Genetic Resources under the CBD and TRIPS: Issues on Sovereignty and Property

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Résumé

Ensemble, sauvons la terre. Tel était le mot d'ordre du Sommet de la Terre de Rio, qui attisa les passions et fit naître de grands espoirs, il y a déjà 10 ans. La Convention sur la Diversité Biologique fut elle à la hauteur des attentes suscitées ? La réponse reste personnelle.

En effet, la Convention sur la Diversité Biologique est complexe, non seulement au niveau du langage, mais surtout parce qu'elle tente de trouver l'équilibre entre conservation et utilisation durable ainsi qu'entre fournisseur et bénéficiaire de la biodiversité.

Cet essai a vocation à assister les signataires de la convention alors qu'ils s'efforcent d'atteindre ces objectifs, en envisageant les divers moyens de mise en œuvre à leur disposition et leurs conséquences.

Cette thèse consiste en une approche pragmatique des considérations de souveraineté et d'accès aux ressources génétiques, éléments clefs de la mise en œuvre de la convention sur la Biodiversité et des accords TRIPS, dans un souci de clarification. L'étude de ces éléments sera entreprise dans une perspective de réconciliation des droits de propriétés et des droits dérivant de brevet en matière de ressources génétiques ; proposant une interprétation de ces droits de propriété tendant à éviter tout conflit avec le droit des brevets, et donc entre la Convention sur la Diversité Biologique et les accords TRIPS.

J'espère que les différentes propositions ainsi exprimées seront prises en compte parmi les diverses approches proposées pour la mise en œuvre de la Convention sur la Diversité Biologique.

Abstract

Coming together to save the Earth. Ten years have passed since the Earth Summit in Rio created such passion and expectations. Whether the Convention on Biological Diversity has met those expectations or not vary from person to person.

Evidently, the Convention on Biological Diversity is complex, not only in its language, but also in its attempt to balance between conservation and sustainable use, and between the providers of and benefiters from biological diversity.

Subsequent to its conclusion, the Parties have strived to achieve these objectives. This thesis attempts to assist in this process by exploring the means of implementing the Convention on Biological Diversity and their consequences.

The scope of the thesis is limited to the matters of sovereignty rights and access to genetic resources, in an effort to clear up the uncertainties in the applications of these components. This thesis attempts to contribute a pragmatic perspective to these matters, which, at their core, rely on the crossing points in the implementation of the Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights. This thesis focuses on ways to reconcile property rights in genetic resources with patent rights in invention using genetic resources. It proposes one interpretation of property rights in genetic resources so as to avoid any conflict with patent rights and accordingly, avoid conflict between the requirements of the Convention on Biological Diversity and those of the Agreement on Trade-Related Aspects of Intellectual Property Rights.

I hope that the views and proposals expressed in this thesis will be considered along with other diverse approaches to the implementation of the Convention on Biological Diversity.

Genetic Resources under the CBD and TRIPS: Issues on Sovereignty and Property

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Am. Soc'y Int'l L. Proc.
Ann. Surv. Int'l & Comp. L.
Berne Convention
Biodiversity
Brit. V.B. Int'l I.

Brit. Y.B. Int'l L. Buff. J. Int'l L. The CBD Colo. J. Int'l Envt'l L. & Pol'y

Colum. J. Transnat'l L. COP CTE Dick. J. Env. L. & Pol'y

EC

Envit'l L. Envit. L. Rep. European L. J. FAO Food Drug L.J. GATT

GA

Golden Gate U. L. Rev. Harv. Int'l L.J. Harv. J. L. & Pub. Pol'y Harv. L. Rev. Hastings Int'l & Comp. L. Rev.

IPR IUCN J. Envtl. L. & Litig.

J. Intell. Prop. L. J. Proprietary Rts. Law & Pol'y Int'l Bus. McGeorge L. Rev. McGill L. J. New Eng. L. Rev.

American Society of International Law Proceedings Annual Survey of International and Comparative Law The Berne Convention for the Protection of Literary and Artistic Works (1971) **Biological** Diversity The British Yearbook of International Law The Buffalo Journal of International Law Convention on Biological Diversity Colorado Journal of International Environmental Law and Policy Columbia Journal of Transnational Law Conference of the Parties Committee on Trade and Environment Dickinson Journal of Environmental Law and Policy European Council Environmental Law Environmental Law Reporter European Law Journal Food and Agriculture Organization Food and Drug Law Journal General Agreement on Tariffs and Trade 1994 General Assembly Golden Gate University Law Review Harvard International Law Journal Harvard Journal of Law and Public Policy Harvard Law Review Hastings International and Comparative Law Review Intellectual Property Rights The World Conservation Union Journal of Environmental Law and Litigation Journal of Intellectual Property Law Journal of Proprietary Rights Law and Policy in International Business McGeorge Law Review McGill Law Journal New England Law Review

OECD

Pace Int'l L. Rev. Paris Convention

Res. Science S. Cal. L. Rev. Syracuse J. Int'l L. & Com.

TRIPS

Touro J. Transnat'l L. UCLA. Pac. Basin L. J. UN UNEP U. Balt. Intell. Prop. J.

U. Pa. J. Int'l Bus. L.

UPOV

UPOV Convention

Vt. L. Rev. The Vienna Convention

Widener L. Symp. J. WIPO WTO Yale L. J. Yale Human Rts. & Dev. L. J.

Wash. U. J. L. & Pol'y

New York University Environmental Law Journal Organization for Economic Cooperation and Development Pace International Law Review The Paris Convention for the Protection of Industrial Property Resolution Science Magazine Southern California Law Review Syracuse Journal of International Law and Commerce Agreement on Trade-Related Aspect of Intellectual Property Rights Touro Journal of Transnational Law UCLA Pacific Basin Law Journal United Nations United Nations Environmental Programme University of Baltimore Intellectual Property Law Journal University of Pennsylvania Journal of International Business Law International Union for the Protection of **New Plant Varieties** International Convention for the Protection of New Varieties of Plants Vermont Law Review The Vienna Convention on the Law of **Treaties** Widener Law Symposium Journal World Intellectual Property Organization World Trade Organization Yale Law Journal Yale Human Rights and Development Law Journal Washington University Journal of Law and Policy

The sovereignty, territorial integrity and independence of States within the established international system, and the principle of selfdetermination for peoples, both of great value and importance, must not be permitted to work against each other in the period ahead. Respect for democratic principles at all levels of social existence is crucial: in communities, within States and within community of States. Our constant duty should be to maintain the integrity of each while finding a balanced design for all.¹

Former UN Secretary-General Boutros Boutros -Ghali

1 Introduction

Potential conflicts between efforts to liberalize international trade and efforts to solve our environmental problems have been the subject of extensive debate. However, such issues did not receive much attention until the early 1990's. On the 14th of April 1994, the World Trade Organization [hereinafter the WTO] established a body, the WTO Committee on Trade and Environment, to reconcile practice conflicts between trade interests and environmental interests.² The Committee addresses, inter alia, "the relationship between the provision of the multilateral trading system and trade measures for environmental purposes, including those pursuant to multilateral environmental agreements",³ with the aim of "making international trade and environmental policies mutually supportive"⁴.

¹ An Agenda for Peace, Preventive Diplomacy, Peacemaking and Peace-keeping, Report of the Secretary-General pursuant to the statement adopted by the Summit Meeting of the Security Council on 31 January 1992, UN Doc. A/47/277; S/24111(1992) reprinted in 31 I.L.M. 956 at 10. ² WTO, *Decision on Trade and Environment*, adopted by ministers at the meeting of the Uruguay Round Trade Negotiations Committee in Marrakesh on 14 April 1994, online:

<http://docsonline.wto.org/gen_search.asp> (last accessed 14 August 25, 2002)/

³ Ibid.

⁴ Ibid.

This thesis probes the relationship between trade and the environment. In it, I address the relationship between the provisions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights⁵ [hereinafter TRIPS] and one environmental agreement, the Convention on Biological Diversity⁶ [hereinafter the CBD].

While patents and biological diversity are conceptually unrelated, they are associated through the CBD. Article 3 on sovereignty rights of countries over their genetic resources (which gives property rights to States over their genetic resources) and Article 15 on access and benefit-sharing (which gives States the authority to determine access to their genetic resources) both raise intellectual property rights issues.⁷ In developing countries, States are claiming national property over their genetic resources. In developed countries, the same phenomenon is taking place, and in addition, patent rights over biotechnological inventions using genetic resources are being consolidated. Thus, two kinds of property rights are being claimed. One is over natural genetic resources; the other is over the intellectual property incorporated into biotechnological inventions. Therefore, the central issues to be examined in this thesis are the extent to which property rights in genetic resources may be inconsistent with the patent rules of TRIPS, and manners in which such inconsistency can be settled within the existing rules.

There is a view that TRIPS and the CBD are in direct conflict. While TRIPS grants patent rights over biotechnological inventions using genetic resources, the CBD grants States

⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C, 15 April 1994, reprinted in Results of the Uruguay Round 6-19, 365-403, 33 I.L.M. 1125 at 1197 (1994) (entered into force 1 January 1995) [hereinafter TRIPS].

⁶ Convention on Biological Diversity, Text and Annexes, 5 June 1992, 31 I.L.M. 818 at 822 (entered into force 29 December 1993) [hereinafter the CBD].

⁷ Article 16 of the CBD on access to and transfer of technology also raises intellectual property issues. See discussion in section 3.3.

property rights over the same resources. In this thesis, I challenge this argument by interpreting the scope of States' property rights in the CBD. I argue that while TRIPS grants patent rights on inventions using the intangible information contained in genetic resources, the CBD grants property rights on genetic resources as tangible property. Thus, interpreting the CBD so as to limit States' property rights to the tangible components of genetic resources may resolve the conflict between TRIPS and the CBD.

In 1994, the completion of negotiations for the Uruguay Round set the course for a further liberalization of international trade. The WTO was formed in 1995 at the end of the Uruguay Round.⁸

TRIPS came into effect on the 1st of January 1995 for the purpose of reducing impediments to international trade, promoting protection of intellectual property and assuring that measures and procedures used to enforce intellectual property rights do not in themselves become barriers to trade.⁹ TRIPS came with the objective of "[c]ontribut[ing] to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".¹⁰ The conclusion of TRIPS marked the most important milestone in the development of international law in the area of intellectual

⁸ The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 15 April 1994, reprinted in The Results of the Uruguay Round of Multilateral Trade Negotiations-The Legal Texts 1-3, 33 I.L.M. 1125 at 1143 (1994) (entered into force 1 January 1995) [hereinafter Results of the Uruguay Round].

⁹ TRIPS, *supra* note 5, the preamble.

¹⁰ *ibid.* Article 7.

1. Introduction

property.¹¹ When implemented, except in the case of least developed countries, TRIPS leveled the minimum standards for the protection of intellectual property. Apart from that, it introduces standards in areas that were considered outside the purview of international law.¹² TRIPS is the first international intellectual property treaty covering new *subject matters* under existing types of intellectual property, at least for developing countries, such as pharmaceuticals, microorganisms, agriculture and biotechnology.¹³

The negotiations of TRIPS towards standardizing intellectual property on an international level paralleled the formulation of the CBD. Recognizing the threat that human activity posed to the environment, conservation and sustainable use of the Earth's riches were emerging as two of the greatest challenges. The conservation and sustainable use of biological diversity are essential to procure a wide range of advances in science, biotechnology, medicine, agriculture and potentially other fields. In particular, the progress of biotechnology in the early 1970's had the greatest implication on perceptions of the potential use and value of biological diversity in biotechnology, if raw materials,

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¹¹ See J. Watal, *Intellectual Property Rights in the WTO and Developing Countries* (The Hague: Kluwer Law International, 2001) at 2.

¹² Ibid. at 3; P. Gallagher indicates that:

[[]t]he standards agreed in TRIPS incorporate and extend to all WTO Members the substantive obligations of the main World Intellectual Property Organization (WIPO) convention:

the Berne Convention on copyright;

the Paris Convention on Industrial Property.

TRIPS also contains obligations on matters not covered by the WIPO Conventions. This involves, in particular:

setting standards on categories of IPRs where they were lacking, for example, patents *Guide to the WTO and Developing Countries* (The Hague: Kluwer Law International, 2000) at 53. ¹³ See Watal, *supra* note 11 at 4.

namely *genetic resources*, are preserved.¹⁴ Thus, early attempts at conservation were seen as primarily motivated by utilitarian considerations of the value of genetic resources.¹⁵

The CBD was adopted on the 22nd of May 1992, in Nairobi, Kenya.¹⁶ Later, on the 5th of June 1992, at the United Nations Conference on Environment and Development in Rio de Janeiro (The Earth Summit), over 150 States signed the CBD.¹⁷ Approximately eighteen months later, on the 29th of December 1993, the CBD entered into force.¹⁸

The CBD marks a historic commitment by the nations of the world to conserve biological diversity, to use biological resources in a sustainable manner, and to share equitably the benefits from the use of genetic resources. It is the first Agreement to take a "comprehensive rather than a sectoral approach" to conserve the Earth's biological diversity and use biological diversity sustainably,¹⁹ including genetic resources, species and ecosystems.

The CBD goes beyond the conservation and the sustainable use of biological diversity. It recognizes that States have sovereignty rights to exploit their own natural resources

¹⁴ W. Lesser, *Institutional Mechanisms Supporting Trade in Genetic Materials: Issues under the Biodiversity Convention and GATT/TRIPS* (Geneva: UNEP, 1994) at 6 [hereinafter *Institutional Mechanisms supporting Trade in Genetic Materials*]. The conservation of biodiversity is also important for moral reasons. Biodiversity has cultural value for countries of origin and local communities. In some societies, biodiversity has spiritual value. However, we address the economic reasons for conserving biodiversity.

¹⁵ See M. Bowman "The Nature, Development and Philosophical Foundations of the Biodiversity Concept in International Law" in M. Bowman & C. Redgwell, eds., *International Law and the Conservation of Biological Diversity* (London, the Hague, Boston: Kluwer Law International, 1996) 5 at 15.

 ¹⁶ Resolution of the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity, 22 May 1992, 31 I.L.M. 842 at 843; see generally F. McConnell, *The* Biodiversity Convention: A Negotiating History (London: Kluwer Law International, 1996) at 82-99.
 ¹⁷ See generally McConnell, *ibid.* at 104-112.

¹⁸ *Ibid.* at 125.

¹⁹ A L. Glowka *et al.*, A Guide to the Convention on Biological Diversity (Gland and Cambridge: IUCN, 1994) at 1 [hereinafter Guide to the Convention on Biological Diversity].

pursuant to their own environmental policies.²⁰ Article 15, on access to genetic resources, recalls again the sovereignty rights of States as the basis of the authority to determine access to genetic resources, and to share benefits from the use of genetic resources.

The CBD is a "framework Agreement",²¹ its provisions are expressed mostly in overall policies, rather as hard and precise obligations.²² The CBD hence leaves the Parties to determine how best to implement most of its provisions, placing the main decisionmaking at Parties at the national level. Because of the framework nature of the text of the CBD, Parties will often have to go beyond the substantive provisions to achieve the overall objectives of the CBD. Specifically, Article 15 on access to genetic resources and sharing benefits leaves many decisions to each Party regarding its implementation.²³ Thus, Parties to the CBD face the challenge of implementing Article 15, realizing that the CBD gives them the flexibility to address the wide-ranging and complicated tasks of access and benefit-sharing.

This thesis focuses on the two Articles of sovereignty rights and access to genetic resources. It aims at promoting a better understanding of the two provisions of the CBD and their possible implications by presenting certain possible approaches for the elucidation of sovereignty rights and the implementation of the access and benefitsharing provision of the CBD.

 ²⁰ The CBD, supra note 6, Article 3.
 ²¹ Guide to the Convention on Biological Diversity, supra note 19 at 1.

²² See Ibid.

²³ See Ibid.

This thesis has been structured on the basis of the relevant provisions of TRIPS and the CBD. Chapter 2 serves to examine the two concepts of patent rights and sovereignty rights. This Chapter is essentially a theoretical approach to the thesis, in which I interpret sovereignty rights in genetic resources as to encompass tangible property, and not genetic information embodied in such property, concluding that there is no formal conflict between the above concepts.

Chapter 3 of the thesis deals with the matter of authority to determine access to genetic resources as one manifestation of States' property rights in genetic resources. I analyze Article 15 on access to genetic resources, including the mutually agreed terms of access, the requirement of prior informed consent, and benefit-sharing. I discuss certain policy issues pertaining to national and international approaches to access to genetic resources. This discussion arises in two different contexts. The first context is the implementation of the CBD. In doing so, Parties are seeking ways that enable Article 15 of the CBD to acquire a practical meaning. Some countries believe one possible way is to identify, through patent applications, the genetic resources extracted from their biological diversity. The second context is the compatibility of such measures with the provisions of TRIPS, which establishes conditions on patent applicants. I examine the implications of such measures for patent rights. In this regard, I contend the tendency towards requiring the disclosure of country of origin in patent applications, as one method of identifying genetic resources extracted from countries of origin. Chapter 3 in effect ascertains that in the light of the framework nature of the CBD, Parties shall, in implementing Article 15 on access and benefit-sharing, conform to the standards of patent rights.

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In chapter 4, I conclude that in implementing the CBD, States shall balance between the authority to regulate access to genetic resources, and the obligation to facilitate access to genetic resources. This will encourage future bio-trade in genetic resources, by protecting the rights of users and providers of genetic resources.

2 Bio-Trade in Genetic Resources as Reflected in TRIPS and the CBD: Patent Rights and Sovereignty Rights in Genetic Resources

The value of genetic resources has been well recognized, particularly in science and technology. The nature and rights over these resources have been, however, commonly debated issues. There is a debate at the level of theory over which norms justify patents, including patents in biotechnological inventions utilizing genetic resources. More practically, during the negotiations of TRIPS, patent protection for biotechnological inventions utilizing genetic resources between the global North (referring to countries with highly developed biotechnology industries but with no or little genetic resources) and the global South (referring to countries with no or poor biotechnology industries but rich with genetic resources).²⁴ Simultaneously, developing countries did not accept the view of such resources as "common heritage of mankind" available freely for everyone, due to the increasing value of genetic resources. They called for the establishment of sovereignty rights over their genetic resources and the abolishment of the common heritage perception. This has been another emerging subject of debate between the global North and the global South.

This chapter addresses the above issues. The discussion begins with illustrating the economic value of genetic resources (section 2.1). The discussion turns next to patent rights and TRIPS (section 2.2). In this section, I state the theories of patents (subsection

²⁴ See discussion in pp. 29-30.

2.2.1), and then I review the negotiating history of TRIPS and the current protection for biotechnological inventions (subsection 2.2.2). In section (2.3), I discuss the principle of national sovereignty over genetic resources in the CBD. I challenge the principle of "human heritage of mankind" that prevailed prior to the adoption of the CBD in (subsection 2.3.1). Subsequently, I examine whether there is any divergence between patent protection in TRIPS and national sovereignty in the CBD (subsection 2.3.2), drawing to the conclusion that the patenting of biotechnological inventions does not inherently threaten the South's genetic resources, nor do countries' sovereignty rights over their genetic resources, conversely, inherently threaten patent rights in biotechnology. There is no formal conflict between the two norms, although in practice, the exercising of sovereignty through access and benefit-sharing measures might lead to a violation of patent rights, creating a conflict between TRIPS and the CBD.

2.1 Genetic Resources: A Considerable Value

The wealth of life forms on Earth today is the product of hundreds of millions of years of evolutionary history, which resulted in the current variation and diversity of genes, species, ecosystems and culture. The totality of these living and non-living organisms sculpts the planet's biological diversity [hereinafter biodiversity]. Biodiversity is defined as "the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of

ecosystems.²⁵ Scientists divide biodiversity into hierarchical categories from genetic diversity, to species diversity, to ecosystem diversity and to cultural diversity.²⁶ Genetic diversity is the sum of genetic information contained in the genes of individual plants, animals and microorganisms. Each species is the repository of an immense amount of genetic information.²⁷

Many species have no or little economic value, although genetic diversity inherent in natural ecosystems is essential for its aesthetic and environmental value.²⁸ In 1994, it was estimated that the probability of finding a useful material when randomly screening

Ecosystem diversity is more difficult to measure than species or genetic diversity because the associations of species and ecosystems are elusive, but criteria have been used to define communities and ecosystems, primarily at the national and sub-national level. In addition to the components of diversity-species, genes and ecosystems- it is important to look at diversity in ecosystem structure and function, such as relative abundance of species, the age structure of populations, the pattern of communities in region, change in community composition and structure over time, and ecological processes.

Cultural diversity refers to the diversity in cultures and cultural practices, which have grown from biological diversity, and which in turn have impacted the diversity we see today. The majority of the world's biodiversity is closely tied to traditional management, resource harvesting, and livelihood practices, and many 'natural' areas bear the mark of the interconnection between cultural and biological diversity.

²⁵ The CBD, *supra* note 6, Article 2.

²⁶ According to K.T. Kate & S.A. Laird:

Genetic diversity refers to the variation of genes within species, and might cover distinct populations of the same species or genetic variations within a population. Different combinations of genes with organisms, or the existence of different variants of the same basic gene are the basis of evolution.

Species Diversity refers to the variety of species within a region. Current estimates of global species diversity range between 8 million and 100 million species, with 10-13 million being considered a 'best estimate', although only 1.4 million species have been scientifically named "...".

The Commercial Use of Biodiversity (London: Earthscan, 1999) at 3.

