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SPECIFIC HUMAN RIGHTS ISSUES

Human rights and the human genome

Interim report submitted by the Special Rapporteur,
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* The end notes are being circulated as received.

** This report was submitted late in order to allow the expert sufficient time to complete her research.

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Summary

In its resolution 2003/4, the Sub-Commission on the Promotion and Protection of Human Rights appointed the Special Rapporteur to undertake a study on human rights and the human genome. In the present interim report, the Special Rapporteur addresses issues related to intellectual property rights in the context of biotechnology and genetic resources, with a view to informing her final report.

Section I provides a detailed overview of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other international instruments, with reference to specific provisions on the application of patents to genetic resources. Section II contains a review of national and regional legislation related to patenting and biotechnology. In her conclusion, the Special Rapporteur recalls the need to reconcile the international patent regime with the promotion of scientific research.

Contents

Introduction

1. In its decision 2004/120, the Commission on Human Rights, taking note of Sub-Commission resolution 2003/4, approved the decision of the Sub-Commission to appoint Ms. Iulia-Antoanella Motoc as Special Rapporteur to undertake a study on human rights and the human genome, based on her working paper (E/CN.4/Sub.2/2003/36). The working paper set out to address some of the potential conflicts between health law, intellectual propriety and human rights regimes from a human rights perspective, taking into account four issues: the human genome - common heritage of mankind; human genetic manipulation and human rights; discrimination; and intellectual property and genetics. The Special Rapporteur was requested to submit her preliminary report to the Sub-Commission at its fifty-sixth session and her final report to the Commission at its current session.

2. The Sub-Commission received the preliminary report of the Special Rapporteur (E/CN.4/Sub.2/2004/38), which set out to consider the question of genetic discrimination in greater detail, addressing a number of issues including privacy, the use of genetic information in the context of employment and determinations of insurability, as well as special considerations related to vulnerable groups. In decision 2004/112, the Sub-Commission requested the Special Rapporteur to submit an interim report to the fifty-seventh session. The present report is submitted in accordance with that request.

3. The Special Rapporteur went to Paris from 22 to 30 November 2004to hold discussions with the United Nations Educational, Scientific and Cultural Organization (UNESCO) and the Government of France. While in Paris she held discussions with the Assistant Director-General of UNESCO; the Director of the Bioethics section and other members of staff; and representatives of the Governments of Belgium, Canada, Japan as well as France. The discussions highlighted the difference between the ethics approach taken at UNESCO and the legal one assigned to the Office of the High Commissioner, as well as other aspects specifically linked to intellectual property and the question of discrimination in the field of genetics and cloning.

4. In view of the important developments in the field of intellectual property, the Special Rapporteur has chosen to devote this year's report to that theme.

5. The General Assembly in resolution 59/280 of 23 March 2005 approved the Universal Declaration on human cloning in which Member States were called on (a) to protect adequately human life in the application of life sciences, as well as measures necessary; (b) to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life; and (c) to prohibit the application of genetic engineering techniques that may be contrary to human dignity.

6. In April 2005, in what scientists say is a stunning leap forward, a team of researchers in the Republic of Korea announced the development of a highly efficient procedure for producing human embryos by cloning and then extracting their stem cells. They reported that they had used their method to produce 11 human stem cell lines that were genetic matches of patients aged 2 to 56. In the United Kingdom, research has continued in the field of therapeutic cloning.

International framework

7. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) contains detailed, comprehensive, substantive rules and is linked to the comparatively hard-edged dispute settlement system of the World Trade Organization (WTO) in which treaty agreement are enforced through mandatory adjudication backed up by the threat of retaliatory sanctions.[1]

8. TRIPs' proponents argue that a uniform set of relatively high standards of protection fuels creativity and innovation, attracts foreign investment, and encourages a more rapid transfer of technology. Strong domestic intellectual property rules, in this view, are essential to economic growth and development. Instrumentally, proponents defend TRIPs as part of a WTO "package deal" in which developing countries receive freer access to the markets of industrialized nations in exchange for their agreement to protect the intellectual property rights of foreign nationals. According to this rationale, Governments importing intellectual property products agree to suffer the (hopefully short-term) welfare losses that strong intellectual property rules can engender in exchange for the immediate benefits and concessions they receive from other WTO agreements.[2]

9. Article 27.2 of the TRIPS Agreement allows members to exclude from patentability inventions whose commercial use would jeopardize the public order or morality. The article allows members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans and animals. The article provides for the possible exclusion from patentability of certain innovations in order to protect human, animal or plant life or health other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. Article 27 is currently under review in the TRIPS Council. The vague wording of the exceptions leaves plenty of room for contradictory interpretations regarding the patentability of the human gene.

