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Jonathan Curci

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THE NEW CHALLENGES TO THE INTERNATIONAL
PATENTABILITY OF BIOTECHNOLOGY:
LEGAL RELATIONS BETWEEN THE WTO TREATY ON
TRADE-RELATED ASPECTS OF INTELLECTUAL
PROPERTY RIGHTS AND THE CONVENTION ON
BIOLOGICAL DIVERSITY

*Jonathan Curci**

I. INTRODUCTION

The patentability of biotechnology took off after the United States Supreme Court's landmark decision in *Diamond v. Chakrabarty*.¹ By acknowledging that statutorily patentable subject matter included "anything under the sun that is made by man," the Court encompassed both foreseeable and unforeseeable subject matter. This *Diamond* standard encompassed the inventive work of biotechnology and gene sequences. Consequently, an "imitation effect" rippled from the U.S. to Europe and other jurisdictions, generating a series of legislative measures to patent living forms. In addition, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights² (TRIPS) internationalized biotechnological practices and enabled genetic engineering to yield important breakthroughs in the new millennium.

Breakthroughs in genetic modification have facilitated the development of thousands of novel organisms, deepening the controversy of patenting such subject matter. The myriad biotechnological applications³ released into the environment for

* Lecturer, LL.M. Intellectual Property Program, World Intellectual Property Organization and University of Torino Law School, Italy; Ph.D. Candidate in International Law, Graduate Institute of International Studies, Geneva, Switzerland; LL.M. Candidate, J. Reuben Clark Law School, Brigham Young University.

¹ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

³ Biotechnology involves techniques for using the properties of living things to market products and services. These techniques include selecting natural strains of

pharmaceutical, agricultural, and medicinal purposes generate transnational concerns that pose an enormous challenge to national and international communities. In particular, developing countries denounce the patentability of biotechnology, which reduces the world's genetic resources down to mere property rights, resulting in corporate control over access to food, medicinal technology, and other resources essential to mankind's health and welfare. Moreover, patents on living forms raise also an economic concern since a significant difference exists between the economic impact caused by a monopoly right on inanimate subject matter and the economic impact caused by animate, or living, subject matter:

[W]hile inanimate matter (which may be subject to patent protection), usually does not self-replicate (e.g., car brakes are not known to give life to subsequent generations of car brakes), the same principle does not hold true in the case of living matter, which on the contrary, tends to self-replicate.⁴

Additionally, potential transnational harm caused by genetic engineering may also arise through the destabilization of regional ecologies via genetic pollution and through an accelerated decline of biological diversity on a global scale. Thus, legal control over biodiversity is an issue of serious international consequence.

This article analyzes the existing treaties that guide interaction between corporations from industrialized states and indigenous communities. Additionally, this article will predominantly focus on the benefit sharing problems that arise between States and private industries when intellectual property rights (IPRs) are

organisms that carry desirable traits; making hybrids by fusing cells from different parental sources; using chemicals and radiation to create mutant strains; or genetically engineering plants, animals, and microorganisms to produce specific phenotypic characteristics. *See generally* Convention on the Grant of European Patents of 5 October 1973, entry into force Oct. 7, 1977, available at <http://www.european-patent-office.org/legal/epc/e/ma1.html>.

⁴ M. RICOLFI, *Intellectual Property and Biodiversity: A Review of Legal and Conceptual Issues and of Policy Options*, in *ATTI DEL SEMINARIO* 13–15 (2003). For a more thorough account of the protections recommended by the International Union for the Protection of New Varieties of Plants, see G. GHIDINI & S. HASSAN, *BIOTECNOLOGIE, NOVITÀ VEGETALI E BREVETTI* (Giuffrè, Milano 1990).

exercised over genetic resources.⁵ Major industrialized countries, realizing the potential gains flowing from new technologies driven by private industries, promote the integration of stronger IPRs in multilateral and bilateral treaties that ultimately conflict with interests of developing countries. Most developing countries join as parties to these treaties despite the benefit sharing problems arising from the international exploitation of genetic resources. At the same time, however, developing countries accuse industrialized states of watering down the patentability requirements of biotechnology within their own national jurisdictions, effectively accommodating corporate interests without precise and careful consideration of the intrinsically complex and multifaceted issues or the consequences involved.

Various international institutions, such as the World Intellectual Property Organization (WIPO), the Food and Agriculture Organization (FAO), the United Nations Educational, Scientific and Cultural Organization (UNESCO), and the International Labor Organization (ILO), are becoming increasingly involved with the production of guidelines and treaties on the matter. Currently, at least two multilateral treaties regulate the transnational behaviors in this field: the United Nations Convention on Biological Diversity (CBD) and TRIPS.

