new molecule; moreover researchers versed in the chemistry of the molecule could see that its patented beta crystalline form would already have the useful properties indicated by Novartis. In other words, the new version of Gleevec would represent a structurally distinct form of a previously known substance, the patenting of which would be specifically vetoed by Section 3 (d) of the Indian patent law. Novartis filed the lawsuit in January 2006 in Chennai High Court, which upheld the patent office's denial to grant a patent for Gleevec. After the company contested, the case reached the Supreme Court, where it has not yet been judged.

Additionally, Novartis has filed a second lawsuit challenging the constitutional validity of Section 3 (d) and claiming that it violates TRIPS. The Chennai High Court considered itself without jurisdiction and unfit to judge the conformity of national legislation with TRIPS, something which can only be done by the WTO in response to a member country

complaint, and denied the unconstitutionality of Section 3 (d). For these reasons, the lawsuit was dismissed on August 6, 2007. Subsequently, Switzerland informed it would not take a complaint to the Dispute Settlement Body of the WTO. Novartis has, nonetheless, decided to continue to pursue the case in the ambit of the Intellectual Property Appellate Board and the Supreme Court of India. Patent applications filed by other multinationals such as Roche were also denied. The Novartis court cases should create jurisprudence with significant implications for the Indian patent regime and the production and pricing of medicines in the country and abroad.

Significantly, the Indian law allows opposition to patents before and after their concession.² Section 25 (1) requires that the Controller publish the patent application and enables any entity or individual to challenge such patent before it is granted. Section 25 (2) allows any entity or individual to submit an opposition to the patent after it is granted, but before the expiration of the one year deadline from the date of its publication. One of the main grounds for patent pre or post-grant opposition is the lack of an inventive or innovative step (Society for Economic and Social Studies, 2007, p. 40-47).

TRIPS established a mechanism whereby developing countries like India, which used the transition period of ten years to comply with the Agreement, would have to accept and file applications for pharmaceutical patents – in what became known as a mailbox – even though they did not need to grant such patents during that transition period. In India, this mechanism was established through the amendment of the patent law of 1999. Between 1995 and 2005 more than 7000 patent applications were filed in the mailbox. However, during this same period many Indian companies began to produce drugs for which patent applications were filed in the mailbox. A major concern regarding the Indian patent law of 2005 was that, once pharmaceutical product patents were recognized, all drugs produced by local companies for which patents were granted via the mailbox mechanism would have to be withdrawn from the market, greatly increasing their prices. This law clarifies, however, that in such cases the Indian companies will be allowed to continue to produce these drugs after paying royalties to the patent holders. In practice, this amounts to compulsory licensing.

Finally, although the object of the patent cannot be commercially exploited by any entity other than the patent holder or a third party licensed by it, TRIPS allows for exceptions in cases where this object is used for non-commercial purposes. Notably, the agreement allows for further research on patented innovations in order to facilitate the market entry as expeditiously as possible of other innovations that may substitute for them and that require a trading license. This exception, known as the “Bolar exception”, therefore allows for the use of patented innovations without permission from the patent holder, and is embodied in Section 107 (a) of the Indian patent law. This is an important provision, because it allows generic drug companies to conduct research on patented drugs and biological resources

2. The decree of 2004 had restricted the possibility of opposition to patenting by reducing the number of conditions under which the grant of a patent could be challenged from nine to two, and by eliminating the provision that allowed the plaintiff a hearing in person. However, subsequent amendments restored the opposition in two stages, before and after the grant of the patent, replacing Sections 25 and 26 in the 2005 law.

in order to obtain the approval of and to market equivalent or similar drugs or biological resources immediately after the patent expires (Society for Economic and Social Studies, 2007, p. 47-48).

3.3 The patenting of biological resources

Within the constraints imposed by TRIPS, Indian law seeks to limit patent protection of living beings and biological materials. The 2002 amendment of the patent law restricts patenting of genetically modified organisms (GMOs) to their processes or preparation methods. Living entities of artificial origin, such as microorganisms or vaccines, may be proprietary, as well as biological material that has been subjected to substantial human intervention, such as recombinant DNA and plasmids. Other manufacturing processes of biological materials that are also produced by substantive human intervention, relating to microorganisms or chemicals using microorganisms, may also be protected by patent rights.