10. Article 31 of TRIPS stipulates the conditions under which members of WTO may grant compulsory licensing, i.e. licences to physicians, researchers and others to use a patented gene sequence without the patent holder's permission, for a reasonable fee paid to the patent holder. Laboratories would be able to undertake genetic diagnostic testing and possibly discover new mutations. Pharmaceutical companies would not be able to prevent pharmacogenomic testing related to their products and research on gene therapies would be stimulated. For example, if a company had a specific patent on a gene or sequence, then that company would receive a portion of the profits when the specific gene or sequence they discovered was used in a mass-market drug. This is a feasible alternative because future drugs are likely to work because they influence the behaviour of many genes. Cross-licensing agreements would still make profits attainable and thus incentive high, while also allowing crucial information to be shared in order to promote disease research.

11. In February 2003, the United Nations Development Programme (UNDP) released a report on the world trading system that was remarkably critical of the treaty. Asserting that the "relevance of TRIPs is highly questionable for large parts of the developing world," the report urged developing countries to "begin dialogues to replace TRIPs ... with alternate intellectual

property paradigms" and, in the interim, to "modify ... the way the agreement is interpreted and implemented.[3]

12. The challenge facing Non-Governmental Organizations (NGOs), and intergovernmental actors appears in the Declaration on the TRIPs Agreement and Public Health adopted in November 2001 as part of the launch of a new round of WTO trade talks in Doha. The Declaration responds to the claim by developing nations that they are unable to afford the patented pharmaceuticals needed to address the massive HIV/AIDS crisis within their borders. It gives least developed countries 15 years before they must apply the relevant sections of the TRIPS Agreement with respect to pharmaceuticals.[4]

13. In 1983 about 100 nations adopted the International Undertaking on Plant Genetic Resources, a non-binding accord negotiated under the aegis of the Food and Agriculture Organization of the United Nations (FAO). It starts by stating that it "is based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction" (art. 1). Although the Undertaking applied only to plant genetic resources, an area in which the concept of a global genetic commons was especially strong, all genetic material had traditionally been viewed as part of a global commons. As such, genetic resources were obtainable for the use of all (often referred to as "open access"). Like information in the public domain, they were a good accessible without restraint.[5]

14. The traditional view that genetic resources formed part of the global commons was eroded by the extension of patents to living organisms and later to genetic material. In most developed countries, patents are now issued for micro-organisms, genetically modified plants and animals, and isolated and purified genes and genetic sequences. Patents will not be granted for genetic material as found in nature, such as a gene in a plant or a fish. A patent can, however, be obtained when that gene has been removed and isolated, and a useful function for it identified. An isolated and purified gene does not exist in that form in nature. Thus, a patent could be issued for a gene that enables a flounder to resist frost, provided that the "inventor" has isolated and purified that gene and identified its role in frost resistance. The ability to patent such genes is significant because the holder of a patent on an isolated and purified gene can prevent all others from making or using that gene.[6]

15. In 1989 some developed countries effectively pressed for the addition of annex I to the Undertaking to make clear that the Undertaking's common heritage of mankind concept did not affect the rights of plant breeders to exclude others from using their new and distinct varieties under the International Convention for the Protection of New Varieties of Plants (UPOV Convention). Two years later, the UPOV Convention was revised to develop these breeders' rights by curtailing exceptions that had been allowed for the free replanting, exchange and use for breeding purposes of protected varieties and their propagating material. These exceptions had reflected aspects of an open system because they had allowed protected varieties to be used for a range of purposes without the original breeders' authorization. By the early 1990s, not only were biological goods subjected to a range of intellectual property rights, but developing countries were facing pressure to extend intellectual property protection to such goods in their own countries.

16. Consequently, developing countries began taking steps to enclose raw genetic material. At the end of 1991, they successfully pressed for the adoption of annex III to the Undertaking. The annex stated that the Undertaking's heritage of mankind concept was "subject to the sovereignty of the states over their plant genetic resources" and that "nations have sovereign rights over their plant genetic resources." This assertion of sovereign rights over raw genetic material represented the death knell of the core concept of a global commons, namely, that sovereigns would not claim or appropriate something in that commons as exclusively their own.[7]

17. By 1992, the concept of a global commons or open system for genetic resources began to be forgotten. The Convention on Biological Diversity begins its discussion of genetic resources by proclaiming not the common heritage of such resources, but rather the sovereignty of nations over them. Article 15(1) of the Convention states, "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation." The Convention broadly defines "genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity" and “genetic resources” as “genetic material of actual or potential value (art. 2). Although earlier proposals had employed the "common heritage of mankind" language, most developing countries emphatically rejected it. Consequently, the preamble to the Convention pointedly refers to genetic resources as the "common concern" rather than the "common heritage" of humankind.