⁵ A vivid example of benefit sharing illustrates this area of concern. Imagine a plant, which produces a natural sweetener, preserved for several millennia in the interstices of a local farming micro-culture. This sweetener performs its sweetening function without dietary or health shortcomings. A bio-prospecting corporation secures samples of the local sweetening genetic resources, maps its genome, and then proceeds to genetically engineer a plant that yields sweetener with a ten-fold potency over the original. The corporation then patents the modified plant and the world quickly forgets the original plant as the patented plant is markedly more productive. Consequently, through commercialization, all of the profits flow to the company patent holder without a farthing to the indigenous farmers who preserved the plant for millennia. Some 6.5% of all genetic research undertaken in agriculture focuses on germ plasma derived by wild species and land races (farmer-developed varieties of crop plants that are adapted to local environmental conditions). Thus, the question is posed: Is it fair to entitle the entire pastry to the one who adds the final cherry to a pie? Marco Ricolfi, *Biotechnology, Patents and Epistemic Approaches*, J. BIOLAW & BUS., SPEC. SUPP., 77-90, (2002). See also THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM; COMMENTARY AND MATERIALS 1820, 1827 (F. Abbott, Thomas Cottier & F. Gurry eds., Kluwer Law Int. 1999); Thomas Cottier, *The Protection of GRs and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law*, 1 J. INT'L ECON. L. 555 (1998) (U.K.); Michael Blakeney, Presentation at the WIPO-Torino Law School Specialization Course in Intellectual Property, *Intellectual Property Aspects of Traditional Agricultural Knowledge*, 2, (Nov. 22, 2001).

These two treaties operate in manner that has generated much conflict and uncertainty. Indeed, portions of TRIPS clash with the concepts and principles provided by the CBD. Granting IPRs to modified, unauthorized appropriations of plant and animal genetic resources frustrates provider countries trying to implement the concepts and principles provided by the CBD of control over their genetic resources. The CBD is far more favorable to conservation of biodiversity and preservation of rights for developing countries while TRIPS is far more aggressive about facilitating biological patentability and promoting private ownership and exploitation of such resources. Nevertheless, the two aims are not necessarily mutually exclusive.

Accordingly, this article formulates interpretative suggestions to reconcile TRIPS and the CBD in a mutually supportive manner that increases the confidence of genetic resource provider countries through increased transparency in the intellectual property (IP) system. The following section discusses the scope and utility of Article 27 of TRIPS, explaining the major issues that arise in its interpretation. The next section outlines the legal debate on the articulation and compatibility of TRIPS and the CBD. The subsequent section then lays out an overview of the TRIPS Council solutions to amend the highly disputed Article 27.3(b) in a manner more compatible with the CBD's transparency measures and its derivative law.

This article concludes with a brief discussion on the diplomatic problems arising from the identification of the best possible treaty within the international patent system where the reconciliation between TRIPS and CBD provisions.

II. THE SCOPE AND UTILITY OF ARTICLE 27 OF TRIPS

Article 27 of TRIPS provides that, subject to certain conditions, patents in all fields of technology shall be available for any invention. TRIPS is the first globally adopted treaty to make the patenting of life legal by requiring WTO Member States to provide patent protection for all fields of technology. Paragraphs 2 and 3 of Article 27 outline the inventions Member States may exclude from patent protection under specified conditions.

Article 27 of TRIPS states:

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. 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 microorganisms, 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.

This patent availability requirement has a few notable exceptions. First—particularly supported by the European States—is the exclusion of inventions from patentability where it is

necessary to “protect *ordre public* . . . including . . . human, animal or plant life . . . to avoid serious prejudice to the environment.” As stated above in paragraph 3(b), members are also not required to grant patents on plants or animals. The prohibition of patents on plant and animal varieties contained in the European Patent Convention strongly influenced this phrasing.⁶ However, in the absence of international jurisprudence, the interpretation of this provision remains subject to domestic patent laws and other judicial bodies. Thus, while providing some exceptions, TRIPS allows Member States to provide patents or a *sui generis* system of protection over living organisms.

Furthermore, Article 27 contains contentious provisions that underpin the new multilateral trade system. A literal interpretation of this provision identifies four possible options of implementation: (i) Member States can allow patents on any invention in biotechnology by not excluding plants, animals, and biological processes; (ii) Member States may exclude from patentability plants, animals, and biological processes, but not exclude new plant varieties; (iii) Member States may choose not to patent new plant varieties (i.e., to exclude new plant varieties from patentability and introduce a *sui generis* system, an IPR protection of its own kind supported by the International Union for the Protection of New Varieties of Plants (UPOV) for the protection of plant varieties); (iv) or Member States can also choose the U.S.-like solution of a double protection system of not excluding new plant varieties from patentability and simultaneously enjoying *sui generis*–UPOV protection. It therefore appears that TRIPS obliges Member States to provide some kind of IPR protection on almost all life forms.

⁶ See also Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT’L L.J. 47 (2001). See generally the Convention on the Grant of European Patents, EPO O.J. 6 (1977), for examples of provisions in the European Patent Office similar to those in the TRIPS and for a discussion on the complexity of the interpretation of patent provisions relating to genetically engineered plants and animals.

The table below illustrates the patentability subject matter of Article 27.3(b):⁷

WTO members must provide protection for:	WTO members may exclude from patent protection:
Microorganisms	Plants
Non-biological processes	Animals
Microbiological processes	Essentially biological processes for the production of plants or animals
Plant varieties* (by an IPR system that may be patents, a <i>sui generis</i> alternative, or a combination thereof)	Plant varieties*

* Plant varieties are defined and protected through the 1991 Act of the International Convention for the Protection of New Varieties of Plants if the plant variety is novel, distinct from other varieties of the same species, and uniform and stable when grown or propagated. Unlike the requirements to receive a patent, the conditions of protection depend on the distinctness (from senior varieties), uniformity (within the same generation), and stability (across generations) of the genome of the variety obtained through breeding. The right differs from that of a patent since it is weaker in its exclusive limitations.