However, the technology of genetic seed sterilization, procedures for cloning or modifying the germ line or genetic identity of either humans or animals, because they are contrary to public order or morality, cannot be patented in India. Furthermore, the use of human embryos or animals for any purpose is also excluded from patent protection. Because it does not meet the invention requirement, the mere discovery of a scientific principle, the formulation of an abstract theory or the discovery of any living matter or nonliving substances occurring in nature are also ineligible for patents in the country. Biological materials, such as organs, tissues, cells, viruses, or substances obtained merely by mixture, resulting only in the aggregation of the properties of its components or in a process for producing such substances, where there is no increase in efficacy, also do not meet the invention requirement and cannot be patented. In addition, agriculture and horticulture methods and any procedures for medical, surgical dressings, prophylactic, diagnostic, therapeutic or other treatments of humans or any process for a similar treatment of animals to prevent them from acquiring diseases or to increase their economic value or that of their products, including prophylactic treatments such as vaccination and inoculation, are not patentable. The whole or part of plants and animals other than microorganisms, including seeds, variety, species and clones, or essentially biological processes for the production of plants and animals, as well as any source of artificial living entities, such as the entirety or part of transgenic plants or animals, cannot be patented. Finally, a matter which has no determined function, nor industrial application or inventive activity, such as sequences or inventions which in effect are traditional knowledge or which are an aggregation or duplication of known properties of traditionally known components, are likewise not eligible for patenting (Inpi, 2007, p. 65-69).

India became a member of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure on December 17, 2001. The Treaty allows that the deposit of micro-organisms in an international depositary authority be recognized for the purposes of patent applications. Its relevance stems from the fact that the reproduction of micro-organisms based solely on their description in patent

applications is not feasible in practice, making it necessary to deposit their lines to allow for their testing and examination by others. In India, the authorized depository is the Institute of Microbial Technology, Chandigarh.

4 INDIA'S PROTECTION OF PLANT VARIETIES AND FARMER'S RIGHTS ACT

Article 27.3 (b) of TRIPS states that “Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by a combination of both”. As indicated previously, India decided not to recognize the patenting of plant varieties. TRIPS negotiators probably supposed that the *sui generis* system adopted by member countries would be the International Union for the Protection of New Varieties of Plants (Union Internationale pour la Protection des Obtentions Végétales – UPOV) although there is no mention anywhere in the Agreement of UPOV. However, India is not a member of UPOV, and, although the government has declared its intention to join the Union, it has confronted strong domestic resistance, motivated by the perception that UPOV generates a bias in favor of breeders’ rights at the expense of the rights of farmers, which are not recognized nor protected. As an alternative to UPOV, the Indian *sui generis* law created to comply with TRIPS is the Protection of Plant Varieties and Farmer’s Rights Act, of 2001.

Significantly, India was the first country to include farmer’s rights in its legislation in order to counterbalance the rights of breeders, the protection of which is required by TRIPS and is almost the only concern of UPOV. Farmers’ rights in the Indian law are protected by provisions that determine the following:

- 1) Farmers have the right to keep and sell seeds, even those of protected varieties, provided they have not been imported and branded with the breeder’s registered name so as to indicate that they are seeds protected by law. The right of farmers to sell seeds is crucial in a country like India, where 87% of the used seeds are provided by the farming community. If the farmers were denied the right to sell seeds, not only their income would be significantly reduced, but the farmers community would no longer be the largest seed producer in the country, possibly affecting the food security of India.
- 2) Farmers who breed or develop new plant varieties also have the prerogative to register these varieties and to benefit from other forms of protection. Thus, the law recognizes the farmer not only as a cultivator but also as a conserver of the agricultural gene pool and an informal breeder.³ Hence the need to protect his or her plant varieties.

3. India defines “breeder” as a person who reproduces, evolves or develops any plant variety. “Farmer” is defined as one who cultivates crops by cultivating the land himself or herself, or who directly supervises the cultivation of the land to conserve and preserve wild species or traditional varieties or to add value to these species and varieties through the selection and identification of their useful properties (Sahai, 2003, p. 15-16).

- 3) The creation of a National Gene Fund through which breeders have to pay for the use of farmers' plant varieties in the generation of essentially derived varieties. Any individual is entitled to register a claim for the protection of a plant variety at a notified center that, if deemed genuine, will lead to the initiation of a procedure for benefit sharing and the deposit of a share of the resulting profits in the Fund. This procedure allows for the registration of plant varieties on behalf of farmers even when farmers themselves are handicapped by illiteracy or ignorance.
- 4) A full disclosure of the sources and origins of plant varieties and of passport data on the part of breeders. Failure to meet this prior requirement is punishable with heavy fines and imprisonment. Thus, the law adopts the principles of prior informed consent and benefit-sharing endorsed by the Convention on Biological Diversity (CBD).
- 5) The use of reproductive technology for genetic seed sterilization, known as the terminator, is prohibited.
- 6) Farmers cannot be prosecuted for violating the rights of breeders if they can prove that they were not aware of these rights.
- 7) Farmers who wish to examine documents and papers or receive copies of the rules or decisions taken by the various authorities may do so with exemption of all fees.