18. The Convention on Biological Diversity, after acknowledging sovereign rights over genetic resources, requires parties to "endeavour to create conditions to facilitate access" (art. 15(2)) to such resources. The trend of genetically rich countries, however, has been the opposite: to restrict and encumber access to raw genetic material within their borders, largely in response to the increased patenting of genetic material and bioengineered goods since the conclusion of the Convention. These countries particularly object to developed countries' granting of patents to genes isolated from material that was taken from or originated in developing countries. Corporations from developed countries increasingly obtain patents over genetic material and biotechnological innovations; developing countries increasingly enclose their raw genetic material.[8]

19. Article 15(5) of the Convention specifies that “access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources", unless that country provides otherwise. As a result, international work on implementation of the Convention includes model legislation prescribing sovereign ownership or extensive control over genetic resources. Since the adoption of the Convention, over 40 nations have passed or are in the process of passing laws that greatly restrict access to raw genetic material within their borders.[9]

20. The evolution of principles, norms and rules for preserving the world's biological diversity has been shaped by disputes over intellectual property protection. The biodiversity regime's foundational agreement - the Convention on Biological Diversity - protects intellectual property rights as part of a package of treaty commitments that mediate competing claims of industrialized and developing countries. In negotiations leading to the Convention's adoption in 1992, biodiversity-rich but biotechnology-poor developing countries saw the financial advantages of technology transfers as incentives to preserve rather than use the genetic resources within their borders. Biodiversity-poor but biotechnology-rich industrialized States, in contrast,

sought to minimize benefits and transfers while maximizing access to those resources. The Convention's recognition of intellectual property rights facilitated a compromise between these two positions, allowing industrialized countries to support the transfer of proprietary technologies to developing states as a quid pro quo for access.[10]

21. Eventually, though, the biodiversity regime's method vis-à-vis intellectual property protection has evolved in ways that could not have been predicted from a simple interpretation of the Convention's text. The Conference of the Parties (COP) - the convocation of States parties that determines how the Convention should be applied and implemented has given comprehensive consideration to bringing the intellectual property rights in the TRIPs Agreement into line with the Convention's objectives. In particular, developing countries active in the COP, such as China, the Group of 77 (G-77), India and several African countries, together with the support of biodiversity NGOs including Greenpeace, the World Wildlife Fund, the International Union for the Conservation of Nature and Natural Resources, and the World Resources Institute, have expressed apprehension about the adverse effects of TRIPs on the Convention and have sought to harness intellectual property rules to promote compliance with the Convention. As explained below, the intellectual property-related work undertaken by the COP is concentrated on two areas: (a) protecting the traditional knowledge of indigenous communities, and (b) advocating that intellectual property rights applicants should disclose the country of origin of the genetic resources or traditional knowledge which form the basis of their applications.

I. INTELLECTUAL PROPERTY RIGHTS AND ACCESS AND BENEFITS SHARING ISSUESS

22. After the entry into force of TRIPs, developing States, led by China and the G-77, and sympathetic NGOs such as the World Wildlife Fund began to express concern over the association between intellectual property rights and the access and benefit-sharing rules in the Convention. The COP convened a panel of experts and later an ad hoc working group to develop guidelines to address this relationship. In October 2001, the working group published draft guidelines (the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization which the sixth COP adopted in April 2002.The Bonn Guidelines' most important recommendation was to encourage “the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge … in applications for intellectual property rights”. The Guidelines advocate the use of these disclosures to monitor whether applicants have obtained the prior informed consent of the country of origin and complied with the conditions of access that that country imposed. The COP also invited the World Intellectual Property Organization (WIPO) and other intergovernmental organizations to contribute to an ambitious series of studies, including analyses of country of origin and prior informed consent disclosures in patent applications, material transfer agreements, and the role of oral evidence of prior art in examining, granting, and maintaining intellectual property rights.[11]

23. Since 1996, the World Health Organization (WHO) has monitored TRIPs, advising WHO member States on ways to attain their national health goals by making use of so-called "safeguards" already in TRIPs that give flexibility to intellectual property protection in the context of public health objectives. In 1996 the World Health Assembly adopted on the Revised Drug Strategy, which requested the WHO Director-General to report on the impact of the work

of the WTO with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate.[12] This resolution led to the publication in 1998 of a WHO-sponsored guide to the public health consequences of TRIPs.