Although TRIPS allows countries to exclude life forms such as plants and animals from patentability, a closer look at Article 27.3(b) reveals that all countries must provide patent protection on microorganisms, non-biological, and microbiological processes.⁸ A distinct disconnect exists between the patentable subject matter in Article 27.3(b) and life forms that may be excluded from patent protection because the former has no commonly accepted definition in international patent law. Even the patent systems that have a

⁷ See Graham Dutfield, *Sharing the Benefits of Biodiversity: Is There a Role for the Patent System?*, 5 J. WORLD INTELL. PROP. 899 (2002).

⁸ A microorganism is an organism that can be seen only under a microscope, usually, an ordinary light microscope. They are typically of the order of microns (millionths of a meter) or tens of microns in linear dimensions, and include bacteria, micro-plasm, yeasts, single-celled algae, and protozoa. Multicellular organisms are normally not included, nor fungi apart from yeasts. Viruses are also not automatically included; many scientists do not classify them as organisms as they depend on cells to multiply. See Kimball Nill, *Glossary of Biotechnology Terms*, <http://biotech.terms.org/sourcebook/index.phtml>.

rather well established tradition of patenting biotechnological inventions (U.S., Europe, and Japan) differ in their interpretation of the patentability of such subject matter. Depending on a patent system's definition, a system may consider a plant cell a microorganism even though it can grow into an entire tree. A patent on such a cell⁹ could extend to trees even if one cannot patent a plant variety. Notably even in scientific practice, the term "microorganism" is inherently flawed since scientific classification continually evolves.¹⁰

Consequently, the language of this provision opens it to wide interpretation. Most developing countries are not sure how TRIPS distinguishes plants, animals, and microorganisms that require patents; they also question why essentially biological processes¹¹ do not require patents while microbiological¹² and non-biological processes do. After all, a microbiological process is essentially a biological process. Indeed, microbiological processes merely utilize an engineered gene¹³ to modify a biological product. Moreover,

⁹ A cell line is a supposedly genetically uniform population of cells derived from one individual, or possibly a clone (theoretically genetically identical descendants) of one original cell. The genetic identity of all the cells is a fiction, as the genetic material is subject to many 'fluid genome' processes that constantly make cells genetically different from one another. A genome is the totality of all the genetic material (deoxyribonucleic acid or DNA) in an organism that organizes in a precise way, though by no means fixed or constant. In the case of viruses, most of them will have ribonucleic acid or RNA as the genetic material. See Nill, *supra* note 8.

¹⁰ For the debate occurring in Europe on the patentable subject matter, see Mike Adcock & Margaret Llewelyn, *Microorganisms, Definition and Options under TRIPS*, Occasional Paper 2 (Nov. 23, 2000) (discussing the reluctance of the European Patent Office (EPO) to introduce a fixed definition because "it does not seem expedient to introduce such a definition as the rapid evolution in the field of microbiology would necessitate its frequent updating").

¹¹ An "essentially biological process" is a scientifically suspect term. Does it mean a process that occurs naturally or one carried out by organisms? Similarly, a "non-biological process" is difficult to define because all processes in biotechnology, by definition, are biological. Some argue that it describes a process that does not occur naturally or not normally carried out by organisms. See Nill, *supra* note 8.

¹² Microbiology is the science dealing with the structure, classification, physiology, and distribution of microorganisms, and with their technical and medical significance. See *id.* Thus, a "micro-biological process" is presumably a process carried out by microorganisms.

¹³ A gene is a stretch of genetic material (DNA or RNA) with a defined function in the organism or cell. It usually codes for a protein. A genome contains many genes. For example, the human genome contains approximately 100,000 genes. A DNA sequence refers to the sequence of bases in a stretch of DNA, a linear molecule consisting of units strung together. There are four different units, each identified by the specific base contained, and four different bases, represented by the letters, A, T, C,

more often than not, the resulting product is new, involves an inventive step, and is capable of industrial application.¹⁴ It is therefore a patentable invention under Article 27. Thus, even though microbiological processes utilize genes, the foundation for all life, Article 27 only excludes “plants and animals other than microorganisms,” and genes are not whole organisms. Rather, they are microorganisms.¹⁵ Nevertheless, States may either argue that genes are not microorganisms since they are unicellular organisms capable of propagation or they may invoke *ordre public* or morality exceptions to deny IPRs. One can only wonder whether TRIPS justifies such a denial when, for example, a company uses a gene to create a vitamin-enriched food product and the State holds no scientific basis for regarding the gene or the food product as harmful to human health or the environment.

Evidently, TRIPS resulted from a painstaking negotiation on a wide number of IP issues. It cannot provide precise guidance but it certainly influences the attitude of certain States towards transnational biotechnology corporations.

III. THE IMPACT OF THE TRIPS AGREEMENT ON THE CBD OBLIGATIONS

This section discusses some of the alleged fundamental legal and political conflicts arising from the implementation of TRIPS Article 27 in light of the obligations that States have with regard to the CBD.