²⁷ According to Pearce & Moran, "[t]he number of genes range from about 1,000 in bacteria, up to 400,000 or more in many flowering plants. Each species is made up of many organisms, and virtually no two members of the same species are genetically identical." See *the economic value of biodiversity* (London: Earthscan Publications Ltd, 1994) at 3.

²⁸ See generally K.A. Goldman, "Compensation for Use of Biological Resources: Under the Convention on Biological Diversity: Compatibility of Conservation Measures and Competitiveness of the Biotechnology Industry" (1994) 25 Law & Pol'y Int'l Bus. 695 at 700.

genetic resources for pharmaceutical use is between 1/6,000 and 1/30,000.²⁹ Moreover, much of genetic material is redundant, meaning that many near duplicates exist, and therefore many products can serve as substitutes for themselves.³⁰

The part of genetic diversity that possesses potential or actual economic value is called genetic resources.³¹ Derived from the world's biodiversity, genetic resources attribute to several sciences, most importantly, biotechnology, which is "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."³² The genetic information carried in the gene alleles³³ of genetic resources furnishes the raw materials for biotechnologists.³⁴ This attribution of genetic resources to biotechnology gives such resources certain economic value.

The economic value of genetic resources is most perceptible in the pharmaceutical and agricultural fields. An empirical study, for example, indicated that while billions of dollars are invested in the research and development of new drugs in the United States,

²⁹ W. Lesser, Sustainable Use of Genetic Resources under the Convention on Biological Diversity: Exploring Access and Benefit Sharing Issues (Wallingford: CAB International, 1998) at 71 [hereinafter Sustainable Use of Genetic Resources].

³⁰ In 1996, for example, "it (was) estimated that 10% of the materials contain 70% of total genetic variability of the species". See *ibid.* at 71.

³¹ Such resources, according to the CBD, Article 2, are genetic materials of actual or potential value. The term "genetic material" is defined as being "any material of plant, animal, microbial or other origin containing functional units of heredity." *supra* note 6.

³² The CBD, *supra* note 6, Article 2.

³³ According to Kate & Laird, allele means "[o]ne of two or more forms of a gene arising by mutation and occupying the same relative position (locus) on homologous chromosomes." *Supra* note 26 at 356.

³⁴ See K. Bosselman, "Plants and Politics: The International Regime Concerning Biotechnology and Biodiversity" (1996) 7 Colo. J. Envt'l L. & Pol'y 111 at 116.

only one in five thousand pharmaceutical compounds reaches the commercial markets.³⁵ Although these statistics apply to pharmaceutical compounds, biomedical products undergo the same rigorous research and development procedures as pharmaceutical compounds. Biomedical products therefore would have a similar likelihood of reaching the commercial market.³⁶ Today, one fourth of the known medicines are based on or derived from plants, and about three quarters of these are used in the same or a similar way as when used by local communities.³⁷ Thus, genetic resources, especially if accompanied by traditional knowledge³⁸, represent a rich supply for drug development. They have proved to have more positive results than synthetic methods, and they are valuable sources to cut down research and development expenditures. This can help reduce the costs and devastation of current diseases.³⁹

In agriculture, the productivity and efficiency of agricultural products is increasing, using plant genetic resources in biotechnology to develop insect resistance and improved nutritional crops, through the transfer of useful features between plant species with plant breeding⁴⁰. This can be achieved by incorporating specific genes from one crop or specie

³⁵ See K. W. McCabe, " The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology" (1998) 6 J. Intell. Prop. L. 41 at 48.

³⁶ See K.B. Lee, Jr. & L.S. Hu, "Biotechnology: Past, Present, Future" (1996) Chemistry & Indsustry at 334-337.

³⁷ See Watal, *supra* note 11 at 170.

³⁸ Traditional knowledge of indigenous peoples or local communities is defined in the CBD, Article 8 (j) (*In-situ* conservation), as the "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity". *Supra* note 6.

³⁹ See Natalie M. Derzko, "Plant Breeders Rights in Canada and Abroad: What Are These Rights and How Much Must Society Pay for Them?" (1994) 39 McGill L.J. 144 at 147. Derzko, for example, highlights that "[b]iotechnology has led to increased yields of the substance used to produce taxol, a compound extracted from the bark of the Pacific yew tree, used in the treatment of ovarian cancer".

of ovarian cancer". ⁴⁰ Plant breeding is "the discovery or creation of genetic variation in a plant species and the selection from within that variation of plants with desirable traits that can be inherited in a stable

into another, conferring on them specific advantages either for dealing with various environmental stresses, including resistance to pests and diseases, or for improving productivity through better nutrient utilization.⁴¹ For example, when yellow dwarf virus threatened California's \$160 million barley crop, the US department of agriculture searched through all 6,500 known varieties before it found an Ethiopian barley plant that conferred resistance to the virus. A virus-resistant crop was developed through transferring the useful feature from the Ethiopian barley plant.⁴²

The above examples suggest that the importance of genetic resources in industry widens, as these resources are increasingly becoming necessary inputs for the continuing growth of biotechnology. Yet, it is shocking that little effort is directed to preserve the variety of species because of faulty economic policies that do not give priority to the importance of the preservation of environment.⁴³ In recent years, countries started to express concerns over the increasing loss of genetic capital and the challenges to preserve the genetic value of biodiversity. The decline of biodiversity reached unparalleled rates. In mid 1990's, it was estimated that species were being lost in tropical forests at a rate that is between one thousand and ten thousand times faster than the natural rate of extinction. ⁴⁴ At these

- ⁴¹ See Goldman, *supra* note 28 at 701.
- ⁴² See Goldman, *supra* note 28 at 701.
- ⁴³ See K.W. Baer, "A Theory of Intellectual Property and the Biodiversity Treaty" (1995) 21 Syracuse J. Int'l L. & Com 259 at 272.

⁴⁴ See A. K. Sharma, "The Global Loss of Biodiversity: A Perspective in the Context of the Controversy Over Intellectual Property Rights" (1995) 4 U. Balt. Intell. Prop. J. 1 at 6.

fashion" See New Plant Varieties and the protection of the rights of their breeders, online: The International Union for the Protection of New Plant Varieties homepage

<http://www.upov.oeg/eng/about/npv.htm> (last visited 15 August 2002); Kate & Laird uses the term cross-breeding, which means "[t]he breeding of distinct and genotypic types or forms in plants. This may entail the transfer of pollen from one individual to the stigma of another of different genotype". *Supra* note 26 at 357.

current rates, one-quarter of all the Earth's species could be eliminated within the next fifty years, and up to one half of all species will be lost by the end of the next century.⁴⁵ Preservation and conservation are indeed serious challenges, particularly if we consider the duration and difficulty of corrective measures. In 1992, according to the geological record of previous extinction spasms, it was estimated that the time required for biodiversity to recover from a catastrophe, such as a meteor strike, is between 10 million and 100 million years.⁴⁶ By such rates, the loss of biodiversity is the contemporary crisis that "our descendants [will] most regret" and "are least likely to forgive".⁴⁷

One of the main causes of biodiversity loss is human activity that causes a rapid acceleration in species extinction, by the destruction of natural habitats, deforestation and desertification.⁴⁸ Another reason is overpopulation, which leads to natural resource overconsumption.⁴⁹ The Global Biodiversity Strategy identified other fundamental reasons for loss of biodiversity. They include legal and institutional systems that promote unsustainable exploitation, economic systems and policies that fail to value the environment and its resources and inequity in the ownership, management and flow of benefits from both the use and conservation of biological resources.⁵⁰

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⁴⁵ See Bosselmann, *supra* note 34 at 113.

 ⁴⁶ See J. Chen, "Diversity and Deadlock: Transcending Conventional Wisdom on the Relationship Between Biological Diversity and Intellectual Property" (2001) 31 Envtl. L. Rep. 10625 at 4.
 ⁴⁷ *Ibid.* at 4.

⁴⁸ See Sharma, *supra* note 44 at 6-7. For other reasons, see generally *Sustainable Use of Genetic Resources*, *supra* note 29 at 2.

⁴⁹ Sharma, supra note 44 at 2.

⁵⁰ C.M. Horton, "Protecting Biodiversity and Cultural Diversity under Intellectual Property Law: Toward a New International system" (1995) 10 J. Envtl. L. & Litig. 1 at 6.

Conservation of genetic resources thus requires a fair approach to bio-trade.⁵¹ The argument made is that, in order for genetic resources to be conserved, there must be an economic value in conservation of such resources for those who can exercise control and conserve them.⁵² In other words, countries possessing genetic resources must capture a proportion of the economic value of genetic resources, so that they will be encouraged to conserve such resources.⁵³ Capturing benefits requires gene-rich countries to hold certain property rights over their genetic resources. The solution seems to render genetic resources as State property.

In the following two sections, I explore how the principle of national sovereignty evolved to grant States property rights in their genetic resources, and how does sovereignty rights interact with patent rights over biotechnological inventions using genetic resources.

TRIPS and Patent Rights: Theories of Patents and the Negotiating 2.2 History of TRIPS

In this section, I discuss the main theories in patents, and the negotiating history of patenting biotechnological inventions in TRIPS. The aim of furnishing patent theories is to justify patents in general, which accordingly apply to biotechnological inventions. The aim of reviewing the negotiating history of TRIPS is to illustrate the perspectives of

⁵¹ See especially D.R. Downes, "New Diplomacy for the Biodiversity Trade: Biodiversity,

Biotechnology, and Intellectual Property in the Convention on Biological Diversity" (1993) 4 Touro J. Transnat'l L. 1 at 24. ⁵² See generally Goldman, *supra* note 28 at 698.

⁵³ See Baer, *supra* note 43 at 275.

developing and developed countries with regard to patenting biotechnological inventions utilizing genetic resources. In this section, I argue that patent protection for biotechnological inventions utilizing genetic resources is a necessity, and TRIPS offers an efficient framework for patent protection.

2.2.1 Theories of Patents

Intellectual property rights are an amorphous bundle of rights with certain limitations, conferred to persons over the creations of their minds.⁵⁴ Intellectual property, which is the subject matter of such rights, is defined by Hughes as a nonphysical object or res whose value is based on some novel idea.⁵⁵ There are seven kinds of intellectual property that are protected by the virtue of TRIPS, namely copyrights and related-rights, trademarks, geographical indications, industrial designs, patents, lay-out designs and undisclosed information. This thesis is centered on one kind of intellectual property: patents.

A patent is defined as a "grant by the State of exclusive rights for a limited time is respect of a new and useful invention."56 A grant of a temporary monopoly has been justified by numerous theories. Most significantly, the industrial revolution (1750-1852) marked the evolution in patents and patent theories. Four main theories justifying patent protection

⁵⁴ See C. Samper K. & P. Ferriera Miani, Intellectual Property and Biological Diversity: Intellectual Property and its Relationship with the Convention on Biological Diversity (Instituto Alexander von Humboldt 1999) [unpublished], online: The Humboldt Institute Homepage

(last accessed 15 August 2002).

⁵⁶ P.W. Grubb, *Patents in Chemistry and Biotechnology* (Oxford: Clarendon Press, 1986) at 3.

were endorsed: the natural-law theory, the reward-by-monopoly theory, the monopolyprofit theory and the exchange-for-secret- theory.⁵⁷

The natural-law theory is based on the assumption that inventors have a natural right of property in their ideas. Thus, using their ideas without certain compensation amounts to theft, and since property is personal and exclusive, the State has to enforce exclusivity by granting patent rights to inventors. This theory assumes that patents in this manner would reward labor and increase inventive activities without harming the public.58

The natural-law theory was mainly based on Lock's labor-based theory of property.⁵⁹ This theory starts by stating that God granted mankind the right to the goods of nature.⁶⁰ The goods of nature are initially common; no one has private dominion exclusive of the rest of mankind. Men own themselves, and by extension, they own their own labor.⁶¹ Therefore, whatever a man removes out of the state that nature has provided, and mixes his labor with to add something to the common more than nature, this makes it his property, and so it becomes his private right.⁶² The right to own property in the state of nature is a direct implication of self-ownership that requires no agreement from others.⁶³ All labor gives men title to property in the state of nature. However, labor that creates

⁵⁷ H.I. Dutton, The Patent System and Inventive Activity During the Industrial Revolution 1750-1852 (Manchester: Manchester University Press, 1984) at 17.

⁵⁸ Ibid. at 18.

⁵⁹ For a discussion on other theories, see T.G. Palmer, "Are Patents and Copyrights Morally Justified? The Philosophy of Property Rights and Ideal Objects" (1990) 13 Harv. J. L. & Pub. Pol'y 817 at 821.

⁶⁰ See J. Locke. Two Treatises of Government, ed. by E.J. Harpham (Kansas: University Press of Kansas, 1992) at 129. lbid.

⁶² See J. Lock, *Two Treatises of Government*, ed. by M. Goldie (London: Everyman, 1993) at 131. ⁶³ Ibid.

property in Lock's theory is not limited to some kind of brute force or physical exertion. Labor is better described as being a creative act that may be mental as well as physical.⁶⁴ The suppositions and assumptions of the natural-law theory lost its command by the late 1820's.⁶⁵ Demonstrated by Lock's justification of property rights, the natural-law theory assumes that the inventor has natural and inherent rights in his labor. His ownership of his labor is derived from his own-ownership. This assumption opposes the nature of patent rights because they are temporary monopolies.⁶⁶ The second criticism is that patents, according to the natural-law theory, are justified because they reward the inventor for his labor. This ignores the utility of labor to society.⁶⁷

The second theory to justify patents is the reward-by-monopoly theory. It assumes that the State should provide a temporary monopoly to inventions because inventors should be rewarded for their inventions. This reward depends on the utility and usefulness of their inventions to society. This theory emphasizes the economic benefits conferred on inventors by patents, with the market being determinative of what the reward should be.⁶⁸ It assumes that an invention, like any commodity, depends on the laws of supply and demand: if the invention is profitable to society, then the inventor will benefit from it, but if it is of no value, he will reap no benefit.⁶⁹ Patents, therefore, are crucial since they

⁶⁴ Ibid.

⁶⁵ See Dutton, *supra* note 57 at 17.

⁶⁶ Ibid. at 18.

⁶⁷ For a discussion on patenting biological objects and its justifications under the natural-law theory, see M. Sagoff, "Animals as Inventions: Biotechnology and Intellectual Property Rights" in L.D. Guruswamy & J.A. McNeely, ed., *Protection of Global Biodiversity: Conservation Strategies* (Durham & London: Duke University Press, 1998) 331.

⁶⁸ *Ibid.* at 19-20.

⁶⁹ Ibid.

allow the inventor a period of time to gain enough return on his effort. Without this kind of protection, competitors would be able to use, make or sell the invention without the inventor's consent and without bearing any of the costs endured to produce the invention. This would result in reducing the inventive activity.⁷⁰

This theory was widely used to support patent rights.⁷¹ However, it was criticized for relying on the market to determine the value of the invention. While patents are sound because they reward the inventor for the value of his invention, they are also sound because they compensate ingenuity and encourage innovation.⁷² Moreover, patents are not instruments to reward the inventor as such, but also to achieve concrete societal objectives.

The third theory is the monopoly-profit theory. It is based on the idea that patents constitute private reward, which acts as an incentive to invent. This argument is related to the duration and exclusiveness of monopoly, and is associated with the notion that economic growth is inherently desirable.⁷³ It suggests that without some protection given to ideas as property, there would be little or no incentive to invent or discover new ideas. This will result in fewer discoveries and less supply of inventions. Thus, patents are means to stimulate inventive activity by enabling the inventor to capture the returns from his investment in the invention, which in return will benefit the society by creating useful

70 Ibid.

73 Ibid.

⁷¹ *Ibid.* at 18. ⁷² *Ibid.* at 20.

innovations that will enhance the "prior art" and motivate further innovation.⁷⁴ Accordingly, the benefits of patent protection offset the burdens of patent monopolies on society.⁷⁵ The associating of the inventive activity with the progress and development as well as with private profit was the reason behind the popularity of this theory.⁷⁶

The final theory for patents is the exchange-for-secrets theory (the disclosure agreement). It is originally based on the idea of contracts, where the society and the inventor enter into an agreement wherein society offers temporary protection and the inventor discloses his knowledge of new techniques.⁷⁷ Here, property rights are needed to induce the inventor to disclose his invention to others. The inventor is granted a temporary monopoly on the production, use and sale of the invention, as a reward for the disclosure of the invention in the patent. The disclosure is called the "quid pro quo" for the grant of patent rights, in which the inventor discloses the information and specification of his invention, the manner and process of making and using it, and the best mode contemplated by the inventor of carrying out his invention.⁷⁸ This theory probably arose since the only legal requirement for an inventor to obtain a patent is his disclosure of the invention. This disclosure seems to be the benefit that justifies the grant⁷⁹ because the

77 See Ibid. at 22.

⁷⁴ Urbanksi notes that the United States Constitution grants the Congress the power to create intellectual property rights to "promote the progress of science and useful arts". M.A. Urbanski, "Chemical Prospecting, Biodiversity Conservation, and the Importance of International Protection of Intellectual Property Rights in Biological Materials" (1995) 2 Buff. J. Int'l L. 131 at 143.

⁷⁵ See J.L. Trotti, "Compensation Versus Colonization: A Common Heritage Approach to the Use of Indigenous Medicine in Developing Western Pharmaceuticals" (2001) 56 Food Drug L.J. 367 at 374. ⁷⁶ See Dutton, *supra* note 57 at 20.

⁷⁸ See Urbanski, *supra* note 74 at 148.

⁷⁹ See J.W. Schlicher, "If the Economic Welfare is the Goal, will Economic Analysis Redefine Patent Law?" (1992) 4 NO. 6 J. Proprietary Rts. 12 at 15.

disclosed information is then made available to other inventors, thus stimulating new inventions.

Among the above theories, the monopoly-profit theory and the exchange-for-secrets theory are the theories that could justify patents by creating two distinct incentives: the *incentive to discover or invent* and the *incentive to disclose*.

These theories are supported by the economic theories justifying property rights, namely the Economic Utilitarian theory, which focuses on efficiency as an object and purpose of property rights.⁸⁰ Garret Hardin first advanced this theory in 1968 to address the problems of over population and the management of scarce resources.⁸¹ Since then, it has been used to tackle other problems in economics, law, and environmental and other fields.⁸² Hardin associated common ownership with several ills: over use, waste, no incentive to conserve, and the eventual destruction of common property.⁸³ This tragedy was called "the Tragedy of the Commons". Hardin argues that "the Tragedy of the Commons" occurs when multiple owners are each endowed with the privilege to exploit a scarce resource, and no one can exclude the others from using such resources. Thus, the resource is prone to be overused.⁸⁴

⁸⁰ K. Yelpaala, "Symposium: Biotechnology and the Law: Owning Secret of Life: Biotechnology and Property Rights Revisited" (2000) 32 McGeorge L. Rev. 111 at 182.

⁸¹ See G. Hardin, "The Tragedy of the Commons" (1968) 162 Science 1243-1248 [hereinafter "The Tragedy of the Commons"].

⁸² G. Hardin, "Extensions of "The Tragedy of the Commons" (1998) 280 Science 682-683 [hereinafter "Extensions of "The Tragedy of the Commons"].

⁸³ See "The Tragedy of the Commons", *supra* note 81 at 1243-1248.

⁸⁴ See M.A. Heller, "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets" (1998) 111 Harv. L. Rev. 621 at 623-624.

Common ownership creates a disincentive for conservation and efficient use, encourages overaccumulation, and ultimately leads to the depletion of common scarce resources.⁸⁵ Hardin, therefore, sees private property as a solution to this tragedy since it creates an incentive for the efficient use and enjoyment of scarce resources and thus minimizes the cost and externalities associated with common ownership.

The Economic Utilitarian Theory was used in support of the monopoly-profit theory and the exchange-for-secrets theory justifying patents. To the extent that inventions are freely appropriable by anyone without them bearing the cost of inventions, there will be overaccumulation of the invention by others. Therefore, the inventor would not be able to recover the costs of the invention. Thus, inventors would prefer to protect their inventions by trade secrets, resulting in fewer inventions available to the public. Another result is that inventors would be less encouraged to engage in inventive activities.

While the "the Tragedy of the Commons" underlines the costs of overuse when too many people are allowed to use a scarce resource, it ignores the possibility of underuse when too many people are given rights to exclude others from its use. Thus, private property can solve one tragedy but creates another. Michael Heller described this as "the Tragedy of the Anticommons".

Viewing it as a mirror of "the Tragedy of the Commons", "the Tragedy of the Anticommons" occurs when multiple owners are endowed with the right to exclude

⁸⁵ *Ibid.* at 624.

others from a scarce resource, and no one has an effective privilege of use. When there are too many owners holding rights of exclusion, the resource is prone to underuse.⁸⁶

Michael Heller and Rebecca Eisenberg apply this theory to patents in order to identify the absurd consequence of patents. Patents hold both promises and risks to technology advancement. Patents encourage inventors to engage in the inventive activity because they result in equitable distribution of the profits of research and development. However, they argue that this could distort the inventive activity when too many owners hold patents in previous inventions that constitute obstacles to future research.⁸⁷

If we consider that the main objective of the Utilitarian Theory is efficiency, the ownership of inventions might undermine the efficiency objective. This occurs when owners are given the right to exclude others from using inventions. Too many patent owners holding the rights of exclusion can cause underutilization of patents because of the innumerable patent holders.⁸⁸ Since inventions are infinite, if every invention were separately owned by an infinite number of people having the right to exclude others, the concept of property would be threatened, and present what is called "the Tragedy of the Anticommons".⁸⁹

In conclusion, patents are considered an efficient and useful tool to promote technological, economic and social progress. They encourage investment in innovation in

⁸⁶ Ibid.