24. In May 2003, WHO member States adopted a resolution establishing a new body to look at the effects of intellectual property protection on the development of new drugs. The new body would "collect data and proposals from the different actors involved and produce an analysis of intellectual property rights, innovation, and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries." The resolution also urge member States "to reaffirm that public health interests are paramount in both pharmaceutical and health policies" and "to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in [TRIPs]".[13]

25. The Sub-Commission and the Commission first considered legal mechanisms to protect the intellectual property of indigenous communities in the early 1990s. Work proceeded along two parallel tracks. The Sub-Commission charged the Working Group on Indigenous Populations with the task of drafting a declaration on the rights of indigenous peoples. The Sub-Commission also appointed a Special Rapporteur to conduct a study on and later to draft Principles and Guidelines for the Protection of the Heritage of Indigenous People (E/CN.4/1995/26, annex).

26. The draft declaration, which was submitted to the Sub-Commission in 1994, recognizes the right of indigenous peoples to "the full ownership, control and protection of their cultural and intellectual property" and to restitution of such property "taken without their free and informed consent or in violation of their laws, traditions and customs." The draft declaration does not specify how these rights are to be given effect, nor does it address their relationship to international intellectual property agreements. According to one commentator, however, these rights, were they to become binding, would stand in opposition to existing approaches to intellectual property protection, including those found in TRIPs.

27. Sub-Commission resolution 2000/7 promises to throw a wider spotlight on the human rights impact of the TRIPS Agreement. It declared that "since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other hand".

28. United Nations human rights bodies have subsequently devoted special attention to intellectual property issues. The actions taken and documents produced by these bodies - many of which contain trenchant critiques of TRIPs - include: (1) four resolutions by the Commission of Human Rights on "Access to medication in the context of pandemics such as HIV/AIDS," initially sponsored by Brazil, which urge States to adopt a variety (E/CN.4/Sub.2/2001/13) of measures to ensure such access; (2) a report on TRIPs by the High Commissioner, which argues that intellectual property laws must put forward the public interest in access to new knowledge

and innovations, opposes the adoption of TRIPs-plus standards, and highlights States' obligations to promote the right to health by providing access to affordable medicines to treat HIV/AIDS; (3) a statement by the Committee on Economic, Social and Cultural Rights (E/C.12/2001/15) which emphasizes that intellectual property rights "must be balanced with the right to take part in cultural life and to enjoy the benefits of scientific progress and its applications," and states that both "national and international intellectual property regimes must be consistent with" the obligation of states parties under the International Covenant; (4) a progress report by the Special Rapporteurs of the Sub-Commission on Globalization (E/CN.4/Sub.2/2001/10), which asserts that intellectual property protection has undermined human rights objectives; (5) a second resolution by the Sub-Commission (resolution 2001/21) that identifies a widening set of conflicts between TRIPs and human rights, including "the rights to self-determination, food, housing, work, health and education, and ... transfers of technology to developing countries"; (6) an effort to increase human rights visibility within the trade regime by having the High Commissioner seek observer status with the WTO and participate in reviews of TRIPs; and (7) a report by the Secretary General on human rights and bioethics based on information submitted by states, intergovernmental organizations, and NGOs (E/CN.4/2005/93).[14]

II. NATIONAL AND REGIONAL LEGISLATION

A. The European Patent Convention and EU Directive 98/44/EC

29. In Europe, existing copyright laws specifically prohibit patenting certain biotechnological inventions. The European Patent Convention (EPC) does not specifically state which classes of invention are patent entitled. EPC explicitly precludes the patenting of certain biotechnological inventions. It prohibits the patenting of medical treatments such as gene therapy, those inventions "the publication or exploitation of which would be contrary to '*ordre public*' or morality", and "plant or animal varieties or essentially biological processes for the production of plants or animals" (art. 53). The European Union Directive on the legal protection of biotechnological inventions (98/44/EC) issued on 30 July 1998 (see below) echoes EPC, prohibiting the patenting of "plant and animal varieties" and "essentially biological processes for the production of plants or animals", inventions whose "commercial exploitation would be contrary to *ordre public* or morality, and the human body and its gene sequence unless isolated from the human being.[15]

30. Article 52(1) of EPC provides that "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step." The broad provision of article 52(1), however, is narrowed in scope in subsequent provisions of the EPC.