A. Principles of the CBD

The Rio de Janeiro Convention on Biological Diversity (CBD) aims to set up an international framework for the preservation and utilization of the world’s biological resources. The CBD is the result of prolonged, international pressure to respond to the destruction of, and unequal profits from, the biodiversity of the southern hemisphere. After years of debate, the United Nations

and G. An example of a DNA sequence is ATTTCCGCTACGCGTTA. An RNA sequence is similar, except that the letter “U” replaces the letter T. *See id.*

¹⁴ TRIPS, *supra* note 2, art. 27(1).

¹⁵ DAN LESKIEN & MICHAEL FLITNER, INTELLECTUAL PROPERTY RIGHTS AND PLANT GENETIC RESOURCES: OPTIONS FOR A *SUI GENERIS* SYSTEM 18–22 (Int’l Plant Genetic Resources Inst., Issues in Genetic Resources No. 6, 1997).

agreed upon the CBD in 1992.¹⁶ It came into force in 1993, and today 188 States have ratified it.¹⁷

There exists a well-established principle of international law: That States have a sovereign right over their territory, including the natural resources contained therein. Before the CBD codified this principle, most States affirmed it in their constitutions,¹⁸ typically stating that the State owns all “flora and fauna” and that all other natural resources, with the exception of agricultural lands, shall not be alienated. If States allow IPRs over flora or fauna, this may result in a form of alienation because IPRs by their nature are exclusive monopoly rights that prevent others from producing the patented flora or fauna. Before the CBD’s adoption, many questioned whether biological resources were under a regime of the “heritage of mankind,” or whether States’ lacked the ability to exercise sovereignty over biological resources and subject genetic resources to private property rights.¹⁹ The shift to the ideas purported by the CBD came from an increasing commercial interest in biological and genetic resources and a desire to subject such resources to private property claims, namely intellectual property. Much of the movement came in the form of plant breeders’ rights and patents, which give their owners an exclusive right to control any commercial use of these resources.²⁰

Amidst the global pressure to privatize biological resources, the CBD stands as an important watershed in international efforts to promote biodiversity conservation. For instance, the Convention binds signatories to a number of basic principles regarding how, by

¹⁶ Convention on Biological Diversity (Rio de Janeiro), June 5, 1992, pmbl., 31 I.L.M. 822 (1992), available at <http://www.biodiv.org/doc/legal/cbd-un-en.pdf>.

¹⁷ *Id.*

¹⁸ See, e.g., 1987 CONSTITUTION OF THE REPUBLIC OF THE PHILIPPINES art. XII, § 2 (“all lands of the public domain, waters, minerals, coal, petroleum, and other mineral oils, all forces of potential energy, fisheries, forests or timber, wildlife, flora and fauna, and other natural resources are owned by the State.”); see also CONSTITUCIÓN DE LA REPÚBLICA BOLIVARIANA DE VENEZUELA art. 124 (prohibiting the registration of patents over genetic resources).

¹⁹ Christopher Joyner, *Legal Implications of the Concept of the Common Heritage of Mankind*, 35 INT’L & COMP. L.Q. 190 (1986).

²⁰ See Barbara Laine Kagedan, *The Biodiversity Convention, Intellectual Property Rights, and Ownership of Genetic Resources: International Developments*, prepared for Industry Canada, Intellectual Property Policy Directorate (Jan. 1996); WALTER V. REID ET AL., *A New Lease on Life, in BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT* 1–52 (1993).

whom, and for whose benefit biodiversity must be conserved.²¹ Article 1 of the CBD states its overall objectives. These objectives include first, the “conservation of biological diversity;” second, the sustainable use of biological diversity components; and finally, the “fair and equitable sharing of the benefits arising out of the utilization of genetic resources.”²² CBD recognizes the sovereign rights of States over their biological resources in Articles 3 through 15.²³ Article 3 recognizes that, “States have . . . the sovereign right to exploit their own resources,” including, under Article 2, biological and genetic resources of actual or potential value.²⁴ Article 8(j) requires Contracting States to:

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 the benefits arising from the utilization of such knowledge, innovations and practices* (emphasis added).²⁵

Article 15 specifically discusses the details of regulating access to genetic resources through increased transparency in patent application. The first paragraph gives States sovereign rights over their resources and confers on them the “authority to determine access to [their] genetic resources.”²⁶ Paragraph 4 allows access to genetic resources, subject to “mutually agreed terms,” while paragraph 5 specifies that the same access “shall be subject to prior informed consent [PIC] of the Contracting Party providing such

²¹ For an in-depth study of the preparatory works of the CBD see Fiona McConnell, *BIODIVERSITY CONVENTION—A NEGOTIATING HISTORY: A PERSONAL ACCOUNT OF NEGOTIATING THE UNITED NATIONS CONVENTION ON BIOLOGICAL DIVERSITY, AND AFTER* (Aspen Publishers, Inc. 1996).

²² Convention on Biological Diversity, *supra* note 16, at 823.

²³ *Id.* at 824–29.

²⁴ *Id.* at 823–25.

²⁵ *Id.* at 826.

²⁶ *Id.* at 828.

resources.”²⁷ Moreover, Article 15 specifies that the transfer of technology is an invaluable instrument for the effective implementation of the CBD.²⁸

As noted above, Article 15 lists a set of rights conferred on provider States. However, the CBD also provides symmetric obligations on the recipient State. For instance, paragraph 7 of Article 15 provides that each contracting party:

*shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 . . . 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 (emphasis added).*²⁹

This provision establishes access to the biological resources of developing countries on a *quid pro quo* basis with a transfer of technology from the industrialized countries.