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⁸⁷ M.A. Heller & R.S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698-701.

⁸⁸ See Heller, *supra* note 84 at 624.

⁸⁹ Heller & Eisenberg, *supra* note 87 at 698-701.

areas that benefit the society. Everyone shares the benefits of a higher level of innovation as a result. In spite of this, patents can also be abused, by limiting for others the availability of inventions in order to conduct further research and improvement. The main task of patent laws is thus to balance between exclusivity of patent protection, and the concept of open access to ideas that serve society.

In this manner, patent laws grant the inventor a temporary period of exclusivity limited to twenty years. It is not justifiable to allow the inventor a permanent monopoly. In addition, patent laws must encourage dissemination of innovation by emphasizing an unrestricted access to innovations for further research and development. Since patent holder has to disclose his invention, this allows others to use information about a patented invention to research new inventions during the patent's life, and ensures that it is truly in the public domain once the patent expires. Moreover, patent laws often defeat patent abuse by allowing a third party to obtain the right to produce the invention, if such an abuse was proved. For example, if a patent holder refuses to license a patented invention on reasonable commercial terms, the government is allowed to license it to other companies or use it itself without the patent holder's authorization, so long as adequate compensation is paid. Finally, patent laws may prohibit the patenting of important inventions on certain socially important kinds of innovation.⁹⁰

⁹⁰ S. Johnston & F. Yamin, "Intellectual Property Rights and Access to Genetic Resources" in John Mugabe *et al.*, eds., *Access to Genetic Resources: Strategies for Sharing Benefits* (Nairobi: ACTS Press, 1997) 245 at 248-249.

2.2.2 The Negotiating History of Article 27 of TRIPS

Patent laws are adopted by each State according to the needs of society and inventors, and in the light of the State's own economic and social objectives. However, the increasingly interdependent world economy and the concept of global intellectual property rights have certainly influenced such adoption.

Over the last two decades, with the increase in the production and international exchange of counterfeit goods, industrialized countries have faced growing competition from newly industrialized countries. This increasing competition has caused the attention to be focused on the domestic policies of countries that might adversely or unfairly disadvantage other countries.⁹¹ As a result, patent rights, as part of intellectual property rights, have become a growing concern for industrialized countries and a dominant item on the trade agenda, mainly reflected by the inclusion of TRIPS in the Uruguay Round,⁹² which was interpreted as a new attempt to promote universality in the protection of intellectual property rights.⁹³

The global trend toward international minimum standards for patent protection was complicated because of the different market structures and the varying needs for patent protection between developed and developing countries.⁹⁴ The global North has

⁹¹ See M.J. Trebilcock & R. Howse. The Regulation of International Trade, 2nd ed. (London: Routledge, 1999) at 307.

² See Results of the Uruguay Round, *supra* note 8; C.A.P. Braga, "The Economics of Intellectual Property Rights and the GATT: A View from the South" (1989) 22 Vand. J. Transnat'l L 243 at 248. ⁹³ *Ibid.* at 252.

⁹⁴ According to Trebilcock & Howse:

The adoption of stringent or lax patent protection depends on the comparative advantage in innovation or imitation. A country will have different levels of protection for industries,

comparative advantage in biotechnological industry; thus, it has high level of protection.⁹⁵ Adversely, the global South has a comparative advantage in imitation, thus tending toward lax protection for biotechnological inventions. For example, many developing countries excluded patent protection for pharmaceutical and agricultural chemical products because they perceived that domestic welfare required that these products be available to the population at the lowest prices.⁹⁶ Accordingly, strong protection for biotechnological inventions is not always beneficial to both, domestic economic welfare and to the global economic welfare.97 In the sector of biotechnology, the effect of increased protection is to shift productive resources from an activity in which developing countries have a comparative advantage (imitation) to that in which they have less comparative advantage (innovation).⁹⁸ Thus, strong patents might increase the economic welfare in countries that have comparative advantage in innovation, while reducing it in countries that have comparative advantage in imitation.⁹⁹

This conflict of interests was clearly present in the TRIPS negotiations, where developing countries showed great resistance to the provisions concerning patenting biotechnological inventions.¹⁰⁰ The key issue in the TRIPS negotiations was mainly Article 27 on

- ⁹⁷ Contra Trebilcock & Howse, *supra* note 91 at 311.
- ⁹⁸ See *Ibid.* at 312.

representing different trade-offs between innovation and imitation in each industry. depending on where its comparative advantage lies. Supra note 91 at 310.

⁹⁵ See V. Date, "Global "Developments" and its Environmental Ramifications – The Interlinking of ecologically sustainable Development and Intellectual Property Rights" (1997) 27 Golden Gate U. L. Rev. 631 at 634-635.

See D. Brenner-Beck, "Do as I Say, not as I Did" (1992) 11 UCLA. Pac. Basin L. J. 84 at 101.

⁹⁹ According to Date, "patents might have detrimental effects on the development of domestic industries in other countries ". Supra note 95 at 634-635.

¹⁰⁰ See Watal, *supra* note 11 at 12.
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patentable subject matter.¹⁰¹ The criteria for patentability, (novelty, inventive step and industrial applicability), were generally accepted from the outset and were subject of relatively little discussion. They apply to all inventions, including biotechnological inventions, without discrimination to the place of invention and whether imported or produced locally.

The patentability of biotechnological inventions based in part on genetic materials, broadly accepted in developed countries, was nevertheless resisted in developing countries. This placed the biodiversity versus biotechnology conflict in the context. This conflict was essentially based on the "fundamental difference in factor endowments".¹⁰² The global North is rich in financial capital and industrial technology but poor in genetic resources. The global South is in precise the opposite situation: rich in genetic resources but poor in capital and technology.

Developed countries argued that minimum standards of protection "increase incentives for technological innovation because they ensure profits to investors in research and development that might otherwise be lost if competitors could reverse engineer a biotechnological product and undercut the innovator's prices by avoiding the costs of research and development."¹⁰³ In particular, they maintained that patent protection creates incentives to develop biotechnological applications based on genetic resources by increasing the profits from the commercialization of those applications. Thus, not only do patent rights reward innovation, but they also increase the technological benefits of biodiversity and promote conservation by enhancing the commercial value of genetic

¹⁰¹ TRIPS, *supra* note 5, Article 27. ¹⁰² Chen, *supra* note 46 at 8.

¹⁰³ See Downes, *supra* note 51 at 7.

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resources contained in biodiversity.¹⁰⁴ Many developing countries have recently recognized both the potential value of their genetic resources and the fact that the biotechnology industry depends on such resources for its own development.¹⁰⁵

Developing countries, however, voiced numerous concerns and held opposing views to patent rights and how they affect biodiversity. The South was of the view that strong patent systems to protect biotechnological inventions will only serve developed countries that export intellectual property, in which they have comparative advantage.¹⁰⁶ Their main complaint was that the global North is patenting products of biotechnology, which are derived in part from genetic materials taken mainly from the South.¹⁰⁷ Biotechnology industry develops new sources for chemical compounds, genes, micro and macro-organisms and other valuable biological products, and patent rights are granted over final products using the South's riches, without any acknowledgement of the contribution of countries of origin or of indigenous communities. Developing countries often named this uncompensated appropriation of genetic materials as "bio-piracy"¹⁰⁸. As a result, developing countries viewed the strong patent protection of technology originating from their countries as a barrier on the development of their own self-sustaining biotechnology

¹⁰⁴ Ibid.

¹⁰⁵ See V.E. Spier, "Finders' Keepers: The Dispute Between Developed and Developing Countries over Ownership of Property Rights in Genetic Material" (2001) 7-SPG Widener L. Symp. J. 203 at 210.

¹⁰⁶ For other concerns, see McCabe, *supra* note 35 at 52.

¹⁰⁷ According to Watal, however, "[t]he stream of genetic resources is not always from the South to the North. For example, two varieties of wheat *Norin 10* and *Brevor* originally came from Japan and the United States". *Supra* note 11 at 129-130.

¹⁰⁸ According to Odek, this expression does not have a precise legal definition. International law has not defined the uncompensated extraction of genetic resources as piracy. Thus, the characterization of such acts as piracy serves as a normative assertion by developing countries that they have an entitlement to their genetic resources. However, biopiracy often focuses on sociological component to the exclusion of the biological, or else treat the two components as if they were inseparable, but genetic information is readily distinguished from communal knowledge of plants and animals. "Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources" (1994) 2 J. Intell. Prop. L. 141 at 145.

industry.¹⁰⁹ The South further feared that the economic effect of patent protection in increasing the domestic prices of patented goods¹¹⁰ would render further innovations in biotechnology inaccessible to the majority of domestic consumers, thus hindering their economic development because of the costs imposed. Hence, throughout the negotiations of TRIPS, developing countries remained on the defensive side with regard to patents in biotechnology.¹¹¹

At the GATT meeting of trade ministers at Punta del Este in Uruguay in 1986, a declaration to launch the Uruguay Round was adopted that contained a decision to launch negotiations on TRIPS, including trade in counterfeit good. Many developing countries agreed to this, believing that they could limit the negotiations on trade in counterfeit goods and other trade-related aspects.¹¹² However, the subsequent phases of negotiations included the tabling of specific suggestions and texts forwarded by developed countries to negotiate all intellectual property rights standards including patents.¹¹³ Developing countries blocked the discussion of substantive issues on intellectual property rights other than counterfeit goods, arguing that only trade-related intellectual property rights were to be discussed. This claim was difficult to sustain given the agreed language of the 1986 Declaration on adequate and effective protection of intellectual property rights.

The opposition to substantive patent protection standards by developing countries was softened, however, through bilateral consultations, after the mid-term ministerial review

¹⁰⁹ See Spier, *supra* note 105 at 210.

¹¹⁰ See Baer, *supra* note 43 at 275.

¹¹¹ See Watal, *supra* note 11 at 17.

¹¹² *Ibid.* at 21.

¹¹³ *Ibid.* at 22.

of the Uruguay Round in Montreal, in 1988.¹¹⁴ Developing countries' main concern was to uphold the principle of differential and more favorable treatment for developing countries in TRIPS, in accordance with their developmental, financial and trade needs. Therefore, during the TRIPS negotiations, developing countries conceded differential treatment mostly in terms of flexible implementation schedules. It was agreed in the midterm review in Geneva, in 1989, that transitional arrangements were to be given to developing countries. This concession was to get developing countries to adhere to the results of the negotiations.¹¹⁵

Developing countries' position in the TRIPS negotiations was not constructive, especially regarding the substantive standards of patent protection. They lost several opportunities to put forward texts on the substantive standards, and thus they were tracking the format of the developed countries' proposals, accepting many of the more reasonable demands being made and in return, demanding limitations on patent protection, reasonable transition periods and moderation of the more extreme demands.¹¹⁶ This has lead to a substantial acceptance of standards demanded by some developed countries.¹¹⁷

¹¹⁴ *Ibid.* at 26.

¹¹⁵ Watal notes that Developing countries missed an opportunity to bargain for more sufficient long transition period, in exchange for conceding the inclusion of standards and a similar transition period on textiles. *Ibid.* at 27.

¹¹⁶ However, there were some proposals from Brazil, India, and other developing countries; see *.lbid.* at 28-29.

¹⁷ *Ibid.* at 28.

TRIPS is based on the two principles of most-favored nation and national treatment.¹¹⁸

The main thrust of TRIPS is to lay down a comprehensive set of minimum standards with

respect to intellectual property protection, including patent protection.¹¹⁹ It also includes

provisions on enforcement of intellectual property rights¹²⁰ and dispute settlement.¹²¹

TRIPS was concluded so as to encompass the protection of biotechnological inventions

utilizing genetic resources. On the other hand, it gives latitude to Member Countries to

¹¹⁸ Article 3 of TRIPS reads:

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection3 of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade. *Supra* note3.

Article 4 reads:

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

- a. deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;
- b. granted in accordance with the provisions of the Berne Convention (1971) or the Rome

Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

- c. in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;
- d. deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members. *Supra* note 5 "[footnote omitted]".
- 119 Ibid. Part II.

¹²⁰ Ibid. Part III & IV.

¹²¹ Ibid. Part V.

exclude from patentability certain biologically-based material, allows flexibility in defining patentability criteria and the enforcement of certain exceptions and limitations to rights conferred to patent holders.

TRIPS gives Member Countries the right to exclude certain biologically based material. Article 27(3) (b) gives Member Countries the right to exclude from patentability certain plant and animal inventions: "Members may also exclude from patentability: "..." (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."¹²²

As for the flexibility in defining patentability criteria under Article 27(1), Member Countries have the right to refuse a patent for the mere discovery of genetic materials.¹²³ It is well accepted under patent laws that discoveries of substances found in nature are unpatentable.¹²⁴ However, the distinction between a discovery of something that exists in nature and an invention is difficult to determine in the field of biotechnology. TRIPS gives no guidance on this, thus giving a certain degree of flexibility to developing countries in forming their patent laws to legitimately consider outside the scope of the concept of invention, substances, including genetic materials that already exist in nature, and thus excluding them from patentability.¹²⁵

¹²² Ibid. Article 27(3)(b).

¹²³ WTO, Committee on Trade and Environment, *Environment and TRIPS*, WT/CTE/W/8 (1995) para. 73, online: < http://www.docsonlinewto.org/gen_search.asp> (last accessed 27 July 2002) [hereinafter *Environment and TRIPS*].

¹²⁴ Watal indicates that "[t]he United States bargained that "anything under the sun made by man" was patentable except human beings, where the European Union faced internal resistance to patenting living organisms." *Supra* note 11 at 131. ¹²⁵ *Ibid.* at 133.

TRIPS further gives countries the right to provide exceptions to the exclusive rights conferred to patent holders, provided that such exceptions "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."¹²⁶ It further enables Member Countries to enforce appropriate measures to "prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."¹²⁷ Member Countries may also refuse to patent inventions that are offensive to *ordre public* or morality, including to human, animal or plant life or health or to avoid serious prejudice to the environment.¹²⁸

Except for the above limitations, biotechnological inventions are protected through patents, or through a *sui generis* system with regard to plant varieties.¹²⁹

¹²⁶ TRIPS, *supra* note 5, Article 30.

¹²⁷ *Ibid.* Article 8(2).

¹²⁸ *Ibid.* Article 27(2); see F. Macmillan, WTO and the Environment, (London: Sweet & Maxwell, 2001) at 29. Macmillan expresses that it is assumed that preventing "serious prejudice to the environment" involves a narrower permissible exclusion from patentability than would one permitting the exclusion of patentability in order merely to protect the environment. *Ibid.* ¹²⁹ We quote at length the resulting text of Article 27 that reads:

^{1.} Subject to the provisions of paragraphs 2 and 3, 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. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

^{2.} Members may exclude from patentability inventions, the prevention with their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

^{3.} Members may also exclude from patentability:

a. diagnostic, therapeutic and surgical methods for the treatment of humans and animals;

Inventions shall comply with the general patentability criteria: they have to be new (novelty), involve an inventive step (non-obviousness) and capable of industrial application (usefulness).

As for plant varieties, they shall be protected either by patents or by an effective sui generis system or by any combination thereof.¹³⁰ If a Member Country excludes plant varieties from patent protection, it must provide protection for plant varieties by an effective sui generis system.¹³¹ Although TRIPS does not explicitly refer to it, the International Convention for the Protection of New Varieties of Plants [hereinafter UPOV Convention], which was signed in Paris in 1961 between European States, and

> plants and animals other than micro-organisms, and essentially biological b. processes for the production of plants and animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. TRIPS, supra note 5 "[footnote omitted]".

Article 53(b) of the European Patent Convention states that no protection is available for: "plants 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 Convention on the Grant of European Patents, concluded October 1979, entered into force on October 1977. Article 28 defines the rights, which shall be derived from a patent. A patent to a product prevents unauthorized making, selling, using offering for sale, selling or importing the patented product: a patent on a process prevents unauthorized use of the process or the above acts relating to at least the product or the process. EC, Directive, Special Report: Patents on Biotechnological Inventions: the E.C. Directive (London: Sweet & Maxwell, 2002) at 16 [hereinafter Patents on Biotechnological Inventions: the E.C. Directive].

¹³⁰ TRIPS, supra note 5, Article 27(3) (b); Article 1 of the International Convention for the Protection of New Varieties of Plants states that:

Variety means a plant grouping within s single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions of the grant of a breeder's right are fully met, can be: defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged.

International Convention for the Protection of New Varieties of Plants, 2 December 1961, revised 10 November 1972, 23 October 1978, and 19 March 1991, online: The International Union for the Protection of New Plant Varieties homepage <http://www.upov.int/eng/convntns/index.htm> (last visited 15 August 2002) [hereinafter UPOV Convention]. ¹³¹ See McCabe, *supra* note 35 at 51.

was most recently amended in 1991,¹³² is the main international agreement that establishes plant breeders' rights.¹³³

In retrospect, given the bargaining powers of developed countries when compared with those of developing countries, and the separate and weak position of developing countries, the achievements of developing countries in maintaining a balance between public interest and strengthened protection were small. However, developing and least developed countries were given grace periods to adjust their national laws.¹³⁴ Some argue that the implementation of TRIPS could have been easier for developing countries had they been given more time to adapt to TRIPS standards.¹³⁵ Assuming the viability of this argument, this should not detract from the fact that protection for biotechnological inventions offered by TRIPS has substantially strengthened protection for such inventions in developing countries, with certain limitations. The strengthened patent systems in developing countries may facilitate the investment and transfer of technology, products and processes. To maximize the benefits of patent protection, developing countries must reinforce their patent legislation with broader modernization programmes for the development of biotechnology industries.

¹³² See Bosselman, *supra* note 34 at 123.

¹³³ See McCabe, *supra* note 35 at 58.

¹³⁴ TRIPS, *supra* note 5, Article 65. The grace for least developed countries was extended until January 1, 2016 upon Doha Ministerial Conference. See *Declaration on TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, adopted on 14 November 2001, online: the World Trade Organization homepage:

<http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> (last visited 15 August 2002).

¹³⁵ Watal, supra note 11 at 46.

2.3 The CBD and Sovereignty Rights

This section discusses the principle of sovereignty rights of States over their genetic resources adopted by the CBD. I discuss the principle of national sovereignty in two subsections. In subsection (2.3.1), I present the theory behind the principle of national sovereignty, as opposed to the principle of "common heritage of mankind". In subsection (2.3.2), I examine whether national sovereignty principle that grants property rights over genetic resources opposes patent rights in biotechnological inventions using genetic resources. I conclude that the former does not impede the latter.

2.3.1 Theories of Nature and Rights over Genetic Resources: The Principle of National Sovereignty over Genetic Resources

In recent years, the recognition of possible devastating results of the global loss of biodiversity and the extinction of genetic species has led to various international efforts to stop or control the rate of species extinction.¹³⁶ The CBD is one expression of these concerns. Some commentators consider the CBD an evolution in international

¹³⁶ See Bosselmann, *supra* note 34 at 111; Lesser notes that these international efforts include multilateral environmental Conventions, dealing with different aspects, for example, Ramsar Convention dealing with wetland habitats (1971), CITES dealing with trade is endangered species (1973), Montreal Protocol dealing with the protection of the ozone layer (1987), Basel Convention dealing with transboundary movements of hazardous wastes (1989), the Framework Convention on Climate Change dealing with Stem the expansion of deserts (1994). *Sustainable Use of Genetic Resources, supra* note 29 at 3.

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environmental law, since it developed certain concepts in this field of international law. Most significantly, the CBD developed the principle of national sovereignty, a longstanding principle in international law, to confront the global environmental crisis.¹³⁷ The CBD begins with an assertion that conservation of the globe's biodiversity is a common concern for the entirety of humankind, and not only countries rich with biodiversity. Such conservation shall face the global "common heritage of mankind" view that genetic diversity had suffered from. Rendering genetic resources the common property of mankind gives rise to the "tragedy of the commons" at a global level, as there is no authority to impose conservation imperatives on the international community.¹³⁸ Therefore, the CBD endorses the view that genetic resources are within the jurisdiction and sovereignty of the Parties. Further, the CBD reaffirms the right of Parties to control access to genetic resources, compensation and benefit-sharing arising from exploiting such resources. These concepts were implications that followed the adoption of the national sovereignty principle.

The principle of national sovereignty over natural resources has its roots from the postwar concerns over the scarcity of natural resources, through the attempts of industrialized countries to maintain equilibrium between the national and global interests in natural resources and their management. Great opposition from developing countries faced these attempts. Since 1952, developing countries have taken an assertive position to recognize national sovereignty over natural resources by means of the power and jurisdiction to

¹³⁷ See Bosselmann, *supra* note 34 at 134.
¹³⁸ See Discussion on "the Tragedy of the Commons", pp. 22-23.

establish how the resources and assets (tangible and intangible) existing in its territory are distributed, used, converted into economically useful goods, and eventually subject to property rights.¹³⁹ This position was essentially fueled by the concerns of developing countries over their economic development.

As it crystallized in the United Nations resolutions, the debate and progress of the national sovereignty principle was difficult and complicated.¹⁴⁰ The development of this principle involved the identification of the needs of developing and developed countries, as well as establishing not only the rights but also the duties incumbent on States that arise from this principle.