31. For instance, the EPC specifically prohibits the patenting of gene therapy under article 52(4). Under this article, treatments of the human or animal body by surgery or therapy, and diagnostic methods, are excluded from patentability since they are inventions that are not "susceptible [to] industrial application".[16]

32. Article 53 additionally limits the scope of article 52 by providing exceptions for patent eligibility. Article 53(a) states that "European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to *'ordre public'* or

morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States". The concept of '*ordre public*' could have profound effects upon the growth of European patent law regarding animal patents and gene therapy patents. '*Ordre public*` gives automatic standing to concerned citizens, empowering them to challenge individual patents on the ground that issuance would be morally offensive and allowing the use of the judicial process to shape the law regulating biotechnology patents. In contrast, this type of standing is not available to United States citizens following the decision on the Animal Legal Defense Fund. Such changes in the United States must instead come by the legislative process.

33. Similarly, article 53(b) states that "European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof". The provisions of EPC, however, do not define the meaning of "varieties" or "essentially biological". The absence of binding definitions creates the potential for differing applications of these terms and insufficient market valuations for inventions that embody this subject matter.[17]

34. The Technical Board of the European Patent Organization (EPO), in Decision T 19/90, addressed the concept of "*ordre public*" or "morality," as well as the meaning of "animal varieties." in a manner that drastically limited the patent-eligible subject matter compared to the reasoning of the Board in the Onco-mouse decision.[18]

35. The Board interpreted the provisions of article 53(b) as stating that plant varieties, if produced by a "microbiological process", are patent eligible and "essentially biological" if it comprised "at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result."[19]

36. Although EPC provides consistent procedures and standards for examining a patent application, the interpretation and enforcement of a patent thus granted are reserved for the laws of the individual member States. To pursue a harmonization of patent policy that would give Europe a competitive advantage in biotechnology innovations, the Council of Ministers in 1988 prepared a first draft of a proposed Directive on the legal protection of biotechnological inventions. The objective of the proposed Directive was to summarize rules for the patentability of genes, cells, and other biological material derived from humans, animals and plants, including the patentability of gene therapy. On 30 July 1998 after 10 years of debate and several drafts, the European Union finally issued Directive 98/44/EC to defend inventors' rights in certain biotechnological products. Article 1 of the Directive provided that the member States must protect such inventions under their national patent laws, and had until 30 July 2000 to reform domestic laws.

37. As with EPC, patent protection under the Directive does not reach certain biotechnological inventions. The Directive expressly prohibits the patenting of animal and plant varieties and inventions whose commercial exploitation would be contrary to *ordre public* or morality. It differs from EPC by not expressly excluding all treatment methods of the human or animal body by surgery or therapy and diagnostic methods from patent protection. Rather, the Directive specifically prohibits processes for modifying the germ line genetic identity of human beings by proclaiming them contrary to *ordre public* or morality. Additionally, the Directive

excludes the human body and its gene sequence from receiving patent protection, except when the gene sequence is isolated from the human body.

38. Under article 4(1), "plant and animal varieties," and "essentially biological processes for the production of plants or animals" are excluded from patent protection. As in article 53(b) of EPC, article 4(3) specifies that the provision of article 4(1) does not apply to microbiological processes for the production of plants or animals. Additionally, article 4(2) expressly states that plant and animal inventions are patent eligible if "the technical feasibility of the invention is not confined to a particular plant or animal variety." Unfortunately, the Directive does not provide a clear and workable definition of a "variety".

39. Under article 5(1), the human body and its elements, including the sequences of its genes, are also excluded from patent protection. If the elements or sequences are isolated from the human body and their industrial applications are disclosed, however, the elements or sequences can constitute patent eligible inventions.[20]

40. Article 6 precludes patentability of inventions on the grounds of damage to *ordre public* or morality. This provision is similar to article 53(a) of EPC. Unlike EPC, however, article 6(2) specifically enumerates types of inventions whose commercial exploitation would be contrary to *ordre public* or morality and which are therefore not patent eligible. They include: (a) "processes for cloning human beings"; (b) "processes for modifying the germ line genetic identity of human beings"; (c) "uses of human embryos for industrial or commercial purposes"; and (d) "processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man and animal, and also animals resulting from such processes."