Finally, paragraph 5 of Article 16 asserts that IPRs must not conflict with the conservation and sustainable use of biodiversity.³⁰ Therefore, the CBD not only gives rights to provider States, but also regulates the transfer and interaction between provider and recipient States.

It is the task of each State and the international community as a whole to interpret the aforementioned CBD principles in a manner harmonious with Article 27 of TRIPS. After identifying the major areas of tension between the two legal instruments, the following sections intend to set forth guidelines to achieve mutual supportiveness.³¹ The following sections intend to contribute to the achievement of this objective.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.* at 829.

³¹ See Vienna Convention on the Law of Treaties art. 31.3(c), May 23, 1969, 1155 U.N.T.S. 331 for the concept of mutual supportiveness in the interpretation of treaties, according to which a treaty has to be interpreted in light of all the other rules of treaties and general law applicable to the parties. International judicial organs more and more frequently adopt this approach in order to avoid the creation of self-

B. General Considerations on the Legal Relations Between TRIPS and the CBD Obligations

While WTO Member States incorporate TRIPS within their national laws, access to genetic resources—from which genetically engineered products are developed—is becoming one of the most critical areas of debate between industrialized and developing countries.

Many developing countries regard the relationship between TRIPS and the CBD as one of opposing principles. On one side stands the principle of economic growth purported by the TRIPS Agreement. On the other side is the principle of sustainable development served by the CBD. Industrialized countries justify globalizing and harmonizing IPRs because such rights will strengthen the supply of innovation to the market. They argue that economic growth will result from improving dynamic efficiency through stronger IPRs. Pushing markets towards the high “technology fix,” however, stands in stark contrast to the kind of economy advocated by committed environmentalists who believe that States should subject development to environmental costs and implications.

Most of the conflict between TRIPS and the CBD is spurred by moral and rhetorical assumptions. One assumption claims that the patent regime is a Western form of IPR, which is totally unsuitable to the majority of the societies in the South that have accepted TRIPS by acceding to the WTO. Another assumption asserts that private rights are completely alien to indigenous communities because the vast majority of their farmers, who manage biodiversity at the local level, are accustomed to collective rights.

The CBD intends to strengthen developing countries' capacities to conserve and use biological diversity on a long-term basis by reserving all rights over those resources for the developing countries and by including the right to enjoy the benefits of their

contained, international legal systems totally independent from general norms and from each other. See also World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746, 751 (2002) [hereinafter Ministerial Declaration] for the concept of mutual supportiveness that has been particularly useful to reconcile international environmental and trade regimes. According to this concept, all of the applicable rules treat the parties on the same level. This rule of interpretation is important, especially in light of the rapid advancement of international norms both in the field of environment (e.g., CBD) and trade (e.g., TRIPS).

resource base. Southern hemisphere countries feel consistently exploited because of the structural imbalances between countries rich in biological diversity and those strong in technological and legal instrumentation.

Conversely, TRIPS intends to provide private property rights over products and processes whether biodiversity based or not. The pressure of certain non-State actor interests, namely those of multinational companies, has overwhelmingly helped achieve TRIPS' intended results.

While describing these apparent points of conflict, it is important to remember that contracting parties to the CBD have an obligation to cooperate and ensure that IPRs are "supportive of and do not run counter to [the CBD's] objectives."³² Moreover, Article 22 of the CBD states that its provisions will not affect countries' rights and obligations to "any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."³³ This harmonization process is mainly "subject to national legislation and international law" and stands as a basis for countering the runaway march of the IPR regimes.³⁴

When a conflict exists between two treaties dealing with the same subject matter, the applicable rule is *lex posterior derogat lex anterior* (the latter law prevails over the first), which Article 30 of the Vienna Convention on the Law of Treaties enshrines.³⁵ In this case, TRIPS will prevail since it came into force after the CBD. However, if evaluated under *prima facie* evidence and by a *stricto sensu* legal point of view, the subject matter of the CBD and TRIPS basically differ; therefore, States should fully and simultaneously implement both of them. For instance, although both Article 27 of TRIPS and some of the provisions of the CBD deal with the utilization of biological resources, they do so to achieve two different objectives that are not necessarily mutually exclusive.³⁶

Although TRIPS subject matter does not does not suffer from an identity problem *per se*, some provisions regulate the same object and have the same purpose as CBD provisions. In order to

³² Convention on Biological Diversity, *supra* note 16, at 829.

³³ *Id.* at 832.

³⁴ *Id.* at 829.

³⁵ Vienna Convention on the Law of Treaties, *supra* note 31, art. 30.

³⁶ Christina Noiville, *Biodiversité et Propriété Intellectuelle. L'impossible Conciliation?*, in BIODIVERSITE ET APPROPRIATION: LES DROITS DE PROPRIETE EN QUESTION (Elsevier, 2002).

fully apply and universally ratify both treaties, certain provisions contained in both treaties need to come into harmonization. Maljean-Dubois defines the controversial relationship between these two international instruments as an apparent conflict (namely an *emboîtement* or *désarticulation*) rather than an incompatibility; he posits that a relationship of complementarity has yet to develop.³⁷ Such complementarity, however, can be realized through adequate interpretation of all the obligations at stake and further legislative work, harmonizing the two treaties for the benefit of the international community.