The Declaration on Permanent Sovereignty over Natural Resources of 1962 was the main cornerstone in the evolution of the national sovereignty principle.¹⁴¹ This Declaration embodied the principle of national sovereignty and the rights and obligations of States respectively. The first paragraph of that Declaration states:

The right of *peoples and nations* to permanent sovereignty over their natural wealth and resources must be exercised in the interest of *their national* development and of the well-being of the people of the *State* concerned.¹⁴²

The question remains whether this principle amounts to international customary law.¹⁴³ Yet, it can be concluded that this principle has at least achieved a legal value through its

¹³⁹ See Correa, C.M., *Sovereign and Property Rights Over Plant Genetic Resources*, Commission on Plant Genetic Resources, First Extraordinary Session, Rome, 7 - 11 November 1994, Food and Agriculture Organization of the United Nations at 5, online: ftp://ext-two.organization of the United Nations at 5, online: ftp://ext-two.organization of the United Nations at 5, online: ftp://ext-two.organization of the United Nations at 5, online: ftp://ext-two.organization of the United Nations at 5, online: ftp://ext-two.organization of the United Nations at 5, online: ftp://ext-two.organization of the United Nations at 5, online: ftp://ext-two.organization of the United Nations at 5, online: ftp://ext-two.organization of the United Nations at 5, online: ftp://ext-two.organization of the United Nations at 5, online: ftp://ext-two.organization.com of the United Nations at 5, online: ftp://ext-two.organization.com of the United Nations at 5, online: ftp://ext-two.organization.com of the United Nations at 5, online: ftp://ext-two.organization.com of the United Nations at 5, online: ftp://ext-two.organization.com of the United Nations at 5, online: ftp://ext-two.organization.com of the United Nations at 5, online: ftp://ext-two.organization.com of the United Nations at 5, online: <a href="http://ext-tw

ftp.fao.org/waicent/pub/cgrfa8/BSP/bsp2E.pdf> (last accessed 15 August 2002) [hereinafter Sovereign and Property Rights Over Plant Genetic Resources]. ¹⁴⁰ See Schrijver, Sovereignty over Natural Resources (Cambridge: Cambridge University Press,

¹⁴⁰ See Schrijver, *Sovereignty over Natural Resources* (Cambridge: Cambridge University Press, 1997) at 371.

¹⁴¹ *Ibid.* at 372.

¹⁴² Permanent Sovereignty Over Natural Resources, GA Res. 1803 (XVII), ST/HR, 17th Session, (1962) [emphasis added].

incorporation in several resolutions and in a number of international treaties. These include the African Convention on Human and Peoples' Rights (1981), the two Vienna Conventions on Succession of States (1978 and 1983), the UN Convention on the Law of the Sea (1982), the UN Framework Convention on Climate Change and The CBD (1992), embracing natural resources such as sea-bed, subsoil, mineral resources, lakes and rivers, biological and genetic resources.¹⁴⁴

With respect to genetic resources, being natural resources, and according to national sovereignty principle. States have the jurisdiction over how such resources existing in their territory are distributed, used and eventually made subject to property rights. Thus, genetic resources may be subject to private or public property rights, in accordance with certain political and social conceptions. Although States can retain certain goods under their control, private property today prevails as the basic feature of most legal systems in the world.¹⁴⁵ Private property may be derived from the ownership of the land where genetic resources are located, as a result of the application of the traditional law principle in accordance with which everything adhered or which is destined to be adhered to the land belongs to the landowner.¹⁴⁶ Land ownership will usually convey rights upon the owner, such as the right to extract genetic materials existing on the surface of the land,

¹⁴³ See Schrijver, *supra* note 140 at 375.

¹⁴⁴ Ibid. at 374.

¹⁴⁵ According to Correa, "[p]ublic property may be declared and exercised with respect to quantified and individualized goods, or with regard to an undetermined amount of resources belonging to a defined category." Sovereign and Property Rights Over Plant Genetic Resources, *supra* note 139 at 5. ¹⁴⁶ *Ibid.*

unless such rights are vested in the State, i.e. declared as being public property.¹⁴⁷ Once separated from the land, they become subject to their own ownership regime as moveable property, including when they are transported outside the original land or to a different country.148

Genetic resources are different from other biological resources in that they are comprised of both genes (genotypes),¹⁴⁹ which determine the physical and functional characteristics of the physical entities, and the physical entities themselves $(phenotypes)^{150}$. Take for example an edible seed: it is a product, a mere chattel. At the same time, the seed is an expression of the genetic information it holds. The seed is both the product and the means of production.¹⁵¹ The fury of the debate lies in the valuable intangible content of genetic resources (genotype information) that genetic resources embody.

This issue requires profound scrutiny. The conventional view of genetic resources is that they are deemed part of the public domain¹⁵² or res communes. In other words, they are part of the common heritage of mankind,¹⁵³ freely and internationally available.¹⁵⁴ This is

¹⁴⁷ See I. Walden, "Intellectual Property Rights and Biodiversity" in Bowman & Redgwell, *supra* note 15, 171 at 180.

¹⁴⁸ See Sovereign and Property Rights Over Plant Genetic Resources, supra note 139 at 6. ¹⁴⁹ J.L. Gellner & W.L. Weaver, "Genetic Engineering Symposium: A Glossary of Genetic Terms" (1994) 3 Dick. J. L. & Pol'y 119 at 125. According to Gellner & Weaver, genotype is "[t]he particular assemblage of genes possessed by an individual. The effects of genotype and environment determine an individuals phenotype."

¹⁵⁰ Phenotype is "[t]he observed expression of a trait, or character, in an individual. Usually, the phenotype is determined, or influenced, by both an individual's genes and the environment of the individual. Symbolically, this relationship can be expressed: Phenotype = Genotype + Environment." Ibid. at 127.

¹⁵¹ See Chen, *supra* note 46 at 9.

¹⁵² "Public domain" means in this context that the concerned resources may be used by anybody (nationals or foreigners), without any restrictions.

 ¹⁵³ See Trotti, *supra* note 75 at 378.
 ¹⁵⁴ According to an OECD survey,

the result of the consideration that the use of the valuable part of such resources, i.e. genotype information simultaneous. In other words, genetic resources can be used without added costs and without reducing their availability to others. In economic terms, they are described as being "public goods"; their consumption is non-rivalrous, and the benefits are non-exclusionary.¹⁵⁵ The most significant argument for this classification is that the intangible content of genetic material is hard to value, and thus hard to price, due to its indeterminate usefulness.¹⁵⁶

"Public goods" are assets, which are non-rivalrous and non-exclusionary. For example, the forest's trees and other biomasses draw carbon out of the atmosphere and pumps back oxygen. A person's benefit from the forest's restoration of a congenial carbon balance does not make it any less valuable in the same way to others. Thus, the persons' consumption of the atmosphere is nonrivalrous. Moreover, the benefits of the atmosphere that the forest provides are also nonexclusionary, that is, the same quality of atmosphere

[[]t]he voluntary international agreement dealing with access to plant genetic resources for food and agriculture, the "International Undertaking on Plant Genetic Resources for Food and Agriculture", when first agreed, was based on the principle that plant genetic resources were the heritage of mankind. Over the years, the Undertaking was clarified through a number of interpretative annexes which inter alia recognized that the concept of mankind's heritage, as applied in the Undertaking, is subject to the sovereignty of the States over their plant genetic resources

See Intellectual Property, Technology Transfer and Genetic Resources, an OECD Survey of Current Practices and Policies (Paris, OECD, 1996) at 24 online:

<http://www.oecd.org/pdf/M00033000/M00033207.pdf> (last accesses 20 July 2002) [hereinafter Technology Transfer and Genetic Resources].

¹⁵⁵ See C.D. Stone, "What to Do About Biodiversity: Property Rights, Public Goods, and the Earth's Biological Riches" (1995) 68 S. Cal. L. Rev. 577 at 580.

¹⁵⁶ See S. Kadidal, "Plants, Poverty, and the Pharmaceutical Patents" (1993) 103 Yale L. J. 223 at 228.

is supplied to each person on Earth, whether or not it is the precise quality each person would prefer, and whether or not that person contributed to the costs of its provision.¹⁵⁷ Genetic resources resemble other biodiversity components that are considered "public goods", such as photosynthesis, production of soil, atmospheric quality and climate, in the sense that genetic resources are non-rivalrous per se. Someone's use of genetic resources does not reduce the availability of such resources to others. Thus, its use does not contradict with anyone's similar use. In addition, genetic resources resemble "public goods" in that they are non-exclusionary. The same quality is supplied to each person on the globe, whether or not that person contributed to the costs of its provision.¹⁵⁸

Although genetic resources are non-rivalrous and non-exclusionary by nature, they differ from other "public goods" in their value. For example, the forest's contribution to the enhancement of the atmosphere cannot be parceled and priced in markets.¹⁵⁹ However, genetic resources can be valued, and the use of genetic resources can well alter their value. This can be presumed because the valuable part of such resources lies in the information they encode as opposed to the physical substance in other resources.¹⁶⁰ Such information can be supplied from a single sample, for example, of a rare rainforest plant. Once copied, it can be transformed into associated process and its synthesized end product, and its value extinguishes upon first use, shifting from the original specimen to lucrative drug or plant variety.¹⁶¹ The use of genetic information by the first person, and patenting the invention in which the resources were used reduces the economic value of

158 Ibid.

¹⁵⁷ See Stone, *supra* note 155 at 580.

¹⁵⁹ *Ibid*.

¹⁶⁰ *Ibid.* at 597.

¹⁶¹ See Chen, *supra* note 46 at 10.

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genetic resources significantly.¹⁶² Thus, despite the fact that the use of such information is non-rivalrous and non-exclusionary, there is an economical feasibility in controlling genetic information and excluding other benefiters from using it.¹⁶³ By supplying genetic resources as "public goods" without an exchange value, the country of origin does not lose the genetic information, however, it does lose the opportunity to receive an economic return for its contribution.¹⁶⁴

With hindsight, genetic resources have value because of their informational content. Such information is easily transferred and used. The distinct issue here is the genetic information extracted from a country without compensation, hence property rights are needed to control effectively their use and ensure benefits.

Such an outcome is supported by Demsetz, who argues that property rights are created when, as a result of changes in relative prices of technology, the benefits of establishing and enforcing them become greater than the costs of continuing without them.¹⁶⁵ According to Demsetz, the creation of national sovereignty rights could be interpreted as a predictable response to the increased value of genetic resources in biotechnology.¹⁶⁶

The goal of sovereignty rights is to establish a form of property rights over tangible genetic resources, by fencing such resources and charge those who most immediately benefit from the information, which is the valuable part in genetic resources.¹⁶⁷ The

¹⁶⁵ Ibid.

¹⁶² See C. Gulati, "The "Tragedy of the Commons" in Plant Genetic Resources: The Need for a New International Regime Centered Around an International Biotechnology" (2001) 4 Yale Human Rts. & Dev. L. J. 63 at 88.

¹⁶³ See Stone, *supra* note 155 at 599.

¹⁶⁴ See Odek, *supra* note 108 at 156-157.

¹⁶⁶ H. Demsetz, "Toward a Theory of Property Rights" (1967) 57 American Economic Review 347-359.

¹⁶⁷ See Stone, *supra* note 155 at 598.

concept of "public goods" has little meaning for genetic resources because capturing value from using genetic resources is premised on exclusion and access control.¹⁶⁸

The crucial point here is distinguishing between rights over the physical entity of genetic resources and rights over the information carried by genetic resources.¹⁶⁹ The aim of the establishment of property rights in genetic resources is the sharing of benefits that arise from the use of the valuable information in biotechnology, through controlling access to tangible resources. This requires the removal of genetic resources from the public domain and their inclusion in the private property of each country. Hence, under the sovereignty principle, genetic resources are no longer "public goods" or common heritage of mankind. States' rights over genetic resources concern the tangible material of such resources. As for the intangible content of genetic resources, they remain to be common property: belonging to no one and not protected by anyone. Establishing property rights to control genetic resources, thus, requires a clear identification of the tangible goods, and how they can be manipulated.¹⁷⁰

The assertion of national sovereignty over genetic resources may well be a case in point. The CBD's rejection of the "common heritage of mankind" principle, which inter alia had resulted in the amassing of large collections of genetic resources held outside the country of origin whose accessions can be acquired freely, coincided with increases in the

¹⁶⁸ See Sustainable Use of Genetic Resources, supra note 29 at 71.
¹⁶⁹ See Chen, supra note 46 at 9.
¹⁷⁰ See Odek, supra note 108 at 151.

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value of genetic resources driven by biotechnological advances in industrialized countries.

The "public goods" classification, in opposition to property rights in genetic resources, facilitates the extraction of genetic resources, and accelerates the uncompensated removal of genetic resources.¹⁷¹ The argument of the "indeterminate usefulness" relies on the fact that genetic resources contain valuable genes, but they are of unknown value until a particular trait is identified. This argument falls through because the fact that a genetic material is of unknown utility does not mean that its value is minimal and that it should be accessed freely.¹⁷² Ignorance of the value of such material in time does not justify appropriating it. Genetic materials can command prices that range from few cents to millions of dollars per kilogram, yet once manipulated, they inevitably command far higher prices.¹⁷³ Therefore, until genetic resources achieve the status of property, these resources will remain free for all subject to the costs of collection and this will lead to an undervaluation of genetic resource. Moreover, the "public goods" principle overlooks the fact that the value of genetic resources may be well-known to local and indigenous communities and who may have legitimate claims over access to and use of these resources and the information they possess about them. Thus, it is perceived that preservation of genetic materials by countries of origin would not yield economic value under the common heritage principle that undervalues such resources.

¹⁷¹ *Ibid.* at 148.

¹⁷² See specially *Ibid.* at 154.

¹⁷³ See S.D. Murphy, "Biotechnology and International Law" (2001) 42 Harv. Int'l L.J. 47 at 70. For an elaborate discussion on approaches to valuation of genetic resources, see *Sustainable Use of Genetic Resources*, supra note 29 at 69-85; K.T. Kate & S.A. Laird offer statistics on genetic resources and derivatives retail price in US dollars per kg or litre. For example, Human growth hormone 20,000,000; Taxotere/ docetaxol 12,000,000; Vincristine sulphate 11,900,000; Cocaine 150,000; Camptothecin 85,000; Lear's Macaw 24,000. *Supra* note 26 at 2.

An illustrative example of this legal problem is the case of rubber transfer from Brazil to Malaysia and Singapore. Brazilian authorities protected rubber production for years, but in 1876, a boatload of 70,000 rubber seeds were taken out of Brazil and eventually reached British colonies in Asia. At the turn of the century, ninety-eight percent of the world's rubber came from Brazil. By 1919, the Brazilian rubber industry was devastated and Singapore was the world's rubber capital. Brazil regarded this as a removal of one of its natural resources, but had no right of redress at international law once the resource left its shores. Britain, as a sovereign State, could do what it liked with the seeds once they arrived within its jurisdiction, with the traditional rationale that biological resources are "common heritage of mankind".¹⁷⁴

This classification was inadequate and had no legal application to genetic resources found within the borders of a sovereign State. States have the prerogative to prevent all persons from interfering with genetic materials found within their borders, since they have jurisdiction over all persons and things found within their territorial boundaries.¹⁷⁵ The CBD is based upon this premise. Before the adoption of the CBD, access to the genetic resources of the developing world was considered as a matter of right.¹⁷⁶ At Rio, however, developing countries strived to ensure recognition of the value of these resources, as well as to the contribution of the indigenous people to preserve these

resources.

¹⁷⁴ Stone, *supra* note 155 at 583; see Goldman, *supra* note 28 at 705. ¹⁷⁵ See generally Odek, *supra* note 108 at 168.

¹⁷⁶ See Sharma, *supra* note 44 at 12.

The CBD defines genetic resources as "genetic material of actual or potential value",¹⁷⁷ containing functional units of heredity, and of microbial, plant, animal, or other origin.¹⁷⁸ Functional units of heredity include all genetic elements containing DNA¹⁷⁹, and in some cases RNA¹⁸⁰. Under the CBD, genetic resources would include, among other things, a seed, cuttings, semen or an individual organism because they contain functional units of heredity.¹⁸¹ The CBD does not include human genetic resources within this definition.¹⁸² The definition embraces genetic materials that have been discovered, and that may

already have been utilized in practical applications, as well as materials that are yet to be discovered.¹⁸³ This definition does not refer to the "information" contained in genetic material; instead, it refers to the tangible genetic materials that contain such information. The CBD is based on the premise that property rights of Parties over their genetic

¹⁷⁸ Ibid.

¹⁷⁷ The CBD, *supra* note 6, Article 2.

¹⁷⁹ Gellner & Weaver indicates the definition of DNA (deoxyribonucleic acid) as:

[[]t]he molecule that stores the "instructions" for development. DNA is comprised of two helical strands which are bound together by hydrogen bonds between pairs of nitrogenous bases. Each strand is a polymer (many copies of a monomer) of four nucleotides. Each nucleotide (the monomers) is comprised of one of four nitrogenous bases, the same deoxyribose sugar, and phosphoric acid. The specific sequence of nitrogenous bases determines which gene is present. Within each strand the nucleotides are bound together by phosphodiester links. That is, the ribose sugars of two adjacent nucleotides are bound together through a phosphate molecule. Supra note 149 at 122.

¹⁸⁰ RNA (ribonucleic acid) is [a] single stranded polymer of nucleotides. The nucleotides are the same as in DNA except that the nitrogenous base thymine is replaced by another nitrogenous base, uracil. RNA is an "intermediate" molecule formed during the process of creating protein from genes (encoded in DNA). In fact, in organism the flow of "information" is DNA to RNA to protein. Ibid. at 128-129.

¹⁸¹ Contra L. Glowka, A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources (Gland and Cambridge: IUCN, 1998) at 4 [hereinafter A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources]. Glowka considers that genetic materials would include the DNA extracted from a plant, animal or microbe such as a chromosome, a gene, a plasmid or any part of these.

¹⁸³ See Technology Transfer and Genetic Resources, *supra* note 154 at 12.

resources strictly involve genetic resources as tangible property and not as intangible property.

A central theme of the CBD is Article 3 that recognizes the sovereign rights of every nation over its natural resources including genetic materials, in opposition of treating them as common heritage of mankind.¹⁸⁴ Article 3 reads:

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.¹⁸⁵

As will be discussed in Chapter 3, the implications for the recognition of sovereignty rights are addressed in Article 15 of the CBD. The main implication is that access to genetic resources is dependent upon conditions established by the legislation and competent authorities of each Party, and is subject to the Party's prior informed consent. The right of access is not absolute and its exercise is subject to an explicit authorization from the requested Party, but it is an enforceable right, which cannot be arbitrarily denied.¹⁸⁶ The other implication is the sharing of commercial and other benefits arising from the utilization of such resources.¹⁸⁷ The CBD further asserts the rights of countries of origin to be compensated for the exploitation of their genetic resources. It considers

¹⁸⁴ See Kadidal, *supra* note 156 at 231.

¹⁸⁵ The CBD, *supra* note 6, Article 3.

¹⁸⁶ Correa points out that "[i]f the requested country has not legislated on the issuance of permits, the understanding could be, however, that said country will not be able to deny access to genetic resources, if it can not invoke a regulation that justifies its decision". *Sovereign and Property Rights Over Plant Genetic Resources, supra* note 139 at 8; see discussion in section 3.1.

¹⁸⁷ See Technology Transfer and Genetic Resources, *supra* note 154 at 16.

that an uncompensated exploitation of such resources amounts to a devaluation of the genetic resources, and detracts from their preservation.¹⁸⁸ Another benefit is technology transfer contemplated by Article 16 of the CBD.¹⁸⁹ This could take the form of licenses to use proprietary technology, sharing of research and development results, or technical information or training.¹⁹⁰

Sovereignty rights, as recognized under Articles 3 and 15(1) of the CBD, are limited by a number of obligations accepted by the Parties to the CBD. National sovereignty serves not merely as the key of every State to manage its own genetic resources, but also as the key of corresponding responsibilities entailing vigilant management, and imposing accountability at national and international levels.¹⁹¹ The principle of national sovereignty acknowledges the right of States to exploit their natural resources, as limited by international law, and the duty to ensure that such activities within their jurisdiction do not cause damage to the environment of other States or areas beyond national jurisdiction.¹⁹²

In conclusion, the objectives of the national sovereignty principle is to serve as a basis for an integrated and comprehensive approach for the exploration and sustainable exploitation of natural resources, terms of trade of resources-endowed countries, and

¹⁸⁸ Sharma, *supra* note 44 at 18.

¹⁸⁹ See discussion in section 3.3.

¹⁹⁰ See Technology Transfer and Genetic Resources, *supra* note 154 at 16.

¹⁹¹ See Schrijver, *supra* note 140 at 393.

¹⁹² The CBD, *supra* note 6, Article 3.

access to and transfer of environmentally sound technologies to assist countries in coping with adverse environmental consequences.¹⁹³

2.3.2 The National Sovereignty Principle in the CBD and Patent Rights in **TRIPS**

The CBD and TRIPS are two equally binding international Agreements and thus have equal status as treaties. They have been ratified by an overwhelming numerical majority of United Nations members.¹⁹⁴ Consequently, conflict between the obligations under the CBD and TRIPS would be resolved by applying the general rules of international law regarding overlapping and inconsistent treaties, and the rules of interpretation of treaties under the Vienna Convention on the Law of Treaties¹⁹⁵ [hereinafter the Vienna Convention].

The Vienna Convention attempts to set down the rules of international law regarding States' treaty obligations and the relationship between conflicting obligations.¹⁹⁶Under Article 30(3) of the Vienna Convention, when Parties to a treaty later become Parties to an inconsistent treaty relating to the same subject matter, the earlier treaty applies insofar as its provisions are not incompatible with the later treaty, unless one of the treaties

¹⁹³ See Schrijver, *supra* note 140 at 394.