41. The differences in EPC and the EU Directive's provisions may cause some confusion to the interpretation of *ordre public* or morality in Europe.[21] In particular, it is unclear whether article 9(2) of the Directive represents an exhaustive list of examples of activities regarded as contrary to public policy or morality.

B. Biotechnology and United States patent law

42. In the United States, biotechnological inventions ranging from human gene therapy to genetically engineered plants and animals, and processes for their production, are all within the scope of patent-eligible subject matter. Worldwide, United States. patent law provides the broadest protection of biotechnological inventions.[22]

43. The United States Patent and Trademark Office (USPTO) and the courts have seldom considered public policy and morality when addressing the issue of patent eligibility. The ultimate position USPTO was that Congress did not intend to allow patents on humans or on creatures that are essentially human when it passed the Patent Act in 1952. The applicant for a controversial invention submitted a revised application to USPTO with the intent of challenging the rules of patenting life forms as set forth in the landmark decisions in *Diamond v. Chakrabarty*[23] and *Allen*.[24]

44. In the United States, patent eligibility is based on section 101 of Title 35 of the United States Code, as interpreted by the Federal courts. Section 101 of Title 35 states in pertinent part that "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 of this title. "To be patent eligible, a biotechnological invention must fall within one of the four statutory classes of subject matter: process, machine, manufacture, or composition of matter.[25]

45. It is in the discretion of USPTO to interpret whether the statutory requirements for patentability (utility, novelty and non-obviousness) are met. In 1999 USPTO adopted new utility guidelines in response to domestic criticism that it was issuing patents for genetic sequences too liberally, which deterred, rather than promoted, innovation.[26]

C. Japan

46. The Japanese definition of patent-eligible subject matter shares some similarities with those of EPC and the EU Directive by excluding inventions that are contrary to public order or morality. The Japanese Patent Office (JPO) regards the morality and security issues associated with the manufacture or sale of an animal invention as separate from that of patent eligibility. It also holds the point of view that the problems raised by the production of animals should be resolved by other legal measures.

47. Specific microbiological inventions can be excluded from patent eligibility in Japan if they are likely to injure public health. As in article 53(a) of EPC, article 32 of the Japanese patent law states that "inventions liable to contravene public order, morality or public health shall not be patented". Under this provision, it is conceivable that Japan's strict health and safety guidelines regarding genetic research may lead to the exclusion of genetically modified organisms viewed as hazardous from patent protection. Because of religious, cultural and governmental influences, inventions directed towards human cloning will not be granted patent protection, based on grounds of morality. The Japanese system also excludes processes in the fields of medicine, diagnosis, therapy and pharmacology in which the human body is an indispensable element as not being part of "industry".[27]

D. Andean Common System

48. One of the main significant and influential regimes restricting access to raw genetic material is the regional Common System on Access to Genetic Resources promulgated by the Andean Pact nations of Bolivia, Colombia, Ecuador, Peru and Venezuela. Together, these five countries may "harbour the largest proportion of the world's biological diversity. In addition, they play a significant role in international negotiations addressing access to genetic resources issues.[28]

49. Under the Common System, ownership of raw genetic material and derivatives of such genetic resources, such as molecules, effectively vests with the nation-State, i.e. the national Government, rather than with the individual or indigenous community whose land or property houses the relevant genetic resource. Under the Common System, the State either expressly owns

or exercises virtually complete control over such resources. The State also ostensibly owns the genetic material of migratory species, such as migrating birds, in their territories.

E. India

50. In December 2002, India passed complete legislation restricting right of entry to genetic material in its territory. India's law generally prohibits any foreign person or foreign corporation from "obtaining any biological resources occurring in India or knowledge associated thereto" for research, survey … or commercial utilization without the prior approval of India's National Biodiversity Authority. Regulation of bioprospecting by Indian resident citizens and Indian corporations is left to subnational (state) biodiversity boards.

51. The National Biodiversity Authority 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 foreign or Indian, from applying for any intellectual property right in or outside India "for any invention based on any research or information on a biological resource obtained from India" without the prior approval of the National Biodiversity Authority.[29]

F. The Phillipines

52. This regime of the Phillipines broadly encompasses all "research, collection and utilisation of biological genetic resources" within the Philippines "for purposes of applying the knowledge derived therefrom for scientific or commercial purposes". It requires the bioprospector to go through multiple layers of national Government appraisal and permission. In addition, the bioprospecting applicant must obtain written prior informed consent from indigenous communities for bioprospecting within their ancestral lands or from other appropriate local authorities. The applicant must also obtain written prior informed consent from any affected private landowner. It must also engage in and document "sector consultation", which involves a "community assembly" to discuss the project. The applicant must agree to pay royalties or other forms of recompense to the national Government and to the indigenous or local community or individual concerned, as well as enter into a host of other benefit-sharing arrangements.[30]