In spite of the politically fundamental contradictions that seem to exist between CBD and TRIPS, legally speaking, inconsistencies between IPRs applied to life forms under TRIPS and the obligations of CBD are multifaceted. The inconsistencies particularly reveal themselves in the following fields: the access to and fair and equitable sharing of benefits from the utilization of genetic resources, the respect for traditional knowledge held by the indigenous communities, and the transfer of technology.

1. Further considerations on the impact of TRIPS and the definition of biopiracy

The alleged inconsistencies between TRIPS and the CBD reside at the schematic crossroad between the opposing perspectives of North and South. The debate over IPRs on biological resources and international trade is embedded in a broad context with so many intertwined aspects and competing interests that even choosing the study approach becomes confusing. Furthermore, this complex debate intensifies by classifying the opposition between the North and South as the opposition between the “haves” and the “have-nots.”³⁸ From a more optimistic perspective, one can find a viable solution that could potentially resolve the North-South conflict by acknowledging that while industrialized countries possess advanced technological manufacturing capabilities, developing countries possess the biological diversity lacking in the industrialized countries.

³⁷ Sandrine Maljean-Dubois, *Biodiversité, Biotechnologies, Biosécurité: Le Droit International Désarticulé*, 127(4) J. DU DROIT INT'L 966–67 (2000).

³⁸ Jean-Faustin Badimboli Atibasay, *The International Legal Regime for Biotechnology Patenting: An Appraisal from the Standpoint of Developing Countries*, 31 REVUE GÉNÉRALE DE DROIT 291–325 (2001).

The private property regime established by TRIPS may undermine the implementation of the benefit-sharing provisions of the CBD that require the knowledge or material holder's prior informed consent (PIC) for the use of genetic resources and traditional knowledge.³⁹ TRIPS does not require the transparency of PIC and is therefore inconsistent with the CBD in that regard. Without such a PIC obligation in TRIPS, private entities from countries (generally industrialized ones) that use genetic resources in innovative processes will limit their efforts to seek and exploit benefit sharing with the countries of origin (generally developing ones). According to developing countries, leaving the negotiation of benefit sharing and PIC to contractual freedom (between private entities and provider countries) is unlikely to ensure compliance with CBD obligations.

The aim of TRIPS, to homogenize national IP regimes, may jeopardize a country's freedom to choose the way it wants to deal with the use and protection of biodiversity and the related traditional knowledge. This issue blatantly arises when firms appropriate genes from a State that manipulates and sells the genetically modified product rather than from the State that patents the original product. Following the imposition of IPRs on life forms and related knowledge, communities of developing countries have risen against this kind of "piracy" of indigenous and local community knowledge.⁴⁰

The well-known phenomenon of "bioimperialism"⁴¹ or "biopiracy" defines the way in which industrialized countries "conquer" biological resources illegitimately. Industrialized countries accused developing countries of pursuing "intellectual piracy," and after the adoption of TRIPS, developing countries

³⁹ Convention on Biological Diversity, *supra* note 16.

⁴⁰ See, e.g., Press Release, RAFI, Enola Bean Patent Challenged (Jan. 5, 2001), http://www.etcgroup.org/documents/news_enolabean.pdf (discussing the recent *Enola bean* case involving yellow beans from Mexico, which POD-NERS, Plc patented in the United States (U.S. Patent No. 5,984,479). POD-NERS, Plc used the patent to bring legal suits against two companies that sold the Mexican yellow beans in the U.S., claiming that the beans infringed its patent monopoly).

⁴¹ Ketih Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection*, 6 IND. J. GLOBAL LEGAL STUD. 11 (1998) (discussing questions raised about the emerging globalized vision of IPR protection embedded in multilateral agreements such as TRIPS, outlining how the international political economy of intellectual property protection should be addressed, and constructing and maintaining an intellectual public domain or commons).

accused industrialized countries of “biopiracy.” Developing countries coined this term as part of a counterattack strategy to describe the misappropriation of genetic resources by private entities in the North. These developing countries felt they were hardly as piratical as corporations that acquire resources and traditional knowledge from their countries and use them in their research and development programs by acquiring patents and other IPRs without compensating the provider countries and communities.⁴² However, such anti-biopiracy rhetoric did little to prevent the legalization of this “conquest.” Through TRIPS, the South has an obligation to grant patents, trademarks, and trade secrets without any compensation to the local communities that preserved and bred biological resources.⁴³

For all these reasons, the argument arises that IPRs can prevent countries from realizing the full and practical meaning of the CBD articles regarding national sovereignty over their natural resources and the rights of their local and indigenous communities.⁴⁴ This prevention frustrates the ultimate goal of fairly distributing the benefits arising from the use of genetic resources situated in the contracting parties’ territories.⁴⁵

⁴² See Pat Mooney, *Why We Call It Biopiracy*, RESPONDING TO BIOPROSPECTING: FROM BIODIVERSITY IN THE SOUTH TO MEDICINES IN THE NORTH 37–43 (H. Svarstad & S.S. Dhillon eds., 2000).