Thus, the Indian law effectively exploits the flexibilities afforded by TRIPS, in addition to meeting the requirements of the CBD. The protection of farmers' rights is considered paramount in a still predominantly agrarian and rural country like India.

The Indian law also allows the use of registered and protected varieties for research purposes, even when creating new varieties, provided that they are not essentially derived varieties, as broadly defined in the UPOV Convention of 1991, so as to include natural selection, mutant selection, somaclonal variants, backcrosses and transformation by genetic engineering.

Moreover, provisions of the law aimed at preserving the public interest allow the exclusion of certain plant varieties from protection when the ban on commercial exploitation of these varieties is necessary to "protect the order or public morality or human, animal and plant life and health, or to avoid serious prejudice to the environment". Compulsory licenses shall be issued if the protected varieties are not available at reasonable prices without justification from the breeders.

Breeders' rights include not only marketing exclusivity for registered plant varieties, but also exclusivity for the production, sale, distribution, import or export of such varieties, or for appointing another party to do so. Moreover, such rights are not applied only to the varieties, but also to their packaging and trademarks; and when there are suspicions of violation or infringement of these rights the burden of proof of innocence is placed on the accused. The use of trademarks or packages similar to those registered by breeders without their permission constitutes a violation of those rights. In cases of conviction, the punishment includes heavy fines and imprisonment for up to two years (Sahai, 2003, p. 59-69).

5 THE LEGAL REGIME FOR THE USE OF OGMs, BIOLOGICAL RESOURCES, STEM CELLS AND GEOGRAPHICAL INDICATIONS

5.1 The regulation of GMOs

The Guidelines on Biosafety and Recombinant DNA (1990) are part of the Environmental Protection Act (1986). In 1994, after India signed the CBD, the Department of Biotechnology revised its earlier guidelines to include the safe handling of GMOs in research, application and transfer of technology. This includes large-scale production and release of transgenic plants, animals and parts thereof in the environment. The guidelines are also provided for the transportation and importation of GMOs for use in research laboratories. In India there is a registry to monitor trials with GMOs, but the regulations are implemented by various ad hoc committees. The most important of these committees are the following:

- Institutional Biosafety Committees, responsible for the local implementation of guidelines;
- The Review Committee on Genetic Manipulations, responsible for issuing permits; and
- Genetic Engineering Approval Committee (GEAC), responsible for monitoring the large scale and commercial use of transgenic materials.

These committees have statutory authority, their members are appointed by the Department of Biotechnology (within the Ministry of Science and Technology), and composed by the scientific community and representatives of the Department and the Ministry of the Environment and Forests. The GEAC should be aided by State Biotechnology Coordination Committees and District Level Committees, yet very few states have established such committees.

There is no national policy on GMOs, whose approval is made on a case by case basis by the GEAC. The authorization of bt cotton⁴ by the GEAC took seven years due to the objection of the Ministry of Agriculture, and was the first granted by the Committee, in March 2002. In 2009, the GEAC gave its second approval for eggplant-bt, but a moratorium on the introduction of this OGM was imposed by the Minister of the Environment. At present, nearly 22 transgenic plants are being tested by different organizations for different purposes in India.

Recently, a report from the Ministry of the Environment and Forests revealed seeds of transgenic unauthorized bt cotton being sowed in hundreds of acres of Indian lands. In 1997, without authorization, the transgenic eggplant was located in a public agricultural research institute in the absence of proper safeguards. Such occurrences motivated the debate on GM crops in India and the questioning of the effectiveness of the safety guidelines'

4. Bt stands for *Bacillus thuringiensis*, a bacterium that is the source of resistance genes in cotton and other plants to insects and pests.

implementation. In fact, most bt cotton seeds used in the states of Gujarat and Rajasthan are pirated, containing the *Cry 1 Ac* gene, patented by Monsanto and licensed abroad to the Indian company Mahyco. An inspection made by the GEAC in a village of Gujarat found unauthorized cotton seeds in areas of 12 hectares, provided by a local company, Navbharat Seeds (Chaturvedi, 2005, p. 47-49).

As result, a task force created by the Ministry of Agriculture in 2003 to examine the management of biosafety in India recommended the establishment of the National Biodiversity Regulatory Authority (NBA) with a broader mandate than the GEAC. The task force report suggested institutional changes and reorientation of policies towards GMOs, as well as several measures to make the system faster and more responsive for the diffusion of biotechnology.