¹⁹⁴ Though with the significant exception, in the case of the CBD, of the United States. See Appendix 5.

The Vienna Convention on the Law of Treaties, 23 May 1969, U.N. Doc. A/Conf. 39/27, 1155 U.N.T.S. 331, reprinted in 8 I.L.M. 679 (entered into force 27 January 1980) [hereinafter the Vienna Convention]. ¹⁹⁶ Ibid. Article 30.

expressly specifies otherwise.¹⁹⁷ Thus, if two States are Parties to the CBD and TRIPS, Article 30(3) of the Vienna Convention provides that the later treaty prevails in the case of inconsistency. The strict application of this rule could certainly invalidate the CBD since it came into effect before TRIPS.

Under Article 30(4), however, when a Party to two of the treaties and a Party to only one of the treaties confront each other, the treaty to which they are both Parties determines their mutual rights and obligations.¹⁹⁸

The most significant problem in applying the Vienna Convention treaty interpretation rules is determining whether the two Agreements relate to the same subject matter, which is a prerequisite under the Vienna Convention.¹⁹⁹ Some scholars argue that the history of the Vienna Convention indicates that the Parties aimed at setting up rules for interpreting successive treaties relating to the same subject matter, such as GATT 1947 and GATT 1994, and not for completely separate Agreements such as the CBD and TRIPS.²⁰⁰ The

¹⁹⁷ Article 30(3) specifies:

When all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the latter treaty. *Ibid.*

¹⁹⁸ Article 30(4) states:

When the parties to the later treaty do not include all the parties to the earlier one:

a. as between States parties to both treaties the same rule applies as in paragraph 3;

b. as between a State party to both treaties and a State party to only one of the treaties, the treaty to which both States are parties governs their mutual rights and obligations. *Ibid.*

This rule is reinforced under Article 34, which specifies that "[a] treaty does not create either obligations or rights for a third State without its consent." *Ibid.* ¹⁹⁹ Article 30 specifies:

Subject to Article 103 of the Charter of the United Nations, the rights and obligations of States parties to successive treaties relating to the same subject-matter shall be determined in accordance with the following paragraphs. *Ibid.*

²⁰⁰ C. Wold, "Multilateral Environmental Agreements and the GATT: Conflict and Resolution?" (1996) 26 Envit'l L. 841 at 910 [hereinafter Multilateral Environmental Agreements and the GATT].

Vienna Convention therefore is not applicable in the CBD/TRIPS conflict.²⁰¹ The two Agreements deal with different topics. While TRIPS sets norms for intellectual property rights in order to promote world trade, the CBD aims at strengthening international biodiversity protection. This suggests that TRIPS does not relate to the same subject matter as the CBD, even for the limited purpose of interpreting the intellectual property provisions of the two treaties.²⁰²

Finally, Article 30(2) of the Vienna Convention reads "[w]hen a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail."²⁰³ The later-in-time doctrine under Article 30(3) thus does not apply to treaties if they contain a provision that specifies its relationship to other international agreements. The CBD includes such a provision. It provides that its provisions "shall not affect the rights and obligations of any Contracting Party deriving from any existing agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."²⁰⁴ The provision contained in the CBD raises the issue of what constitutes serious damage or a threat to biological diversity to allow the CBD to take precedence over TRIPS. Hence, the issue arises as to whether the patent system of TRIPS poses a serious damage or threat to biologiversity, so as to allow the CBD to take precedence over TRIPS.²⁰⁵ A broad

²⁰² See Multilateral Environmental Agreements and the GATT, *supra* note 200 at 910; but see A.E. Brunner, "Conflicts Between International Trade and Multilateral Environmental Agreements" (1997) 4 Ann. Surv. Int'l & Comp. L. 74. The author suggests that one can argue that the two Agreements relate to the same subject matter.

²⁰³ The Vienna Convention, *supra* note 195.

²⁰¹ See G.H. Fox, "International Organizations: Conflicts of International Law" (2001) 95 Am. Soc'y Int'l L. Proc. 183 at 185-186.

The CBD, *supra* note 6, Article 20.

²⁰⁵ G.L. Gaston & R.S. Abate, "The Biosafety Protocol and the World Trade Organization: Can the Two Coexist?" (2000) 12 Pace Int'l L. Rev. 107 at 118.

interpretation of "serious damage" or "threat" would therefore provide the CBD with preeminence over all conflicting TRIPS provisions.²⁰⁶

Article 30 of the Vienna Convention potentially conflicts with the rule of lex specialibus, a widely supported general rule in international law.²⁰⁷ This rule presumes that when conflicting provisions of two treaties between the same Parties apply to the same situation, the more specific provision overrides the general provision, even if the general provision is later in time.²⁰⁸ Under this rule, the CBD provisions would most likely govern since the CBD speaks more specifically on the issue of genetic resources than TRIPS.209

The issue of how international law should address conflicts between inconsistent two treaty-based multilateral provisions under the CBD and TRIPS is of paramount importance. Nevertheless, rather than focusing on this issue, I attempt to consistently interpret the national sovereignty principle in the CBD and patent rights in TRIPS.

In discussing the CBD and TRIPS, there is an argument of a direct conflict between the two Agreements because they offer two conflicting visions of future global trade in genetic resources. The argument developing countries forward is that the CBD assigns sovereignty rights in genetic resources to countries of origin, whereas TRIPS allows these

²⁰⁶ B. Hendricks, "Postmodern Possibility and the Convention on Biological Diversity" (1996) 5 N.Y.U. Envt'l L. J. 1 at 19.

²⁰⁷ Sir G. Fitzmaurice, "The Law and Procedure of the International Court of Justice 1951-4: Treaty Interpretation and Other Treaty Points" (1957) Brit. Y.B. Int'l L. 203 at 236.

²⁰⁸ R.A. Brand, "Sustaining the Development of International Trade and Environmental Law" (1997) 21 Vt. L. Rev. 823 at 868. ²⁰⁹ See Brunner, *supra* note 202 at 88-89.

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resources to be patented. Developing countries therefore say that TRIPS undermines rights that are granted by the CBD. Another charge branching from this is that patenting inventions using genetic resources encourages the unsustainable use of such resources. The opposite argument is against the principle of national sovereignty in the CBD. It asserts that national sovereignty principle impedes the rights of patent right holders. This assumption was the key argument advanced by the US in opposition for the signing of the CBD.²¹⁰ The above arguments suggest that there is a substantial conflict between the two Agreements. However, a consistent interpretation of sovereignty principle in the CBD and patent rights in TRIPS could possibly eliminate such conflict.

First, it is central to understand that patent protection cannot be extended or enforced with regard to naturally occurring genetic resources, although patents can be granted for a limited period of time to novel products or processes derived from such resources, and to genetic resources themselves where there has been a human technical intervention that achieved a result that doesn't occur in nature, subject to national laws.²¹¹ So, with regard to genetic resources as they occur in nature, countries have the right to exclude them from patentability.

²¹⁰ According to Chen, the US main concern and reason for not signing the CBD was its "[d]issatisfaction with "the text's treatment of intellectual property rights". However, President Clinton signed the Biodiversity Convention on the 4th of June 1993. The Senate is considering the ratification of the treaty in the next two years. *Supra* note 46 at 19. ²¹¹ According to the OECD survey,

[[]t]he availability of such intellectual property protection, in both the "home" country and that to which technology is to be transferred, is seen as a fundamental prerequisite of co-operative activities that can lead to technology transfer agreements and to foreign investment in technology-importing countries.

Technology Transfer and Genetic Resources, supra note 154 at 7-8.

Regarding sovereignty rights over genetic resources, I previously mentioned that States' rights could only be exercised over the tangible property in genetic resources.²¹² Patent rights, on the other hand, concern the ideas involved in inventions. The CBD is quite open; it allows the international treaties on intellectual property rights to regulate this area.

Under TRIPS, the issue of patentable technology that exploits natural genetic resources is not explicitly addressed. Therefore, the general standards of patentability apply in this case.²¹³ However, there must be more profound studies on the granting of patents for inventions related to genetic materials. Moreover, the patentability of such inventions needs to be examined at the next review of Article 27.²¹⁴

The above is crucial for the realization that intellectual property systems do not have a clear role to play with regard to sovereign rights over genetic resources.²¹⁵

Second, I address the argument that patents encourage activities that damage the environment and result in loss of biodiversity. For example, some commentators argue that a patent on a genetically modified organism can promote its commercial exploitation, which may have unforeseen damaging environmental effects, or that protection for a new plant variety, can promote over-wide commercial use, with loss of biodiversity in the

²¹² See subsection 2.3.1.

²¹³ See generally Trebilcock & Howse, *supra* note 91 at 334; Technology Transfer and Genetic Resources, *supra* note 154 at 17.

²¹⁴ See Samper & Ferriera Miani, *supra* note 54 at 15; V. Tejera, "Tripping Over Property Rights: Is It Possible to Reconcile the Convention on Biological Diversity with Article 27 of the TRIPS Agreement?" (1999) 33 New Eng. L. Rev. 967 at 987.

²¹⁵ See Technology Transfer and Genetic Resources, *supra* note 154 at 7-8.

form of less productive but more diverse traditional varieties.²¹⁶ For example, a few new commercial plant varieties of broadly similar genetic background displace many diverse farmers' varieties, and thus, promote uniformity at the expense of biodiversity.²¹⁷

In challenging this view, it is important to value the importance of genetic resources to mankind, the need to conserve genetic resources for future generations, and the need to prevent any negative impact on biodiversity.²¹⁸ We have to bear in mind that the scientific exploration of the microbial, plant and animal kingdoms with a view to producing innovative processes and products of potential industrial and commercial value is not inconsistent with, or inimical to, the conservation of genetic resources.²¹⁹ Biotechnology in particular, offers new opportunities for increasing the productivity of agriculture, reducing the cost of food production and decreasing the environmental damages of agricultural practices.²²⁰

Although patent protection in biotechnology inventions does not per se contribute to the preservation of genetic diversity, the promotion of patent protection in fact supports the CBD's objectives because it can actually help to encourage uses of genetic material in biotechnology, including sustainable uses of genetic material.²²¹ There is evidence that the

²¹⁶ See generally V. Shiva, *Biopiracy: The Plunder of Nature and knowledge*, (Boston: South End Press, 1997) at 87-99.

²¹⁷ Ibid.

²¹⁸ The Preamble of the CBD addresses the issues as follows: "Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at sources", and "Noting also that were there is a threat of significant reduction or loss of biodiversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat". *Supra* note 6.

²¹⁹ See Technology Transfer and Genetic Resources, *supra* note 154 at 28.

²²⁰ See R.B. Horsch & R.T. Fraley, "Biotechnology Can Help Reduce the Loss of Biodiversity" in Guruswamy & McNeely, *supra* note 67, 45 at 50.

²²¹ According to Urbanski, intellectual property protection provides incentives for conservation. Absent legal protection, there will be little incentive to protect wild stock of species. The result is

patent system creates incentives for private investments in certain industries such as crop breeding, which makes significant use of genetic resources and related biological resources.²²²

The preamble of the WTO Agreement recognizes the extent to which sustainable use and other environmental factors are linked to the WTO. The preamble seeks to ensure "expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns as different levels of economic development".²²³

TRIPS is an Agreement that depends from the one previously mentioned and therefore, the Preamble of the WTO Agreement also applies to it. n this regard, TRIPS states that "Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect vital health and nutrition "…" provided that such measures are consistent with the provisions of this Agreement."²²⁴

an open-access to natural resources, which inevitably lead to "destructive extractive practices", sometimes leading to the extinction of such resources. *Supra* note 74 at 145. ²²² See specifically Conference Of the Parties to the Convention on Biological Diversity, The

²²² See specifically Conference Of the Parties to the Convention on Biological Diversity, The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use: A Preliminary Study, Note by the Executive Secretary, UNEP, 3rd Meeting, UNEP/CBD/COP/3/22 (1996) 10, online: <http://www.biodiv.org/doc/decisions/cop-03-dec-en.pdf> (last accessed 27 July 2002) [hereinafter the Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use].
²²³ Marrakech Agreement Establishing the World Trade Organization, 15 April 1994, reprinted in Results of the Uruguay Round 6-19, 365-403, 133 I.L.M. 1141 (entered into force 1 January 1995), the preamble, [hereinafter WTO Agreement].

²²⁴ TRIPS, *supra* note 5, Article 8(1). For a discussion on the relationship of other WTO Agreements and the environment, see Macmillan, *supra* note 128.

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The foregoing promotes the sustainable use of genetic resources, which is dealt with in Article 10 of the CBD. This Article states that conservation and sustainable use of genetic resources should be integrated into decision-making national processes. The CBD also points out that Parties should adopt measures related to the use of biological resources to avoid, or reduce to the minimum, adverse effects.

Last, I address some of developed countries concerns regarding the unfavorable impacts that the national sovereignty principle might have on intellectual property rights. These concerns do not rest on any factual basis. National sovereignty as recognized by the CBD is not a new principle; it is a re-affirmation of a recognized principle that a sovereign nation has control over whatever goes on within its borders. It can control exports and imports, and set conditions for them, and it is by virtue of this power of control that it is enabled to set conditions for access to genetic resources within its borders. Property rights in tangible property simply give countries the right to control or restrict the action of access to genetic resources; they do not give the right to claim an extended right to control or restrict other actions such as, the patenting of inventions using genetic resources. The CBD does not create a new right t of property in genetic materials, let alone one that nullifies other possible rights such as patent rights.²²⁵

²²⁵ Contra Kadidal, supra note 156 at 231. According to L. Glowka et al.,

Article 15(1) reaffirms that States have sovereign rights over the genetic resources found within their jurisdiction, but it does not grant the State a property right over them. Who owns genetic material within the country is a fundamental question which the Convention does not answer. This is typically determined by the country's constitution or national law.

A Guide to Undertaking Biodiversity Legal and Institutional Profiles, Environmental Policy and Law Paper No. 35 (Gland and Cambridge: IUCN, 1998) at 28 [hereinafter A Guide to Undertaking Biodiversity Legal and Institutional Profiles].

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Thus, the principle of sovereignty rights in the CBD is not inconsistent with rights to private property, though it may well limit the way in which such rights are exercised. For example, seed or timber remains with whoever owned it, whether farmers, private companies or the State, according to national legislation. So, just as property rights are allowed by the CBD, so are other possible rights that may affect the use of genetic materials, such as patent rights.

Despite this deference to State sovereignty regarding genetic resources, the CBD does recognize the need to protect patent rights. The CBD, in Article 16(5) mandates adequate and effective protection of intellectual property rights for the transfer of biotechnology, yet these rights must be supportive and not run counter to the objectives of the CBD.²²⁶ Despite the initial concern expressed by some developed countries, particularly the US, over the CBD, the subsequent TRIPS seems to refute the suggestion that the CBD represents a significant threat to the rights of patent holders. Indeed, a reinterpretation of the CBD's provisions, in light of TRIPS, may mean that the CBD will actually strengthen the patent regimes in developing countries.²²⁷ After all, the protection of patent rights at appropriate levels benefits both developed and developing countries. Therefore, there is no conflict between the concepts of sovereignty over genetic resources and patent rights.

 ²²⁶ However, this Article remains a highly contentious point in the global community.
 ²²⁷ See I. Walden, "Intellectual Property Rights and Biodiversity" in Bowman & Redgwell, *supra* note 15, 171 at 179.

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The North fears the CBD's illusory threat to intellectual property, and the South is provoked at any hint of biopiracy. "Neither position is particularly healthy".²²⁸ Therefore, developed countries that are not yet Parties of the CBD should sign the Agreement, rather than claim erroneously that the CBD threatens patent regimes. Likewise, developing countries should not overemphasize their sovereignty over their genetic capital in this globalizing era, where the rest of the world is just as interested as they are in such genetic treasures.

The CBD obliges its Parties to respect the established norms of intellectual property. Equally, it adopts norms that acknowledge the genetic contribution of developing countries. In hindsight, there was never a formal conflict between TRIPS and the CBD, or between biotechnology and biodiversity.²²⁹ However, a consistent implementation of the CBD and TRIPS is primarily contingent on Parties abiding by the limits of sovereignty rights, which results in an appropriate framework for access to genetic resources and benefit sharing.

Notwithstanding the above, there are some concerns regarding the CBD's contested provisions relating to access to genetic resources and benefit sharing, and the interpretation of these provisions. These concerns are addressed in the next chapter, by critically appraising the current implementation of access and benefit sharing provisions.

- ²²⁸ Chen, supra note 46 at 22.
- ²²⁹ See especially *Ibid.* at 19.

3 Bio-Trade and Access to Genetic Resources

In chapter 2, I concluded that there is no formal conflict between the principles of sovereignty rights over genetic resources in the CBD and patent protection in TRIPS. In this chapter, I discuss the right of Parties to regulate access to genetic resources and sharing benefits arising from the commercialization of such resources, as one manifestation of sovereignty rights.

I proceed by outlining the provision of access to genetic resources in the context of the CBD (section 3.1), reviewing the rights and obligations of Parties in regulating access to genetic resources. I conclude that the lack of clear wording in Article 15 increases the possibility of misinterpreting the right of countries in regulating access, and thus it warrants an unambiguous and consistent clarification. I then turn to the implementation of this provision, and illustrate how the misinterpretation of Article 15 interferes with patent rights in biotechnological inventions using genetic resources (section 3.2). I conclude that the right to control access to genetic resources stems from sovereignty rights. Sovereignty rights of countries over their genetic resources strictly target genetic resources as tangible property. Therefore, access to genetic resources should be strictly interpreted as being executed against genetic resources as tangible property and not against intangible property contained in such resources. The extension of States' control to include the intangible part of genetic resources would have two consequences. The first would be the altering of the rights of Parties under the CBD. The second would be the conflict with Member Countries' obligations under TRIPS. It would specifically violate the two substantive provisions of TRIPS: Article 27(1) on patentable subject

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matter and Article 29 on conditions on patent applicants. In section (3.3), I discuss benefit-sharing and technology transfer as part of the access regime. I evaluate the importance of patent protection in benefit-sharing and technology transfer. I conclude this chapter by asserting that access and benefit-sharing can lead to new life-saving drugs, food to nourish the population and countless benefits for humankind. Access and benefitsharing can also help protect the rights of countries, communities, individuals, corporations and industries. Since I found linkage between the CBD and TRIPS, it is important to ensure that both Agreements are implemented through fair and practicable approaches for benefit from genetic resources. But when laws and policies go wrong, these opportunities can be missed, to the detriment of the people and the environment.

3.1 Access to Genetic Resources in Article 15 of the CBD

Inventions based on genetic resources²³⁰ have always relied on physical access to these resources. No international regime existed prior to the conclusion of the CBD to regulate access to genetic resources and promote benefit-sharing. Informally, genetic resources were considered the "common heritage of mankind". They have been collected from developing countries, which are known to possess most of the world's genetic resources, and transformed into new products, mainly by pharmaceutical and biotechnology

²³⁰ Article 2 states: "*Genetic Resources* means genetic materials of actual or potential value. "*Genetic Material*" means any material of plant, animal, microbial or other origin containing functional units of heredity." The CBD, *supra* note 6.
companies of developed countries, without any agreements accompanying.²³¹ In some cases, genetic resources extraction has been associated with the appropriation of the indigenous knowledge of local people. Countries, local communities and individuals providing their genetic resources or related knowledge about the use of those resources have not benefited from the use of their resources and knowledge. Many argued that this open-access regime was essential for ensuring that genetic resources were widely available for research and commercial use in the agriculture and biotechnology sectors. Material donors argued, however, that they are giving their genetic resources freely to developed countries and buying them back in form of crops and medicine.

The lack of an international regime controlling access to genetic resources and benefitsharing was perceived as an inequitable system that undermined incentives and efforts to conserve biodiversity and ensure the sustainable use of its components. This led several developing countries to argue for a more equitable approach to the use of genetic resources.

Opposition to the common heritage principle began to materialize by the early 1980s. Developing countries sought property rights in genetic resources in response to the increasing value of genetic resources in biotechnology.²³² It was not until the negotiations of the CBD that they proposed the establishment of an internationally recognized property rights in genetic resources. Such rights would enable them to regulate access to genetic resources and to share benefits derived from using such resources. This proposal was mainly justified under the incentive theory.233 It is based on the argument that the

 ²³¹ See Sustainable Use of Genetic Resources, supra note 29 at 19.
 ²³² Ibid.

²³³ See discussion in subsection 2.2.1.

conservation and collection of genetic resources should be rewarded and encouraged by incentives similar to the incentives created to encourage intellectual property rights. Therefore, the creation of property rights in genetic materials would allow countries to control access to their genetic resources, thus enabling them to capture monetary and non-monetary gains from the collection and use of genetic resources. Consequently there would be stronger incentives to conserve and sustainably exploit genetic resources since the enhanced benefits would help meeting the opportunity costs of conserving such resources while securing long-term benefits from their application in biotechnology.

This argument prevailed in the CBD. The CBD was a forum to redefine access to genetic resources and the flow of benefits from the use of such resources, shifting from the principle of *unrestricted access* to *controlled access* to genetic resources, in order to secure that benefits arising from the use of such resources are shared equitably.

Article 15 of the CBD defines the rights and obligations of Parties regarding access to genetic resources and fair and equitable sharing of benefits derived from their use. The CBD provides the general legal framework for access and benefit-sharing. However, the details of the practical implementation of Article 15 will be defined primarily at the national level through the creation or adaptation of legislation, administrative procedures and institutions.