G. African Union

53. The legislation of the AU requires a bioprospector to obtain prior informed consent from both the national Government and concerned local communities. In addition, collectors may not transfer obtained biological resources or their derivatives to any third party without prior authorization from the national competent authority and the concerned local community or communities.[31]

H. Brazil

54. In August 2001, Brazil adopted a provisional measure to restrict access to genetic material within its territory. The measure requires national Government authorization for "access to components of the genetic heritage" of any non-human organism within Brazil. Such

authorization, however, may be granted only with the prior consent of the indigenous community involved, where access occurs on indigenous territory. Where access occurs on private land, authorization requires the private landowner's prior consent. In addition, the consent of the owners of the tangible property involved, such as the plant containing the sought genetic resources, must be secured. Where there is a prospect of commercial use, access to the components of the genetic heritage requires a benefit-sharing contract. The national Government may, but need not, be a party to the contract. However, all contracts must be submitted to the national Government for registration and approval. Where the national Government is not a party to the contract, it shall be assured where applicable of a share in the benefits.[32]

I. Costa Rica

55. Costa Rica is the country must often cited for the successful regulation of access to genetic material. Costa Rica has concluded multiple benefit-sharing arrangements with corporations. It has adopted a value-added approach to genetic material and created a national organization, INBIO, to provide initial assaying services for raw genetic material.

III. CONCLUSION

56. As a recent phenomenon, international intellectual property lawmaking has broken out of the confined institutional spaces of WIPO and WTO and permeated deeply into international regimes concerning biodiversity, plant genetic resources, public health and human rights. At the same time, the TRIPs Agreement has come under increasing challenge, especially but by no means exclusively from developing countries and NGOs. The recent growth of intellectual Property lawmaking is the result of regime-shifting by State and non-State actors who are dissatisfied with many of the intellectual property treaty agreements negotiated by WTO members and are actively seeking ways to revise or supplement them.[33]

57. It is clear that there are two systems: one for developed countries and one for developing countries. A system that puts too much weight on the patent and privatization can inhibit innovation. On the other hand, that same system has led developing countries to close their system around the notion of State sovereignty, which cannot encourage scientific research. In fact, both systems call into question the notion of “a common human heritage”, by preventing scientific research from developing. Efforts should therefore be made to reconcile them.

58. Any solutions have to take into account the role of the private sector in the genome industry. Biotechnology has become more and more private. It involves both State and non-State actors. Any legal framework that targets only intergovernmental relationships cannot adequately regulate human genomics. It is important to create a transnational forum for biotechnologies. Numerous NGOs are interested in transnational biotechnology. There are sound arguments in favour of engaging all parties through voluntary structures while at the same time imposing a coercive regime.

Notes

[1] Laurence R. Helfer, Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking, 2004, *The Yale Journal of International Law*.
[2] Ibid.
[3] UNDP, *Making Global Trade Work for People*, pp. 221, 222.
[4] See also "Mainstreaming the right to development into international trade law and policy at the World Trade Organization" (E/CN.4/Sub.2/2004/17).
[5] Resolution 8/83 of the FAO Conference, Rome 1983, annex, at http://www.fao.org/ag/cgrfa/IU.htm.
[6] Rebecca S. Eisenberg, Re-examining the Role of Patents in Appropriating the Value of DNA Sequences, Emory Law Journal, vol. 49 (2000).
[7] Ibid.
[8] P. Drahos, Biotech Patents, Markets and Morality, European Intellectual Proprety Review, vol. 21.
[9] K. Raustiala and David Victor, The Regime Complex for Plant Genetics Resources, *International Organization*, vol. 58 (2004).
[10] S. Safran, Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life, *American Journal of International Law*, vol. 98.
[11] Ibid.
[12] World Health Assembly Res. WHA49.14 of 25 May 1996, para. 2(10).
[13] World Health Assembly, Res. WHA56.27 of 28 May 2003 on Intellectual property rights, innovation and public health.
[14] See also Helfer, op, cit.
[15] Jasmine C. Chambers, Patent Eligibility of Biotechnological Inventions in the United States, Europe and Japan: How Much Patent is Public Policy? *George Washington International Law Review*, vol. 34 (2002).
[16] Ibid.
[17] Sandrine Maljean-Dubois, Biodiversité, biotechnologies, biosécurité: le droit international désarticulé. *Journal du droit international*, vol. 127, No. 4 (octobre décembre 2005), pp. 949-996.
[18] The invention in Decision T 19/90 was directed to a transgenic mouse having an activated oncogene introduced into its genome, resulting in an increased propensity to develop cancer. The scientists at Harvard University had earlier sought and received a patent for their "Onco-mouse" in the United States; however, the Examining Division (the "Division") of the EPO rejected the application, interpreting the term "animal variety" in Article 53(b) to exclude any patent on an animal. On appeal, the Technical Board (the Board) reversed the Division's decision and remanded the case. The Board ordered the Division to consider whether the subject matter of the application constituted an "animal variety" within the meaning of Article 53(b), and whether Article 53(a) bars patenting the invention. On the issue of "animal variety," the Board found that the wording of Article 53(b) precludes an interpretation excluding animals as such. The Board concluded that the legislators could not have intended for the terms, "animal varieties" and "animals," to mean the same thing because the two terms were used in the same provision. In addressing the issue of ordre public or morality, the Board articulated a balancing test involving "a careful weighing up of the suffering of animals and possible risks to the environment on one hand, and the invention's usefulness to mankind on