5.2 The system of access to genetic resources

In December 2002, India approved extensive legislation restricting access to genetic material in its territory. This legislation prohibits any individual or foreign company to “obtain any biological resource occurring in India or knowledge associated thereto” for research, survey or commercial use without the prior approval of the NBA. The regulation of bioprospecting by resident Indian citizens and Indian companies is the responsibility of state boards and is less restrictive. The statute also prohibits any individual or foreign company to “transfer the results of any research relating to biological resources occurring in or obtained from, India” without the prior consent of the NBA. Moreover, even if the NBA approves the acquisition or transfer of any such resource or information, the applicant may not subsequently transfer this resource or information without its consent. The law, in turn, requires the NBA to ensure equitable benefit sharing for the use of “accessed biological resources, their byproducts (...) and knowledge related thereto”. When a biological resource or associated knowledge has been acquired from a specific individual, group or organization, the NBA may, but is not obligated to, direct payment of moneys collected to such individuals, groups or organizations. The law does not require that bioprospectors obtain the consent of affected individuals or groups before obtaining biological resources. However, the NBA must consult with specially created local committees when making decisions “relating to the use of biological resources” and associated knowledge. Finally, the law prohibits any person, whether foreigner or Indian, to apply for any intellectual property right, inside or outside India, “for any invention based on any research or information on biological resource obtained from India” without the prior approval of the NBA (Safrin, 2004, p. 651-652).

5.3 The regulation of stem cell research

In response to a global debate provoked by the Administration of U.S. President George W. Bush, which had identified India in its list of sources of stem cell lines, the Department of Biotechnology has written to all major biotechnology companies to clarify that any transfer of biological material is subject to clearance by the Ministry of Health and Family

Welfare and the Indian Council of Medical Research. A National Committee on Bioethics was formed to grant such permissions and to monitor research projects. Since then, it has been ascertained that human stem cells lines do exist in the country, and the company Reliance Life Sciences announced that it had requested a “provisional patent” in the field of embryonic stem cells in the United States. While much of the debate has focused on possible U.S. funding for such research, the Indian government is particularly concerned about the possibility of the occurrence of a scenario in India similar to the ones seen in Singapore and Australia, in which stem cells from aborted fetuses and frozen embryos in *in vitro* fertilization clinics are sold in the United States.

The guidelines for biomedical research in India were drafted in 1992, but only completed after several rounds of discussions in 2000. They define the human material with potential for use in biomedical research as organs and parts of organs, tissues and cells, subcellular structures and cell products, blood, gametes (sperm and oval), embryos and fetal emissions and waste (urine, feces, sweat, hair, epithelial scales, chips nails, placenta cell lines and human tissue). The Bioethics Committee is expected to announce in the near future a policy which does not allow human cloning in the country, but which promotes embryonic stem cell research provided that a consent form accompanies each study.

To date, only one Indian private company, Reliance Life Sciences, has developed a product in this area, Christened Relicord, which contains stem cells taken from the umbilical cords of babies and used to treat patients with leukemia and other disorders. As mentioned above, the company has already applied patent for this product in the United States (Chaturvedi, 2005, p. 49-50).

5.4 Geographical indications and biological resources

The Indian law on geographical indications of goods, of 1999, affords protection to traditional Indian products like Basmati rice and Darjeeling tea. India is still conducting a survey to compile a list of products for which the country will seek rights of geographical indication (Sahai, Kumar and Ahmed, 2005, p. 29).

6 FINAL CONSIDERATIONS

The laws and institutions that regulate the use and ownership of biotechnology in India are multifaceted and complex. Moreover, as already mentioned, these laws and institutions are still very incipient and subject to contestation. The process of creating jurisprudence certainly transforms the meaning and interpretation of many of its provisions.

Nevertheless, it is possible to discern patterns in what concerns the protection of the public interest in the various laws that impact the use and ownership of biotechnology in India. Restrictions on patenting of pharmaceuticals and possibilities of opposition to such patenting are intended to ensure broad access to essential medicines and to protect public

health. The *sui generis* legislation on the protection of plant varieties is unique in offering ample recognition of the rights of farmers, counterbalancing the international obligation to protect breeder's rights. Similarly, the regulation of access to biological resources in India seeks to prevent biopiracy as well as to protect the rights of the holders of these resources and of the traditional knowledge associated with them, introducing differential treatment for research, survey and commercial use made by firms and individuals, foreigners and Indians. For such purposes, the exploitation of the flexibilities offered by TRIPS and the notable creativity in developing new forms of protection were crucial.

Finally, it is worth stressing the high degree of innovation present in the Indian legislation that relates to biotechnology. Remarkably, the requirement of an inventive or innovative step for pharmaceutical patenting, mainly expressed in Section 3 (d) of the Patent Act, the broad protection of farmers' rights in a *sui generis* and unprecedented law that protects plant varieties, and the broad legal and institutional protection afforded to Indian biological resources and traditional knowledge constitute important precedents that can be replicated or adapted to the biotechnology laws of other developing countries, like Brazil.

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