Access to genetic resources is interpreted as "obtaining samples of genetic resources for purposes of research, conservation, commercial or industrial applications."²³⁴ Access to genetic resources is regulated in Article 15(1) of the CBD.²³⁵ It recognizes that the authority to determine access to genetic resources rests within the national governments and is subject to national legislation, without guidance for the formation of such legislation.

This provision implies that the CBD is only enforceable if countries follow up with their own domestic legislation providing for access to genetic resources.²³⁶ Some argue,

²³⁴ L. Glowka, "Legal and Institutional Considerations for States Providing Genetic Resources" in Mugabe *et al.*, *supra* note 90, 33 at 36.

²³⁵ Article 15 of the CBD specifically articulates the following:

^{1.} 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.

^{2.} Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
 Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that party.
 Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

^{7.} Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms. *Supra* note 6.

²³⁶ See M. Jain, "Global Trade and the New Millennium: Defining the Scope of Intellectual Property Protection of Plant Genetic Resources and Traditional Knowledge in India" (1999) 22 Hastings Int'l & Comp. L. Rev. 777 at 784.

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however, if the Party has no legislation providing for access, it "will not be able to deny access to genetic resources, if it can not invoke a regulation that justifies its decision".²³⁷ By controlling access to genetic resources, the CBD does not intended to unduly restrict such access. Parties to the CBD are obliged to make "best efforts" ²³⁸ to endeavor to establish conditions that facilitate access to genetic resources for environmentally sound uses, and "not to impose restrictions which run counter to the objectives of the Convention."²³⁹ Although the conditions that would facilitate such access are unclear, the provision implies that Parties are to accord special treatment to each other.²⁴⁰ Furthermore, there is no reference as to what constitutes restrictions on access to genetic resources. In addition, conditioning the facilitation of access for environmentally sound uses is ambiguous since the CBD does not identify what amounts to environmentally sound uses. Subsequently, such conditioning is left to be determined by the Party in the legislation providing for access to genetic resources.²⁴¹ Article 15(4) of the CBD requires that the granting of access to genetic resources shall be

on "mutually agreed terms". This phrase implies that those seeking access to genetic

²³⁷ See Sovereign and Property Rights Over Plant Genetic Resources, supra note 139 at 8, footnote 15.

²³⁸ *Ibid.* at 11.

²³⁹ The CBD, *supra* note 6, Article 15(2).

 ²⁴⁰ See A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources, supra note 181 at 5.
 ²⁴¹ Glowka forwards an example on facilitating access for environmentally sound uses:

Glowka forwards an example on facilitating access for environmentally sound uses: Article 45 (a)-(g) in Decision 391 of the Andean Pact list a number of situations where national legislation can impose limitations on access. Limitations can be imposed where "(1) endemic, rare, threatened or endangered species are targeted, (2) the activity involves a fragile ecosystem, (3) adverse impacts to human health or the essential elements of cultural identity are at stake, (4) undesirable environmental impacts may occur, (5) there is a danger of genetic erosion, (6) biosecurity issues present themselves or (7) the proposed activity targets strategic genetic resources or geographical areas." *Ibid.* at 64.

resources shall enter into negotiations and try to reach an agreement with the provider of such resources. Providers and users of genetic resources have to negotiate the concrete provisions of a particular agreement and therefore agree on the terms for access and the nature of the benefits to be shared. If the negotiation is successful, its result is a legally binding agreement between the two sides. The terms and details will vary between agreements and countries since the CBD provides a uniform set of minimum standards and norms without setting any specific terms or conditions.

The concept of "mutually agreed terms" establishes a new relationship between providers and users of genetic resources. It creates a *quid pro quo* between those parties providing genetic resources and potential users. In order to obtain genetic resources, users must be committed to sharing the benefits. Users must also endeavor to develop and carry out research together with the institutions in the providing countries.

Article 15(5) of the CBD deals with the prior informed consent of countries of origin. Any person seeking access to genetic resources is required to obtain the consent of the country of origin in order to collect or obtain any genetic resources within the jurisdiction of the country of origin. This consent must be an "informed" one. This means that the country of origin has the authority to require any potential user of genetic resources to obtain prior authorization, and to provide information that may determine whether the country of origin will grant access. Such information may include the resources that will be obtained or used, how they will be used, and by whom.²⁴² However, from the wording of Article 15(5), "unless otherwise determined by that Party", prior informed consent is more an option than a requirement. This means that users of genetic resources are not

²⁴² See A Guide to the Convention on Biological Diversity, supra note 19 at 81.

obliged to obtain the country's consent unless the country establishes the necessary procedures in its legal system. Accordingly, users are not required to obtain the prior informed consent in the absence of such procedures.²⁴³

Along with the requirements that access to genetic resources is to be founded on mutually agreed terms and on the basis of prior informed consent, the CBD further establishes the principle of fair and equitable sharing of benefits derived from the use of genetic resources. Article 15 explicitly links access to genetic resources with the sharing of benefits arising from the use of these resources. Such benefits may entail scientific and technological knowledge, skills enhancement, up-front payment for the collection of genetic resources, and royalties on products developed from the material.²⁴⁴

Although the CBD does not provide explicit guidelines on how benefits are to be shared, Article 15 draws an expectation that specific measures to facilitate benefit-sharing are to be formulated at the national level. Such measures shall aim at promoting technological innovation, rewarding local and indigenous peoples for their knowledge, innovations and practices, and providing incentives for conservation.²⁴⁵

As noted above, there is certain complexity in interpreting Article 15. Phrases such as "create conditions to facilitate access to genetic resources for environmentally sound uses", "not to impose restrictions that run counter to the objectives of this Convention", "access to genetic resources shall be subject to prior informed consent", "sharing in a fair

²⁴³ Ibid.

²⁴⁴ Ibid. at 82-83.

²⁴⁵ Watal states that "[i]t is unclear what 'fair and equitable' means since these terms are to be agreed mutually and since there is no effective international arbitration envisaged to help determine this outcome." *supra* note 11 at 172.

and equitable way" and "mutually agreed terms" are difficult to interpret. It essential to bear in mind that the elasticity of such phrases reflects the struggle to find fair and practical solutions to the challenge of achieving the objectives of the CBD, with 182 Parties having varying ecosystems, disparate economic, political, and cultural situations, and different legal systems. These standards reflect the State's relative capabilities by imposing different legal obligations, and by making implementation proportional on the capabilities of each country. Without such consideration, a clear understanding of the goals of the CBD would be elusive.²⁴⁶

The ambiguity of Article 15, however, increases the likelihood of a misinterpretation that could lead to an implementation that is inconsistent with its purpose. For example, some fear that countries hosting rich varieties of biodiversity might exercise comprehensive control over those resources or implement practices that may have the effect of hindering exploitation and further research and development of products using genetic resources.²⁴⁷ An appropriate interpretation of Article 15 that reflects the spirit of the CBD will effectively result in a similar implementation,²⁴⁸ acknowledging that "interpretation and implementation will likely co-evolve".²⁴⁹

²⁴⁶ See Sustainable Use of Genetic Resources, supra note 29 at 10; See C. Wold, "The Futility, Utility, and Future of the Biodiversity Convention" (1998) 9 Colo. J. Int'l Envtl. L. & Pol'y 1 at 16 [hereinafter The Futility, Utility, and Future of the Biodiversity Convention]. The author argues that such differentiated responsibility is accepted in international law. Both the Framework Convention on Climate Change and Montreal Protocol on Substances that Deplete the Ozone Layer impose different obligations on developed and developing countries. The breadth of the Biodiversity Convention reinforces this conclusion.
²⁴⁷ Sharma, supra note 44 at 21; see G. Rose, "International Regimes for Conservation and

²⁴⁷ Sharma, *supra* note 44 at 21; see G. Rose, "International Regimes for Conservation and Control of Plant Genetic resources" in Bowman & Redgwell, *supra* note 15, 145 at 149. As a result of the ambiguity of Article 15, several countries filed interpretative statements with regard to the ambiguous parts of this Article.

²⁴⁸ Jain and Sharma advance the arguments on the interpretation of the Convention: some argue that it could be interpreted to result in a reduction in the extent of intellectual property rights

3.2 Access to Genetic Resources in Practice: Patent Rights and Access to Genetic Resources

This section examines the access policy involving co-implementation of the access provision in the CBD and the patent system in TRIPS. The aim of this section is to illustrate that the lack of clarity in Article 15 might lead to a misinterpretation of the rights of Parties in regulating access to their genetic resources, resulting in policies practically incompatible with TRIPS. The focus here is on the right of countries of origin to require "prior informed consent" from users of their genetic resources. This right has not been well clarified within the context of Article 15, and in this case, has been misinterpreted. Focusing on this case, I illustrate and conclude that in interpreting Article 15, two factors must be considered: the objectives, rights and obligations of Parties under the CBD, and the rights and obligations of Member Countries under TRIPS.

The right of access to genetic resources, governed by Article 15 of the CBD, is subject to the prior informed consent of the country of origin. The CBD adopted this novel approach as the corollary of the declaration that States hold property rights in genetic resources. Prior informed consent can secure for countries of origin a fair share in the returns from the exploitation of genetic resources.²⁵⁰ It can also serve as a tool for the conservation of genetic resources and the prevention of overaccumulation of such

protection, while others argue that it has the effect of enabling access to biological resources, and thus, facilitating research into those resources. *supra* note 236 at 784, *supra* note 44 at 30-31.

²⁵⁰ See Technology Transfer and Genetic Resources, *supra* note 154 at 17.

resources.²⁵¹ For example, the State can impose penalties for the uninformed unlawful taking of genetic resources, and empower the appropriate agency to claim damages in the courts for the injury of the national heritage. All that is necessary is a legislative provision to that effect.²⁵² The prior informed consent does not come into play unless it is established in the legal system.²⁵³

To support compliance with prior informed consent, there have been several proposals recently that patent applications should include a clear indication of the country of origin and a proof of the prior informed consent, as one means to ensure that patent applicants obtained the prior informed consent of the country of origin. One of the recent documents that adopt this added requirement are the Bonn Guidelines.²⁵⁴

The information should be provided in a manner and language comprehensible to the provider.

Consent should be construed strictly.

Prior informed consent of indigenous and local communities is dependent on clear recognition and protection of their rights, knowledge and innovation and practices. For this reason the development of sui generis legislation may need to be considered.

²⁵¹ Conference Of the Parties to the Convention on Biological Diversity, *Report of the Panel of Experts on Access and Benefit-Sharing*, UNEP, 5th Meeting, UNEP/CBD/COP/5/8 (1999) 27-28, online: http://biodiv.org/doc/decisions/cop-05-dec-en.pdf> (last accessed 26 July 2002) [hereinafter *Report of the Panel of Experts on Access and Benefit-Sharing*]. The report indicates the principles that should guide in the development of prior informed consent procedures as follows:

An applicant must supply sufficient information to allow for informed consent, including the best scientific and commercial information, and information regarding relevant social, cultural and environmental issues.

The provider must be allowed to request further particulars.

 ²⁵² See C. de Klemm & C. Shine, Biological Diversity Conservation and the Law: Legal Mechanisms for Conserving Species and Ecosystems (Gland & Cambridge: IUCN, 1993) at 60.
 ²⁵³ See Sustainable Use of Genetic Resources, supra note 29 at 87.

²⁵⁴ Conference of the Parties to the Convention on Biological Diversity, *Access and Benefit-sharing as Related to Genetic Resources*, UNEP, 6th Meeting, UNEP/CBD/COP/6/24 (2002), adopting the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefit Arising out of their Utilization, online: http://biodiv.org/doc/decisions/cop-06-dec-en.pdf> [hereinafter the Bonn Guidelines].

The Bonn Guidelines intend to be an effort to clarify the provisions of Article 15 on access to genetic resources. The Conference of the Parties²⁵⁵ decided to establish an Ad Hoc Open-ended Working Group with the mandate to develop guidelines and other approaches for access to genetic resources and benefit-sharing. The working group convened in Bonn, Germany, from the 22nd to 26th October 2001. The outcome of the meeting was the conclusion of the Draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.²⁵⁶ The Conference of the Parties adopted the Bonn Guidelines at its sixth meeting in The Hague, in April of 2002.²⁵⁷ "These Guidelines may serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing".²⁵⁸ The Guidelines are voluntary; their purpose is to guide parties (providers and users of genetic resources) in access and benefit-sharing arrangements on a voluntary basis. They also aim at assisting Parties to "develop an overall access and benefit-sharing strategy, which may be part of their national biodiversity strategy and action plan, and in identifying the steps involved in the process of obtaining access to genetic resources and sharing benefits."259 Thus, "nothing in these Guidelines shall be

- ²⁵⁷ The Bonn Guidelines, *supra* note 254.
- ²⁵⁸ Ibid Article 1.

²⁵⁵ Article 23 of the CBD establishes the Convention's highest organ: the Conference of the Parties. The Conference assembles representatives of all Parties to the Convention and observers, including Non-Governmental Organizations. Its main function is to supervise and guide the entire process of implementation and further development of the Convention. The Conference meets regularly, with the discretion to decide at which intervals it should meet. Articles 14(2), 18(3), 19(3), 20(2) and 21(1) refer to specific actions to be taken by the Conference of the Parties. Supra note 6 .See generally A Guide to the Convention on Biological Diversity, supra note 19 at 111-117.

²⁵⁶ Conference Of the Parties to the Convention on Biological Diversity, *Report of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing*, UNEP, 6th Meeting, UNEP/CBD/COP/6/6 (2001) 14-25, online: http://biodiv.org/doc/meetings/cop/cop-06/official/cop-06-06-en.pdf> (last accessed 28 July 2002).

²⁵⁹ *Ibid* Article 6.

construed as changing the rights and obligations of Parties under the CBD", and "[n]othing in these Guidelines is intended to substitute for relevant national legislation."²⁶⁰

The Bonn Guidelines introduce several procedures with the objective of explaining the provision of access in the CBD, to be followed by the Parties on a voluntary basis. One of the provisions in the Guidelines seen as contradictory is Article 16(d). To support compliance with the prior informed consent in the CBD, the Guidelines propose that Parties could consider measures to encourage the disclosure of the country of origin of

genetic resources.²⁶¹

A number of commentators similarly support the requirement on applicants to disclose

the country of origin of genetic resources when seek patents for their inventions.²⁶² They

²⁶⁰ Ibid Article 3.

²⁶¹Article 16(d) states:

[[]C]ontracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, *inter alia*, the following measures:

i. Mechanisms to provide information to potential users on their obligations regarding access to genetic resources;

ii. Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights;

iii. Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources;

iv. Cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements;

v. Voluntary certification schemes for institutions abiding by rules on access and benefitsharing;

vi. Measures discouraging unfair trade practices;

vii. Other measures that encourage users to comply with provisions under subparagraph 16 (b) above. *Ibid.*

²⁶² Conference Of the Parties to the Convention on Biological Diversity, The Convention on Biological Diversity and The Agreement on Trade-Related Intellectual Property Rights (TRIPS): Relationships and Synergies, UNEP, 3rd Meeting, UNEP/CBD/COP/3/23 (1996) 10, online: <http://biodiv.org/doc/meetings/cop/cop-03/official/cop-03-23-en.pdf> (last accessed 28 July 2002) [hereinafter The Convention on Biological Diversity and The Agreement on Trade-Related Intellectual Property Rights].

argue that there is evidence that suggests such disclosure is already common practice in filing patent applications, and that such a step would in large part involve simply regularizing a practice that is already common in filing patent applications.²⁶³ A number of commentators also suggest that Parties could improve benefit-sharing by creating a positive link between their patent legislation and their legislation governing access to genetic resources.²⁶⁴ One of the suggestions made would require patent applicants to disclose the country of origin of the genetic resources used in research leading to the invention in the normal invention description submitted to the patent office.²⁶⁵

This trend towards encouraging such disclosure has been preceded and paralleled by similar recommendations and reports by the Conference of the Parties.²⁶⁶ For example, the Conference of the Parties, in its Decision VI/24 adopting the Bonn Guidelines, invited the Parties to "encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application

²⁶³ One recent study reviewed over five hundred patent applications in which the invention involved the use of biological materials, such as materials derived from plants or animals; most were in the pharmaceutical field, with some in other fields such as cosmetics and pesticides. The applications reviewed came from a number of jurisdictions, including France, Germany, the UK, Spain, the USA, and the European Patent Office. Of the applications involving plants, the country of origin was invariably mentioned unless the plant was widely distributed or well known (such as the lemon or rosemary). Ibid. at 18.

Conference Of the Parties to the Convention on Biological Diversity, Knowledge, Innovations and Practices of Indigenous and Local Communities; Implementation of Article 8(i), UNEP, 3rd Meeting, UNEP/CBD/COP/3/19 (1996) 21-22 online:

<http://biodiv.org/doc/meetings/cop/cop-03/official/cop-03-19-en.pdf> [hereinafter Knowledge. *Innovations and Practices of Indigenous and Local Communities*] (Last accessed 28 July 2002). ²⁶⁵ Other specific suggestions were that patent applications should include disclosure of all places of origin in the material/knowledge used in the application, disclosure of all communities/persons of origin, proof of consent having been obtained from the community/persons of origin, proof of benefit sharing arrangement having been entered into with the community/persons of origin, disclosure of any previous rejection of application in the country or other jurisdictions, prior public notice in all relevant languages in the place or communities of origin. Ibid. See also Macmillan, supra note 128 at 130. ²⁶⁶ For example, UNEP/CBD/COP/3/22, UNEP/CBD/COP/3/19 and UNEP/CBD/COP/5/8.

concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted."267 The Conference of the Parties suggested at another occasion that "countries implementing measures that implicate both agreements-such as rules requiring patent applications to disclose the country of origin of biological material-might report them to the TRIPS Council while at the same time disclosing the same information to the clearing-house mechanism for scientific and technical cooperation established under Article 18(3) of the CBD, or including information regarding the measures in the national reports required under Article 26 of the CBD."268

A survey conducted by the Food and Agriculture Organization (FAO) in 2000, on the implementation of legislation providing for access to genetic resources in Latin America,²⁶⁹ reveals other examples of access legislations that require the indication of country of origin. According to the survey, eight countries have legal mechanisms to regulate access to genetic resources.²⁷⁰ These countries are the Andean Group, Brazil, Costa Rica and Paraguay. All of these legislations include Articles demanding applicants for patents based on genetic resources to indicate the country of origin and to prove that access to such resources was based on the prior informed consent of the country.

 ²⁶⁷ The Bonn Guidelines, *supra* note 254 at 17.
 ²⁶⁸ The Convention on Biological Diversity and The Agreement on Trade-Related Intellectual Property Rights, supra note 247 at 10.

²⁶⁹ J. Wendt & J. Izquierdo, *La Práctica del acceso a los Recursos Genéticos y de los Derechos* de Obtenciones Vegetales en América Latina, first draft, the FAO, regional office in Latin America and the Carribean, Santiago, Chile, 13 December 2000, online:

<http://rlc.fao.org/prior/recnat/pdf.biogen.pdf> (last accessed 10 August 2002). ²⁷⁰ *Ibid*.

In general terms, Latin American countries, especially those who have tropical and subtropical ecosystems within their territories, have shown a rapid interest in developing policies and legal frameworks to regulate access to genetic resources. The Andean Community Common System on Access to Genetic Resources is an illustration of such access legislations.

In 1996, the Andean Group countries²⁷¹ (Bolivia, Colombia, Ecuador, Peru and Venezuela) adopted the "Common System on Access to Genetic Resources"²⁷². The Andean Community Decision 391, establishing the "Common System on Access to Genetic Resources" was the culmination of a two-year process to integrate an access and benefit-sharing system, which establishes minimum common regulations on access to and sharing benefits from genetic resources in the Andean Community.

In conformity with the CBD, the Decision proclaims that Member States have sovereignty rights over the use and exploitation of their genetic resources and the right to determine conditions of access.²⁷³ However, the Andean Community has gone further than the CBD by extending sovereignty rights to the intangible component of these resources. Article 3 establishes the scope of the Decision, which applies to genetic resources for which the Member States are the countries of origin, their by-products²⁷⁴,

²⁷³ *Ibid*. Article 5.

²⁷¹ Formally known as the Cartagena Accord and previously commonly referred to as the Andean Pact.

Pact. ²⁷² Cartagena Agreement, Decision No. 391, Common Regime on Access to Genetic Resources, (July 2, 1996), online: http://www.comunidadandina.org/ingles/treaties/dec/d391e.htm> (last accessed 10 August 2002) [hereinafter Andean Decision]. The Andean Group consists of Bolivia, Colombia, Ecuador, Peru and Venezuela. ²⁷³ Itial Action 5

²⁷⁴ "By-products" is defined in Article 1 as "[a] molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings." *Ibid.*

and their intangible components²⁷⁵, as well as to the genetic resources of migratory species found for natural reasons in the territory of the Member States. By including intangible components, the Decision goes beyond the CBD, which regulates access only to genetic resources as tangible property.

The Decision states in its Supplementary Provisions that the Member States shall not recognize any rights, including patent rights, over genetic resources, by-products, synthesized products or related intangible components obtained or developed through an access activity that does not comply with the provisions of this Decision. Moreover, the affected Member State may request the nullification of patents and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.²⁷⁶ Patents granted abroad could be difficult to challenge since the decision can only be enforced among the Andean Community and has no legal effect outside the Andean Community's Member States.