⁴³ See Thomas Cottier, *The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law*, 1 J. INT’L ECONOMIC LAW 555 (1998) (stating that all this is done knowing that some 90% of genetic information and traditional knowledge are found in developing countries).

⁴⁴ Convention on Biological Diversity, *supra* note 16, at 825–26. Due to the importance of Article 8(j) and other related provisions, several workshops have been organized to advance their implementation. See, e.g., WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge, Geneva, Switz., Apr., 2001, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders*, 50.

⁴⁵ See Convention on Biological Diversity, *supra* note 16, at 828, 830 (CBD Articles 1, 15.7, and 19.2 present the relevant provisions on benefit sharing relating to the conservation of traditional knowledge and the conservation of biodiversity contained in Articles 8(j) and 10(c)). For some socio-economic consideration, see 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*, 25 LAW AND POLICY INT’L BUS. 695 (1994); S. Prakash, *Towards a Synergy Between Biodiversity and Intellectual Property Rights*, 2 J. OF WORLD INTELL. PROP. 821 (1999).

2. *The impact of TRIPS on the access to genetic resources*

The IPR system construed by TRIPS may affect the genetic resources addressed by the CBD. The TRIPS preamble defines IPRs as private rights. Because these rights are subject to the general WTO principle of national treatment, the implementation of TRIPS Article 27.3(b) will give global jurisdiction to private, individual property rights. Therefore, the global scope of these rights may destabilize the national sovereignty espoused by the CBD, which aims to recognize the inherent rights of indigenous and local communities.⁴⁶ Although Article 15.1 of the CBD recognizes “the sovereign rights of States over their national resources” and the national governments’ ability to determine access to genetic resources, the provision does not refer to the question of the ownership of these resources. The CBD simply submits access to genetic resources to the PIC of the party on mutually agreed terms aimed at sharing the benefits arising from the utilization of such resources.⁴⁷

Not only can firms find genetic resources within the boundaries of States, but also in a number of germplasm and seed banks. The CBD, dealing with “the *ex-situ* conservation of components of biological diversity,”⁴⁸ leaves legal issues on the ownership of biological resources held in trust in gene banks unanswered. Therefore, biopiracy has benefited from a loophole in the legal status of materials held by gene banks like the Consultative Group on International Agricultural Research (CGIAR).⁴⁹ The

⁴⁶ Convention on Biological Diversity, *supra* note 16, at 829. 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.

⁴⁷ See Convention on Biological Diversity, *supra* note 16, at 827–28.

⁴⁸ *Id.* at 826. *Ex situ* means “outside the place,” i.e. “conservation of a plant outside of its original or natural habitat, such as in a gene bank or greenhouse.” CGIAR, Future Harvest Center Glossary, <http://www.futureharvest.org/about/glossary.shtml#e> (last visited Nov. 21, 2005).

⁴⁹ The CGIAR, established in 1971, is an informal association of fifty-seven public and private sector members that supports a network of sixteen international agricultural research centers. For a thorough discussion on the controversies raised by their interaction with IPRs, see Michael Blakeney, *Intellectual Property Rights in the Genetic Resources of International Agricultural Research Institutes—Some Recent Problems*, 1 *BIO-SCI. L. REV.* 3–11 (1998).

International Treaty on Plant Genetic Resources (ITPGRFA)⁵⁰ is progressively trying to close this loophole through the creation of the Multilateral System for plant genetic resources. According to CBD Article 15.3,⁵¹ national authorities should provide for the acquisition, conservation, storage, and management of these *ex situ*⁵² collections.⁵³ Therefore, the CBD does nothing to centralize the governance of genetic material stored in gene banks around the world.

From a legal perspective, there is no conflict between the affirmation of sovereign rights over States' genetic resources recognized in Articles 3 through 15 of the CBD and the recognition of private rights upon the same resources in Article 27 of the TRIPS Agreement. Under TRIPS the same States as those who adopted the CBD have expressly exercised their sovereign rights to commit IP protections to inventions based upon their own genetic resources in accordance with the stated conditions of patentability. Rather, conflicts between the CBD and TRIPS may arise from the conditions of patentability of these resources as discussed in the following paragraphs.

3. The impact of TRIPS on the protection of traditional knowledge

Traditional knowledge is the information on genetic resources that people in a given community have developed over time. This information is based on constantly evolving experiences, adapted to local cultures and environments. The community uses traditional knowledge to sustain its culture and maintain the biological resources necessary for the community's continued survival.

Traditional knowledge includes mental inventories of local biological resources, animal breeds, local plants, crops, and tree species. It may also include such information as which trees and

⁵⁰ The International Treaty on Plant Genetic Resources, *available at* <ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRRe.pdf>

⁵¹ Convention on Biological Diversity, *supra* note 16, at 828 (article 15.3 states, "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").

⁵² *See Id.* at 826.

⁵³ An in-depth analysis of the interaction among the IPRs, the CBD, and the ITPGRFA falls outside the scope of the present article.

plants grow well together and which plants are indicator plants, plants that indicate soil salinity or that flower at the beginning of the rains. It also includes practices and technologies such as seed treatment, storage methods, and tools used for planting and harvesting. Traditional knowledge also encompasses belief systems that play a fundamental role in a peoples' livelihood and in maintaining their health and the environment.⁵⁴

The term "traditional" implies knowledge "based on traditions" and created in a manner that reflects the traditions of the community, rather than old or non-technical knowledge. Traditional knowledge is therefore easily distinguishable from cosmopolitan knowledge, which is drawn from global experience, combining "Western" scientific discoveries, economic preferences, and philosophies with those of other widespread cultures.