the other." On remand, the Division determined that "rodents" and "mammals" constitute a taxonomic classification unit much higher than species, and an "animal variety" is a sub-unit of a species. Thus, the subject matter of the claims is not within the scope of the "animal varieties" set forth in Article 53(b). Applying the balancing test advanced by the Board, the Division concluded that the invention's usefulness to mankind outweighed animal suffering and risks to the environment''. J. Chambers, op .cit.

[19] Based on these interpretations and conclusions, the Board held that while the claimed plant cells did not fall under the definition of a "plant variety," the descendant plants grown from the plant cells were not patent eligible because they were not produced by a microbiological process. The Board eviscerated much of the invention's value. The Board's reasoning rested on the conclusion that the production involved a multi-step process that included not only the initial microbiological step of DNA transformation, but also the later steps of regenerating the plants from the transformed plant cells and of reproducing them. Because a plant or animal variety is only patent eligible if it is produced by a "microbiological process," the interpretation by the Board essentially enunciates that a multi-step process by which transgenic animals and plants are produced is no longer patent eligible as a "microbiological process." Chalmers, op. cit.

[20] See J. Sandor, Genetic Information: Science, Society and Legal Norms in J. Sandor (ed.), *Society and Genetic Information, Codes and Laws in the Genetic Era,* CEU Press, 2003, p. 45.

[21] Richard Ford, The Morality of Biotech Patents: Differing Legal Obligations in Europe, *European Intellectual Property Review*, vol. 6 (1997), p. 315.

[22] Chambers, op. cit.

[23] In 1980 the United States Supreme Court issued an opinion unequivocally heralded as the landmark case in biotechnology-related patent law. In *Diamond v. Chakrabarty,* the Court held that an oil-digesting microorganism produced by genetic engineering was not excluded from the patent protection set forth in 35 U.S.C. 101. According to the Court, the test for patent-eligible subject matter in biotechnology is whether the living matter is the result of human intervention, not whether an invention embraces living matter. See Chalmers, op. cit.

[24] In the 1987 case *Ex parte Allen,* the Board of Patent Appeals and Interferences had to resolve the issue involving patent eligibility of living organisms. In *Allen,* the Board held that a polyploid oyster was a non-naturally occurring manufacture or composition of matter and a proper subject of a patent under 35 U.S.C. 101, if all the criteria for patentability were satisfied. The Board relied primarily upon *Chakrabarty,* placing little emphasis on any potential ethical and social policies potentially underlying animal patents.

[25] Ibid.

[26] In *Eldred v. Ashcroft,* the Supreme Court found that Congress's extension of the copyright term by 20 years did not violate the constitutional restriction of those terms to "limited periods of time." See Safrin, op. cit.

[27] Chambers, op. cit.

[28] Sandrine Maljean-Dubois, Le Protocole de Carthagène sur la biosécurité et le commerce international des organismes génétiquement modifiés, *L'Observateur des Nations Unies,* vol. 11 (2001) automne-hiver, p.p. 41-66.

[29] Biological Diversity Act, 2002. See S. Safran, op.cit.

[30] Philippines Department of Environement and Natural Resources.

[31] Safran, op. cit.

[32] Ibid.
[33] Helfer, op. cit.

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