The following discussion examines the requirement on patent applicants to disclose the country of origin as the requirement adopted by the Bonn Guidelines, the Andean Community Decision, and by other access regulations. It focuses on the compatibility of the requirement to disclose the country of origin with the rules of the CBD and TRIPS.

²⁷⁵ The "Intangible component" refers to "[a]II know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its byproducts or the biological resource that contains them, whether or not protected by intellectual property regimes." *Ibid.* Article 1. ²⁷⁶ *Ibid.* Complementary provisions.

The CBD gives Parties the right to make access to genetic resources subject to the obtaining of prior informed consent from the country of origin.²⁷⁷ The requirement to obtain prior informed consent will usually be spelled out in the conservation legislation. Ultimately, through such a measure, the country of origin can ensure the use of genetic resources happens under its supervision, and can detect the commercial gains from the use of genetic resources and share benefits. However, there is no requirement that patent applications disclose the country of origin. In no part of Article 15 does the CBD adopt such a requirement. Requiring users of genetic resources to obtain prior informed consent cannot be interpreted as giving the right to countries to deny a patent based on non-compliance with the requirement of prior informed consent. Similarly, the use of legislative or administrative measures to ensure the sharing of benefits cannot be interpreted as giving countries the right to refuse the granting of a patent if the application does not disclose the country of origin.

Practical and legal problems arise when interpreting Article 15 to require the disclosure of the country of origin. This measure is not practically feasible, and legally, it both goes beyond the scope of the CBD and is incompatible with TRIPS.

The measure of the disclosure of country of origin is not practically feasible. Several problems might arise in adopting this measure. For example, how will it be possible to determine the true country of origin in the case of a dispute between the State where genetic resources have been collected, and the actual country of origin of the same genetic resources, or when the inventor does not know the origin of genetic resources?

²⁷⁷ The CBD, *supra* note 6, Article 15(5).

What sort of recourse will a country of origin have if the genetic materials have been smuggled out of the country? How can a country establish that it is the actual holder of rights over such resources? What happens where the country of origin is unknown? The CBD does not give solutions to such problems.²⁷⁸ Given the uncertainties in the questions of "origin" of genetic materials, the use of the patent system to enforce such conditions would likely inhibit both the beneficial use of such resources and any sharing of benefits. Therefore, such a requirement might constrain the requirement of Article 15 of the CBD to facilitate access. Additionally, there is no dispute settlement mechanism to which Parties can resort in case of any dispute, which seems to be a likely possibility, if the requirement to disclosure the country of origin is interpreted as being incorporated in the CBD.²⁷⁹ Therefore, the CBD does not seem to go into the direction of requiring disclosure of country of origin.

Legally, the requirement to disclose the country of origin goes beyond the scope of the CBD, and is incompatible with TRIPS. The proposed requirement of disclosure goes beyond the scope of the CBD for the following reasons. The provisions pertaining to the obtaining of prior informed consent of the country of origin is a logical extension of the accepted idea that the countries of origin of genetic resources hold rights over such resources as tangible property within the country's jurisdiction. However, States would be exceeding the rights the CBD grants them if they were to refuse a patent to an

²⁷⁸ Article 27 of the CBD deals with dispute settlement. Any dispute arising has to be settled within this provision. This provision emphasizes on negotiations, mediations, conciliations and good offices as main procedures to settle disputes. At any time, a State may declare in writing to the Depositary that for a dispute not resolved with the above means, it accepts Arbitration or the submission of the dispute to the International Court of Justice or both means of dispute settlement as compulsory. *Supra* note 6; see Generally *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources, supra* note 181 at 118-119.

applicant who failed to indicate the country of origin of genetic resources used. By doing so, they seek not only to control tangible genetic resources but also the information they contain. As discussed in chapter 2, the CBD abolished the principle of "common heritage of mankind" in genetic resources as tangible property by giving Parties property rights in their genetic resources. Thus, exercising property rights over genetic resources such as controlling access and requiring prior informed consent should target such resources as tangible property. However, the intangible property in genetic resources remains "public goods" whose use is non-rivalrous and non-exclusionary. Thus, property rights do not extend to intangible property. Accordingly, the control of access and the requirement of prior informed consent do not extend to intangible property. Any act to the contrary exceeds the scope of the CBD. Thus, I consider the requirement of disclosure interprets Article 15 in a divergent manner. It deviates from the concept of obtaining prior informed consent to add a novel requirement to disclose the country of origin for the patenting of biotechnological inventions. As a result, the requirement predictably alters the rights the CBD originally grants to the Parties.

As for the Bonn Guidelines, they are merely designed to serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefitsharing,²⁸⁰ and "[n]othing in these Guidelines shall be construed as changing the rights and obligations of Parties under the Convention on Biological Diversity."²⁸¹ The Guidelines state in Article 8 that the term "genetic resources" is used as defined in Article

²⁸⁰ The Bonn Guidelines, *supra* note 254, Article 1.

²⁸¹ *Ibid.* Article 2.

2 of the CBD²⁸². However, the Guidelines adopt the requirement of the disclosure of country of origin, entitling the country of origin to refuse a patent application that does not comply with such a requirement. As a result, the Guidelines go beyond the meaning of "genetic resources" as understood by the CBD. Thus, the requirement to disclose the country of origin goes beyond the rights conferred to Parties in the CBD, and therefore, it alters the rights of Parties under the CBD.

Apart from going beyond the scope of the CBD, the requirement to disclose the country of origin violates TRIPS in two ways. The first is a formal violation. It includes patent laws in implementing environmental measures that are out of the scope of such laws. The second violation is a substantive one. The very requirement of disclosure violates the provisions of TRIPS.

The first aspect of violation is the formal violation that relates to the invalidation of a patent, which does not indicate the country of origin or provide evidence of the prior informed consent of the country of origin. In no case should the failure to disclose the country of origin render a patent invalid or prevent its issue, since this requires existing patent laws to accommodate concepts traditionally outside of the scope of patents. The aim of the disclosure of the country of origin is to ensure compliance with prior informed consent before accessing genetic resources. Since the requirement to obtain prior informed consent is a procedure that precedes the inventive activity, compliance with such procedure shall be assured through access regulations. Adding the requirement to

²⁸² Article 2 of the CBD states:

[&]quot;Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

[&]quot;Genetic resources" means genetic material of actual or potential value. Supra note 6.

disclose the country of origin, which is a formal or procedural burden, does not pertain to the substance of patent laws. Patent laws are concerned only with the steps taken on after the acquisition of genetic resources. Moreover, the imposition of such a requirement into the complex patent system is necessarily beyond the international commitments incorporated in the CBD. Article 22 of the CBD asserts that the provisions of the CBD shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement.²⁸³

Additionally, "requiring additional disclosure would increase the costs of research because of the record keeping required, thereby reducing research and increasing the costs of products".²⁸⁴ The introduction of such conditions to patent applications would be burdensome since it requires monitoring applications from patent offices around the world to make sure they comply with the requirement of disclosure. Moreover, such practices will increase the complexity and cost of obtaining patents; thus, it may encourage users, where possible, to protect their rights through trade secrets rather than patents, resulting in no information available to the public about the invention.²⁸⁵

If the patent applicant does not obtain the prior informed consent from the country of origin or does not indicate the country of origin, this should make him accountable for the

²⁸³ Article 22 states:

The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. The CBD, *supra* note 6.

²⁸⁴ WTO, Committee on Trade and Environment, *Report to the Meeting Held on 24 November* 1997, *Note by the Secretariat,* WTO Doc. WT/CTE/M/16 (1997) 19, online:

<http://www.docsonlinewto.org/gen_search.asp> (last accessed 22 July 2002) [hereinafter Report to the Meeting Held on 24 November 1997].

²⁸⁵ This was expressed in another document. See WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *Review of the Provisions of Article 17.3(b), Communication from the United States*, WTO Doc. IP/C/W/162 (1999) 7, online:

<http://www.docsonlinewto.org/gen_search.asp> (last accessed 22 July 2002).

infringement of the national laws implementing the mentioned provisions (the conservation or access legislation), and not patent laws.

The United States underlined this point in a comment during a meeting of the Committee on Trade and Environment.²⁸⁶ The United States argued that patent laws should not be involved in regulating access to genetic resources. Instead, national legislation governing private or public property, conservation laws, and private agreements are the proper means of regulating access to genetic resources, and of establishing conditions under which access would be granted.²⁸⁷

Interestingly, in July 1997, during the first reading of the European Commission Directive on the legal protection of biotechnological inventions²⁸⁸, the European Parliament adopted an amendment through introducing a new Article, Article 8a, to the Directive.²⁸⁹ The amendment proposed that biotechnological patents would only be granted if the geographical place of origin of the material on which it is based was listed with a proof that it had been removed in accordance with the laws and regulations of the country of origin, or if the application was accompanied by evidence that the material would be used with the fully-informed consent of the country of origin.²⁹⁰ Of all the amendments proposed by the European Parliament, this is the only amendment that the European Commission did not accept. The Commission rejected the proposal because it goes beyond the requirements of the CBD, violates TRIPS, and does not comply with

²⁸⁶ Report to the Meeting Held on 24 November 1997, supra note 284.

²⁸⁷ Ibid. at 89-92.

²⁸⁸ Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions, [1998] O.J.L. 213/13.

 ²⁸⁹ See E.R. Gold & A Gallochat, "The European Biotech Directive: Past as Prologue" (2001) Vol. 7 No. 3 European L. J. 331 at 342.
 ²⁹⁰ *Ibid*.

European rules on personal privacy.²⁹¹ The Council also rejected the proposal because it was viewed as being "unworkable"292. However, the Council agreed to include a nonenforceable Recital to the same effect.²⁹³

The second aspect of violation is the substantive violation of the requirement to disclose the country of origin to two provisions of TRIPS. The relevant provisions of TRIPS in this context are Articles 27(1) on patentable subject matter²⁹⁴ and 29 on conditions on patent applicants²⁹⁵.

In examining the patentability criteria in Article 27(1), it is clear that the requirement to disclose the country of origin does not relate directly to the act of inventing. The method of obtaining genetic resources utilized in the invention is irrelevant to the patentability of the invention. Therefore, even if genetic resources were illegally obtained, this would not give rise to the refusal of a patent because it does not meet the patentability conditions. This is similar to the situation where an invention is made using a stolen microscope. This act gives rise to criminal and civil liability under the competent laws where the

²⁹¹ Ibid.

²⁹² Ibid.

Article 29 reads:

²⁹³ *Ibid.* at 347. Recital 17 states that: "[w]hereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted

patents." ²⁹⁴ Article 27(1) of TRIPS reads: "[s]ubject to the provisions of paragraphs2 and 3, 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". Supra note 5.

^{1. [}m]embers shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

^{2.} Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants." TRIPS, supra note 5.

stolen subject matter was located, but not under Article 27(1) of TRIPS, under which the patentability is independent from the previous acts, and dependent only on meeting the three conditions of patentability. In this manner, it is clear that no conditions shall be admitted for patentability other than the three substantive conditions indicated in Article 27(1). Since the requirement of disclosure is not a substantive requirement of patentability as novelty, non-obviousness and industrial application, the requirement of disclosure is an "accessory, which relates to the invention collaterally".²⁹⁶

The requirement to disclose the country of origin also violates Article 29, which deals with the disclosure conditions of the invention. According to this Article, the inventor is required to disclose the manner and process of making and using the invention sufficiently and clearly that a person skilled in the art could carry it. Some patent laws further require the disclosure of the "best mode contemplated by the inventor of carrying out his invention."²⁹⁷ This Article does not encompass the disclosure of the country of origin, since the person skilled in the art does not need to know the country of origin in order to carry out the invention. Hence, TRIPS does not require the disclosure of the country of the country of origin within the wording of Article 29.²⁹⁸

 ²⁹⁶ N.P. de Carvalho, "Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution" (2000) 2 Washington University Journal of Law and Policy 371 at 378.
 ²⁹⁷ See Urbanski, *supra* note 74 at 148.

²⁹⁸ de Carvalho, *supra* note 296 at 380-381. The author indicates "sometimes the source of the material may be relevant, even though it may not be of essence. In that case the information may even constitute a trade secret. For instance, a natural extract obtained in some particular geographical area may be more effective than a similar extract obtained somewhere else."

Concisely, the disclosure of the country of origin is a requirement inconsistent with TRIPS. The disclosure of the country of origin is relevant to the commercial exploitation,²⁹⁹ and cannot be interpreted as being part of the substantive conditions of Article 27(1) and 29.

This section has shown how Article 15 of the CBD, which deals with access to genetic resources, is an ambiguous provision. Therefore, its interpretation and accordingly its implementation should take into account the broader image of the CBD. The misinterpretation of Article 15 could lead to the granting of the CBD rights to Parties not originally granted to them. This runs counter to the CBD's objectives, including the appropriate access to genetic resources, the sustainable use of such resources, and the fair and equitable sharing of benefits arising out of utilization of genetic resources. Correspondingly, the misinterpretation of Article 15 of the CBD unavoidably violates the obligations of Member Countries under TRIPS, and wipes out the rights of inventors under this Agreement. This might lead to the reduction of incentives to engage in research and development of new technologies using this natural genetic capital.³⁰⁰

3.3 Benefit-Sharing and Technology Transfer

Property rights in genetic resources manifested in national sovereignty, access and benefit-sharing provisions are part of a global treaty requiring its Parties to fulfill the

²⁹⁹ Ibid. at 381.

³⁰⁰ See discussion in subsection 2.2.1.

objectives of conserving biodiversity, using its components sustainably, and sharing fairly and equitably the benefits arising from the use of genetic resources.³⁰¹ There are several indications that the access system may well achieve these objectives. However, such a system is unlikely to achieve these objectives without clarifying the ambiguity found in the access provision of the CBD, or without ensuring that the legal regimes for access and benefit-sharing are not incompatible with the patent standards adopted by TRIPS.

The relationship between the CBD and TRIPS does exist. Both Agreements are likely to influence the future exploitation of genetic resources to the benefit of the source countries as well as of co-operating and exploiting industries.³⁰² For that reason, an interrelated implementation of the two Agreements is a necessity. Both the CBD and TRIPS allow a significant degree of flexibility in national implementation. This suggests that there is potential for complementary and perhaps synergistic implementation.³⁰³

In implementing the benefit-sharing, TRIPS does not refer to sharing benefits arising from the commercialization of inventions using genetic resources between the inventor and the country of origin. However, there is nothing is in TRIPS that appears to prevent the development of legislative, administrative or policy measures aimed at sharing benefits between the inventor and the countries of origin providing genetic material, as prescribed in Article 15(7), provided that such measures do not violate the TRIPS

³⁰¹ The CBD, *supra* note 6, Article 1.

³⁰² Technology Transfer and Genetic Resources, *supra* note 154 at 17.

³⁰³ The Convention on Biological Diversity and the Agreement on Trade-Related Intellectual Property Rights, supra note 262 at 10.

minimum standards.³⁰⁴ There is also nothing in TRIPS that stands in the way of contractual arrangements aiming at sharing benefits between countries and companies who seek to use genetic resources from these countries.³⁰⁵ Similarly, country of origin can agree to carry out joint research of genetic resources through its institutions with users of such resources. This would likely be consistent with both the standards of TRIPS and the CBD,³⁰⁶ the latter of which encourages Parties to "endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties, with the full participation of and where possible in, such Contracting Parties."307 This could lead to a joint ownership of inventions developed, in which parties to the arrangement could equitably share the results of research and development as part of the benefits shared.³⁰⁸ Such practices could be defined under TRIPS-compatible intellectual property rights systems.309

It is worthy here to distinguish between genetic resources and communal knowledge regarding such resources. Article 8(j) deals separately with sharing benefits arising from the use of the innovations and practices of indigenous people.³¹⁰

Each Contracting Party shall as far as possible and as appropriate:

³⁰⁴ WTO. Committee on Trade and Environment, *Environment and TRIPS, supra* note 123, para. 78. ³⁰⁵ Ibid.

³⁰⁶ The Convention on Biological Diversity and the Agreement on Trade-Related Intellectual Property Rights, supra note 262 at 10. ³⁰⁷ The CBD, supra note 6, Article 15(6). However, this Article is loosely drafted, therefore, there

is no firm obligation on Contracting Parties to engage in such joint scientific research. ³⁰⁸ The CBD, *supra* note 6, Article 15(7).

³⁰⁹ The Convention on Biological Diversity and The Agreement on Trade-Related Intellectual *Property Rights, supra* note 262 at 10. ³¹⁰ Article 8(j) of the CBD reads:

⁽j) Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices. Supra note 6.

There are, however, certain concerns regarding benefit-sharing practices that are incompatible with the objectives of facilitating access and sharing benefits. These practices are aimed at the restriction of the ability to maintain exclusive patent protection over inventions that utilize genetic resources.³¹¹ One such example involves making access to genetic resources conditional on the seeker's agreeing to relinquish some or all patent rights over the products derived from genetic resources.

Other concerns that need to be addressed are those over patent protection in the context of access to and transfer of technology in the CBD. The CBD adopts access to and transfer of technology, as one means of achieving its objectives, through cooperative efforts among Parties. Article 16 encourages Parties to take "appropriate" measures to ensure access to and transfer of technology. In the case of a patented technology, access to and transfer of technology shall be provided on mutually agreed terms that recognize and are consistent with adequate protection of patent rights.³¹² Since mutuality is a precondition for an agreement, this may be a guarantee against unilateral expropriation.³¹³ Thus, access is feasible only if the requirements of patent owners are respected.³¹⁴ Some consider Article 16 inadequate for the protection of patent rights because it provides for the involuntary transfer of technology. Although this issue is still contested and is subject to different interpretations, I emphasize in the following discussion on the voluntary nature of access to and transfer of technology under Article 16.

³¹¹ Conference of the Parties to the Convention on Biological Diversity, *Access to Genetic Resource: Note by the Secretariat*, UNEP, 3rd Meeting, UNEP/CBD/COP/3/20 (1996) 14, online: http://biodiv.org/doc/meetings/cop/cop-03/official/cop-03-20-en.pdf> (last accessed 10 August 2002).

³¹² The CBD, *supra* note 6, Article 16(2).

³¹³ Macmillan, *supra* note 128 at 120.

³¹⁴ Sustainable Use of Genetic Resources, supra note 29 at 138.

According to J. Chen, the operative verbs regarding "access to and transfer of technology" are joined by the disjunctive "and/or", and one of those verbs is "facilitate".³¹⁵ This language imposes a duty to facilitate access and transfer and renders voluntary any obligation to transfer technology under Article 16.³¹⁶ Moreover, Article 15, which deals with access to genetic resources and Article 16, which deals with access to and transfer of technology are similarly phrased. Article 15 urges Parties to facilitate access to genetic resources, while Article 16 demands the facilitation of access to and transfer of technology. Any reading of Article 16 to require the involuntary transfer of technology would lead to an equally aggressive interpretation of Article 15 compelling nations to provide access to their genetic resources.317 Other Commentators similarly conclude that the CBD merely encourages, but does not mandate access to and transfer of technology.³¹⁸ In clarifying Article 16, M.D. Coughlin, Jr. identifies three kinds of technology.³¹⁹ First, technology that has a direct application to the conservation measures sought by the CBD.³²⁰ Second, technology necessary to biotechnological research generally, but which does not entail the revelation of how to identify and produce a

³¹⁵ See Chen, *supra* note 46 at 4.

³¹⁵ *Ibid.* at 16.

³¹⁶ *Ibid.* at 4.

³¹⁶ Ibid. at 16.

³¹⁷ *Ibid.* at 20.

³¹⁸ C.D. Hardy, "Patent Protection and Raw Materials: The Convention on Biological Diversity and its Implications for U.S. Policy on the Development and Commercialization of Biotechnology" (1994) 15 U. Pa. J. Int'l Bus. L. 299 at 321. ³¹⁹ M.D. Coughlin, Jr., "Using the Merck-INBio Agreement to clarify the Convention on Biological

Diversity" (1993) 31 Colum. J. Transnat'l L. 337 at 358-359.

³²⁰ According to Coughlin, [t]his would include, for example, scientific understanding of ecology and biology, economic theories which elucidate the pressures on the environment, techniques for surveying ecosystems, classifying organisms, and monitoring their disappearance, techniques for preventing soil erosion and leaching of vital nutrients, replanting and other forest management techniques, pollution control strategies, and devices which clean water, air, and soil. Ibid. at 358-359.

specific biotechnological invention.³²¹ Third, technology that enables others to imitate existing biotechnological inventions.³²² The CBD does not seem to distinguish clearly between these three kinds of technology in its provisions on technology transfer. Rather, it uses the term "technology" too broadly.³²³

Coughlin contends that the transfer of the first two kinds of technology is consistent with the text of Article 16. However, the provision does not necessarily extend to the third kind of technology.³²⁴ Article 16(1) deals with technology that is relevant to the conservation and sustainable use of biodiversity or the use of genetic resources without causing significant damage to the environment.³²⁵ Article 16(3) mentions only technology that makes use of those genetic resources.³²⁶ Both the first and second kind of technology is "relevant to the conservation and sustainable use of biological diversity". The second kind is also, strictly speaking, one that "makes use of" genetic resources, in that countries provided with such technology would have the capacity to conduct the same type of biotechnological research as biotechnology companies in developed countries.³²⁷

The reference to patents protection in paragraph 2, 3 and 5 does not undermine this conclusion; there are certainly technologies within the first two kinds that enjoy such protection.³²⁸ While technology of the third kind fits the definitions of technology mentioned in paragraph 1 and 3, nothing in Article 16 requires the transfer of "all" or

³²¹ This would include genetic engineering laboratory techniques, tests for screening samples of genetic material for potentially useful characteristics, and laboratory equipment itself. *Ibid.* at 359. ³²² Components of this type of technology might include information as to the specific source of the genetic material, the specific genetic engineering procedures for purifying it or synthesizing it in large quantities, and, if it has to be altered chemically to be effective, the genetic and chemical information needed to achieve that goal. Ibid.

³²³ *Ibid.* at 360.

³²⁴ Ibid.

³²⁵ Ibid.

³²⁶ Ibid.

³²⁷ Ibid.

³²⁸ Ibid.

"any" technology within those definitions.³²⁹ Thus, technology for the manufacture of a particular biotechnological invention, as opposed to research generally, may properly be excluded from transfer under Article 16.³³⁰ The meaning given to "technology" in Article 2 does not defeat this interpretation.³³¹ "Technology" is stated here to include "biotechnology", which is "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.³³² While this definition does bring within the meaning of "technology" all product-specific biotechnology, it does not alter the fact that Article 16 does not expressly include "any" or "all" technology that otherwise fits these various definitions.³³³

Article 16(5) addresses patents' implicit impediments to access to and transfer of technology.³³⁴ "[R]ecognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention", Article 16 encourages Parties "to ensure that such rights are supportive of and do not run counter to its objectives." The mandate that Parties shall cooperate to ensure that patent rights are supportive and do not run counter to the objectives of the CBD is a contested provision. Thus, this Article is a highly *interpretative issue*.³³⁵ Some argue that it mandates compulsory licensing, and thus

³²⁹ Ibid.

- ³³⁰ Ibid.
- ³³¹ *Ibid*.

335 Ibid.

³³² The CBD, *supra* note 6, Article 2.

³³³ Coughlin, Jr., *supra* note 319 at 361.

³³⁴ Sustainable Use of Genetic Resources, supra note 29 at 173.

it might raise TRIPS issues if owners of proprietary technology were compelled to license technology on grounds other than those prescribed in TRIPS.³³⁶

Others argue that since the CBD is silent about compulsory licensing, this cannot be construed to mandate compulsory licensing, and this Article can be regarded as a diplomatic boilerplate.³³⁷ I tend to support the second position. Compulsory licensing is dealt with in Article 31 of TRIPS. According to this Article, countries are allowed to bypass onerous requests by patent holders by using the subject matter of a patent without the authorization of a right holder, if the law of a Member Country allows for such use.³³⁸ However, this must be preceded by efforts to obtain authorization from the rights holder on reasonable commercial terms and conditions.³³⁹ The Article confines the scope and duration of such use, as well as the purpose for which it was authorized. Article 31(h) entitles the patent holder to adequate remuneration based on the value lost through compulsory licensing. It is obvious in some cases that some developing countries will be seeking or relying on compulsory licensing to access patented invention using genetic resources.³⁴⁰ However, it seems to be unlikely that this can happen under the rigorous system of compulsory licensing under TRIPS.³⁴¹

In retrospect, the CBD does contemplate the appropriate access to and transfer of relevant technology, but only to the extent that access and transfer take into account all rights over the resources and the technology in question. However, rules for technology transfer in

³³⁶ The Convention on Biological Diversity and the Agreement on Trade-Related Intellectual Property Rights, supra note 262 at 10.

³³⁷ See Chen, *supra* note 46 at 20; also see Macmillan, *supra* note 128 at 42.

³³⁸ TRIPS, *supra* note 5, Article 31.

³³⁹ Ibid. Article 31(b)8

³⁴⁰ Macmillan, *supra* note 129 at 31.

³⁴¹ Ibid.

the CBD are very general and the current tendency is to try to precisely determine what are the contents of these rules. Accordingly, some countries issued interpretative statements of the contested language to guide the actual implementation of Article 16 on access to and transfer of technology.³⁴²

From the above, it appears that there are still obstacles to overcome in implementing the provisions of the CBD with regard to access and benefit-sharing. The main obstacle that can be identified is the lack of legislation providing for access to genetic resources while effectively protecting patent rights. In this case, contractual arrangements appear to be a convenient way for access and benefit-sharing to take place. Biotechnology institutions, which no longer oppose sharing benefits with developing countries, are mostly depending on the use of contractual arrangements to achieve such partnership.³⁴³ This is because a mutually bargained arrangement need not involve any reduction of protection offered by international patent regimes. The assertion of patent rights, in conjunction with contractual arrangements, can effectively control the exploitation of genetic resources.³⁴⁴ Therefore, while meeting the mandates of the CBD, its implications seem consistent with TRIPS.³⁴⁵ The contractual arrangements between institutions in developing countries and corporations or other institutions from developed countries should be an important focus

³⁴² See Institutional Mechanisms Supporting Trade in Genetic Materials, supra note 14 at 22. The US refused to sign the CBD in response to an interpretation that impaired intellectual property rights. However, the US position changed, because of the increasing number of biotechnology companies that feared the continuing opposition to the CBD would prevent them from the opportunities to develop genetic resources in developing countries. Thus, President Clinton signed the CBD in 1993, waiting to be ratified by the Senate, with an interpretative statement. Chen, *supra* note 46 at 19 ³⁴³ Hardy, *supra* note 318 at 322.

³⁴⁴ I. Walden, "intellectual Property Rights and Biodiversity" in Bowman & Redgwell, *supra* note 15, 171 at 184.

³⁴⁵ See Sharma, *supra* note 44 at 30-31.

for the evaluation of the access and benefit-sharing policies because they seem to provide the main vehicle through which access to genetic resources and transfer of benefits are to be effected.

More time is required, however, to judge whether legislation providing for access will likely improve or restrict access to genetic resources. This is because there are simply too few attempts to create such legislation to evaluate their impact.³⁴⁶ It should be taken into account that fair and equitable sharing of benefits that arise from the commercialization of genetic resources coupled with adequate patent protection for biotechnological inventions can play an active role in the promotion of bio-trade.³⁴⁷ Benefit-sharing is also expected to create incentives for the conservation of genetic material in the form of financial benefits for park systems, projects and government departments involved in the conservation of biodiversity.348

There are indications that patent protection encourages technology transfer and foreign direct investment in sectors like biotechnology where research and development costs are high and products are easily copied. In such a sector, biotechnology companies are reluctant to transfer technology to countries with inadequate patent protection, especially if the possibility of encouraging competitors exists.³⁴⁹ In such a sector, potential

 ³⁴⁶ See Watal, supra note 11 at 174.
 ³⁴⁷ The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use, supra note 222 at 10; also see Sustainable Use of Genetic Resources, supra note 29 at 11.

³⁴⁸ Kate & Laird, *supra* note 26 at 323.

³⁴⁹ Sustainable Use of Genetic Resources, supra note 29 at 163.

technology suppliers are more willing to transfer technology voluntarily if the host country has an effective patent regime in place.³⁵⁰

In summary, gene-rich countries can share significant amount of benefits through the adoption of access legislation. The main issue here is how to design an access system that both protects genetic resources efficiently by preventing uncompensated use and sustains interest in access to such resources by respecting patent rights. Flexible regimes that allow for partnerships and collaborative efforts are thus urgently needed.

³⁵⁰ The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use, supra note 222 at 16.

4 Conclusion

In this thesis, the main issue has been to create a well-defined approach to the characterization of sovereignty rights and patent rights. I first approached this issue by identifying two separate concepts: patent rights in biotechnology in the context of TRIPS, and State's property rights in the context of the CBD. I defined the framework in which sovereignty rights over genetic resources are to be exercised. Sovereignty rights under the CBD grant property rights to States over their genetic resources. In this sense, there is no formal conflict between the two concepts.

Secondly, I turned to the implementation of sovereignty rights. I identified the right of States to determine access to their genetic resources, as a result of the recognition of States' sovereignty rights over such resources. I recognized, after reviewing the access and benefit-sharing provision, that the CBD emphasizes national implementation. This compels States to exercise their rights to control access to genetic resources with transparency and to facilitate such access by developing a uniform policy on access to genetic resources. This is achieved by creating legislation providing for access to genetic resources and administrative procedures that establish clear jurisdictional and administrative competencies and efficient access procedures.

The main goal of this thesis has been to resolve the conflict between patent rights in TRIPS and property rights in the CBD. I advanced an interpretation of property rights in the CBD that may resolve this conflict. The interpretation is based on the distinction between property rights over the physical material containing the expressed genetic information, the area of tangible property rights, and legal protection over the use of the information represented within the genetic material, the area of intangible intellectual property rights. This thesis interprets State property rights over genetic resources in the CBD as rights over tangible material in genetic resources. Such a scheme would be based on controlling access to genetic materials and the assertion of property rights with respect to its collection and use.

The interpretation suggested in this thesis promotes a better and consistent understanding of the CBD. It also offers a realistic approach in avoiding conflict between TRIPS and the CBD and in securing legal certainty in co-implementing both Agreements. Legal certainty in access to genetic resources leads to more investments by biotechnology industry in the exploitation of genetic resources, and thus, the promotion of conservation efforts.

States are now recognizing genetic resources within their jurisdictions as property, and thus, are subject to legal rights of exclusive control. The control of access to genetic resources through property rights enables economic returns to be achieved and promotes conservation and utilization of genetic resources. Parties should capture these options by bolstering their cooperative efforts toward facilitating the flow of genetic resources and disseminating related technology. As a counterbalance to this tendency, assertion that intangible information remains available in the public domain not subject to any control has to be underscored. Conversely, inhibiting access to information may lead to unwanted impediments to desired gene and technology flow.
The matter of property rights in genetic resources, however, remains to be controversial, particularly to the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. This thesis demonstrated an opposing view of that of the Bonn Guidelines. I argued that the Bonn Guidelines go beyond the mandate of the CBD for certain measures such as requiring patent applicant to disclose the country of origin of genetic resources. Such measures also violate Member Countries' obligations under TRIPS. Therefore, there is a need for the revising of the Bonn Guidelines by the Conference of the Parties.

Wisdom begins with the recognition of the limits of property rights over genetic resources. Parties should allow the unrestricted access to intangible genetic property and abolish measures that control access to such property. Most prominently, Parties should allow the unrestricted use of genetic information in biotechnological inventions.

We have to acknowledge that no country can be self-sustained as regards genetic resources. Thus, instead of overstating sovereignty over genetic resources, global interdependence imposes an obligation of conserving and sustainably using genetic resources to meet the food, health and other needs of growing world population, "for which purpose access to and sharing of both genetic resources and technologies are essential."³⁵¹

³⁵¹ The CBD, *supra* note 6, the preamble.

Extracts from the Convention on Biological Diversity

[...]

Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 2. Use of Terms

For the purposes of this Convention:

"*Biological diversity*" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

"*Biological resources*" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

"*Biotechnology*" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"Country of origin of genetic resources" means the country which possesses those genetic resources in *in-situ* conditions.

"Country providing genetic resources" means the country supplying genetic resources collected from *in-situ* sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.

"*Domesticated or cultivated species*" means species in which the evolutionary process has been influenced by humans to meet their needs.

"*Ecosystem*" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

"*Ex-situ conservation*" means the conservation of components of biological diversity outside their natural habitats.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"Genetic resources" means genetic material of actual or potential value.

"*Habitat*" means the place or type of site where an organism or population naturally occurs.

"*In-situ conditions*" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"*In-situ conservation*" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"*Protected area*" means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives.

"*Regional economic integration organization*" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Convention and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it.

"Sustainable use" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

"Technology" includes biotechnology.

Article 3. Principle

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

[...]

Article 15. Access to Genetic Resources

- 1. 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.
- 2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
- 3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
- 4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
- 5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
- 6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
- 7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention,

undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

- 2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.
- 3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.
- 4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.
- 5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Extracts from the Agreement on Trade-Related Aspects of Intellectual Property Rights Annex 1C

[...]

Article 7 Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8 Principles

- 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
- 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

[...]

SECTION 5: PATENTS

Article 27 Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, 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.³⁵² Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

- 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
- 3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28 Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing6 for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing³⁵³ for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

³⁵² For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

³⁵³ This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Article 29 Conditions on Patent Applicants

- 1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
- 2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30 Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31 Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use³⁵⁴ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

³⁵⁴ Other use" refers to use other than that allowed under Article 30.

- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public noncommercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
 - i. where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply: the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - ii. the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
 - iii. the use authorized in respect of the first patent shall be nonassignable except with the assignment of the second patent.

Extracts from the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization

I. GENERAL PROVISIONS

A. Key features

- 1. These Guidelines may serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions under Articles 8(j), 10 (c), 15, 16 and 19; and contracts and other arrangements under mutually agreed terms for access and benefit-sharing.
- 2. Nothing in these Guidelines shall be construed as changing the rights and obligations of Parties under the Convention on Biological Diversity.
- 3. Nothing in these Guidelines is intended to substitute for relevant national legislation.
- 4. Nothing in these Guidelines should be interpreted to affect the sovereign rights of States over their natural resources;
- 5. Nothing in these Guidelines, including the use of terms such as "provider", "user", and "stakeholder", should be interpreted to assign any rights over genetic resources beyond those provided in accordance with the Convention;
- 6. Nothing in these Guidelines should be interpreted as affecting the rights and obligations relating to genetic resources arising out of the mutually agreed terms under which the resources were obtained from the country of origin.
- 7. The present Guidelines are voluntary and were prepared with a view to ensuring their:
 - a. Voluntary nature: they are intended to guide both users and providers of genetic resources on a voluntary basis;

[...]

B. Use of terms

8. The terms as defined in Article 2 of the Convention shall apply to these Guidelines. These include: biological diversity, biological resources, biotechnology, country of origin of genetic resources, country providing genetic resources, *ex situ* conservation, in situ conservation, genetic material, genetic resources, and in situ conditions.

C. Scope

9. All genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity and benefits arising from the commercial and other utilization of such resources should be covered by the guidelines, with the exclusion of human genetic resources.

[...]

II. ROLES AND RESPONSIBILITIES IN ACCESS AND BENEFIT-SHARING PURSUANT TO ARTICLE 15 OF THE CONVENTION ON BIOLOGICAL DIVERSITY

[...]

[...]

C. Responsibilities

- d. Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, *inter alia*, the following measures:
 - i. Mechanisms to provide information to potential users on their obligations regarding access to genetic resources;
 - ii. Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights;
 - iii. Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources;
 - iv. Cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements;
 - v. Voluntary certification schemes for institutions abiding by rules on access and benefit-sharing;
 - vi. Measures discouraging unfair trade practices;
 - vii. Other measures that encourage users to comply with provisions under subparagraph 16 (b) above.

Extracts from the Andean Community Decision 391 Establishing the Common Regime on Access to Genetic Resources

TITLE I ON THE DEFINITIONS

Article 1.- The following definitions shall apply for purposes of this Decision:

ACCESS: the obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things.

[...]

BIOLOGICAL RESOURCES: individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its by-products.

[...]

BY-PRODUCT: a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings.

[...]

GENETIC DIVERSITY: variation of genes and genotypes between and within species. Sum total of the genetic information contained in biological organisms.

GENETIC EROSION: the loss of or decrease in genetic diversity.

GENETIC RESOURCES: all biological material that contains genetic information of value or of real or potential use.

[...]

INTANGIBLE COMPONENT: all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes.

[...]

SYNTHESIZED PRODUCT: a substance obtained through the artificial processing of genetic information or of information from other biological molecules. Includes semiprocessed extracts and substances obtained by converting a by-product through an artificial process (hemisynthesis).

[...]

TITLE III ON THE SCOPE

Article 3.- This Decision is applicable to genetic resources for which is the Member Countries are the countries of origin, to their by-products, to their intangible components and to the genetic resources of the migratory species that for natural reasons are found in the territories of the Member Countries.

[...]

TITLE IV ON THE PRINCIPLES

CHAPTER I ON THE SOVEREIGNY OVER GENETIC RESOURCES AND THEIR BY-PRODUCTS

Article 5.- The Member Countries exercise sovereignty over their genetic resources and their by-products and consequently determine the conditions for access to them, pursuant to the provisions of this Decision.

The conservation and sustainable use of the genetic resources and their by-products are regulated by each Member Country in keeping with the principles and provisions of the Biological Diversity Agreement and of this Decision.

Article 6.- The genetic resources and their by-products which originated in the Member Countries are goods belonging to or the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation.

Those resources are inalienable, not subject to prescription and not subject to seizure or similar measures, without detriment to the property regimes applicable to the biological resources that contain those genetic resources, the land on which they are located or the associated intangible component.

[...]

COMPLEMENTARY PROVISIONS

[...]

SECOND.- The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.

Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.

THIRD.- The Competent National Offices on Intellectual Property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries.

The Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.

Schedules of the Members of the WTO and the Parties to the CBD

(Status as on the 1st of January 2002) Members of the WTO= 144 countries Parties to the CBD= 182 countries

Countries	Members of the WTO	Parties to the CBD
Albania	X	X
Algeria		X
Angola	X	X
Antigua and Barbuda	X	X
Argentina	X	X
Armenia		X
Australia	X	X
Austria	X	X
Azerbaijan		X
Bahamas		X
Bahrain	X	X
Bangladesh	X	X
Barbados	X	X
Belarus		X
Belgium	X	X
Belize	X	X
Benin	X	X
Bhutan		X
Bolivia	X	X
Botswana	X	Х
Brazil	X	X
Brunei Darussalam	X	
Bulgaria	X	<u> </u>
Burkina Faso	X	X
Burundi	X	X
Cambodia		X
Cameron	Х	X
Canada	Х	Х
Cape Verde		<u>X</u>
Central African Republic	X	<u> </u>
Chad	X	X

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Chile	X	X
China	X	X
Colombia	X	X
Comoros		X
Congo	X	X
Cook Islands	tana tana tana tana tana tana tana tana	X
Costa Rica	X	X
Cote D'Ivoire	X	X
Croatia	X	X
Cuba	X	X
Cyprus	Х	X
Czech Republic	X	X
Democratic Republic of the	X	X
Congo		
Denmark	X	X
Djibouti	X	X
Dominica	X	X
Dominican Republic	X	X
Ecuador	X	X
Egypt	X	X
El Salvador	X	X
Equatorial Guinea	· · · · · · · · · · · · · · · · · · ·	X
Eritrea	· · · · · · · · · · · · · · · · · · ·	X
Estonia	X	X
Ethiopia		X
European Communities	X	X
Fiji	X	X
Finland	X	X
France	X	X
Gabon	X	X
The Gambia	X	X
Georgia	X	X
Germany	X	X
Ghana	X	X
Greece	X	X
Grenada	X	X
Guatemala	X	X
Guinea	X	X
Guinea- Bissau	X	X
Guyana	X	X
Haiti	X	X
Honduras	X	X
Hong Kong, China	X	Х
Hungary	X	X

Iceland	X	X
India	X	X
Indonesia	X	X
Iran	······································	X
Ireland	X	X
Israel	X	X
Italy	X	X
Jamaica	X	X
Japan	X	X
Jordan	X	X
Kazakhstan		X
Kenya	X	X
Korea, Republic of	X	X
Kiribati		X
Kuwait	X	
The Kyrgyz Republic	X	X
Lao's People Democratic	· · · · · · · · · · · · · · · · · · ·	X
Republic		
Latvia	X	X
Lebanon		X
Lesotho	X	X
Liberia		X
Libyan Arab Jamahiriya		X
Liechtenstein	X	X
Lithuania	X	X
Luxembourg	X	Х
Macao, China	X	X
Madagascar	X	X
Malawi	X	X
Malaysia	X	X
Maldives	X	X
Mali	X	X
Malta	X	X
Marshall Islands	······	X
Mauritania	X	X
Mauritius	X	X
Mexico	X	X
Micronesia	n an	X
Moldova, Republic of	X	X
Monaco		X
Mongolia	X	X
Morocco	X	X
Mozambique	X	X
Myanmar	X	X

Namibia	X	X
Nauru		X
Nepal		X
Netherlands	X	X
New Zealand	X	X
Nicaragua	X	X
Niger	X	X
Nigeria	X	X
Niue		X
Norway	X	X
Oman	X	X
Pakistan	X	X
Palau		X
Panama	X	X
Papua New Guinea	X	X
Paraguay	X	X
Peru	X	X
Philippines	X	X
Poland	Х	X
Portugal	X	X
Oatar	X	X
Romania	Х	X
Russian Federation		Х
Rwanda	X	X
Saint Kitts and Nevis	X	X
Saint Lucia	X	X
Saint Vincent and the	X	X
Grenadines		
Samoa		X
San Marino		X
Sao Tome and Principe		X
Saudi Arabia		X
Senegal	X	X
Separate Customs Territory	X	
of Taiwan, Penghu, Kinmen		
and Matsu		
Seychelles		X
Sierra Leone	X	X
Singapore	X	X
Slovak Republic	X	X
Slovenia	X	X
Solomon Islands	X	X
Somalia		X
South Africa	X	X

Spain	X	X
Sri Lanka	X	X
Sudan		X
Suriname	X	X
Swaziland	X	X
Sweden	X	X
Switzerland	X	X
Syrian Arab Republic		X
Tajikistan		X
Tanzania	X	X
Thailand	X	
Togo	X	X
Tonga		X
Trinidad and Tobago	X	X
Tunisia	X	X
Turkey	X	X
Turkmenistan		X
Uganda	X	X
Ukraine		X
United Arab Emirates	X	X
United Kingdom	X	X
United States	X	
Uruguay	X	X
Uzbekistan		X
Vanuatu		X
Venezuela	X	X
Viet Nam		Х
Yemen		X
Zambia	X	X
Zimbabwe	X	X

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