"[W]hat is traditional about traditional knowledge is not its antiquity, but the way it is acquired and used. In other words, the social process of learning and sharing knowledge, which is unique to each indigenous culture, lies at the very heart of its 'traditionality.' Much of this knowledge is actually quite new, but it has a social meaning, and legal character, entirely unlike the knowledge indigenous people acquire from settlers and industrialized societies."⁵⁵

Indeed, traditional knowledge does not relate to the nature of the knowledge itself, but to the way in which that knowledge is created, preserved, and disseminated. This implies a blend of knowledge and experience integrated with a coherent world-view

⁵⁴ In recent years, the international community has placed considerable emphasis on traditional knowledge that relates to the environment and the conservation and sustainable use of biodiversity, particularly for the maintenance of world food, medicinal security, and commercial value to the so-called life industries. However, this paper does not restrict traditional knowledge to that concerned only with the environment or biodiversity as there are many categories of traditional knowledge that have application in many different fields of human interest and endeavour.

⁵⁵ R.L. Barsh, *Indigenous Knowledge and Biodiversity, in Indigenous Peoples, Their Environments and Territories, in CULTURAL AND SPIRITUAL VALUES OF BIODIVERSITY 73* (D.A. Posey ed., IT Publications and UNEP 1999), *quoted in GRAHAM DUTFIELD, PROTECTING TRADITIONAL KNOWLEDGE AND FOLKLORE: A REVIEW OF PROGRESS IN DIPLOMACY AND POLICY FORMATION 23* (UNCTAD-ICTSD, June 2003), *available at* http://www.ictsd.org/pubs/ictsd_series/iprs/CS_dutfield.pdf.

and value system. Therefore, traditional knowledge is usually collective in nature and considered the property of the entire community. Because ownership and property rights under the common law are foreign to most traditional, knowledge-based communities, many conclude that traditional knowledge is *res nullius*—the property of nobody until it is discovered by explorers, corporate scientists, governments, and so on. This ignores the fact, however, that customary laws recognize forms of ownership separate from those designated by IP law.⁵⁶ Traditional communities view traditional knowledge ownership as a responsibility rather than as an exclusive property right.

In the TRIPS Agreement, the categories of IPRs customarily recognized do not adequately guarantee the protection of traditional knowledge. Traditional knowledge is a fundamental source for the sustainable management of biological diversity and for the development of new and socially beneficial products through, for instance, long-term selective breeding of food crops or knowledge of medicinal plants.⁵⁷ For this reason, the CBD established the aforementioned Article 8(j) for the preservation of traditional knowledge.

The conservation of biological resources implies enormous responsibilities. TRIPS does not allocate these responsibilities to those who will benefit from ownership rights in these resources. Instead, TRIPS allocates these responsibilities to IPR holders, which only cultivates their monopoly by effectively suspending national or community sovereignty over local genetic resources. Consequently, governments and communities have little means of regulating access or demanding a share of benefits in their own genetic resources in which they no longer own the rights.

The IP protection of the holistic nature of traditional knowledge thus appears fraught with various difficulties, and IP laws will only marginally satisfy the needs and expectations of traditional knowledge holders. Furthermore, because of the anecdotal nature of traditional knowledge, governments attempting to incorporate

⁵⁶ See Carlos M. Correa, *Traditional Knowledge and Intellectual Property: Issues and Options Surrounding the Protection of Traditional Knowledge 3* (Quaker United Nations Office, Discussion Paper, 2001), available at <http://www.quno.org/geneva/pdf/economic/Discussion/Traditional-Knowledge-IP-English.pdf> (citing STEPHEN FISHMAN, *THE PUBLIC DOMAIN: HOW TO FIND AND USE COPYRIGHT-FREE WRITINGS, MUSIC, ART AND MORE 1–3* (Richard Stim & Spencer Sherman eds., Nolo 2000)).

⁵⁷ Graham Dutfield, *The Public and Private Domains: Intellectual Property Rights in Traditional Knowledge*, 21 *SCI. COMM.* 276–78 (2000).

traditional knowledge in their various natural resource management processes generally view it as unreliable. Traditional knowledge is hard to qualify as legitimately protected material because it can be anything that traditional knowledge holders claim.⁵⁸

Although economic interests might not constitute communities' most important or only priority, many communities oppose the integration of their inherent rights over traditional knowledge into a commercial system.

4. *The impact of TRIPS on the transfer of technology*

Whether or not TRIPS will promote the transfer of technology is highly controversial. On the one hand, the rigorous implementation of the CBD provisions on technology transfers can be negatively challenged by the TRIPS regime's ability to hinder the transfer of environmentally sound technology among States or develop environmentally harmful technologies. On the other hand, TRIPS may also create extraordinary incentive for innovation.⁵⁹

An inflexible IP regime without derogations can seriously hinder the environmentally sound technology transfer among States—particularly from industrialized countries to developing ones. Indeed, transfer of appropriate technology is a key tool for achieving the goals fixed in the CBD.⁶⁰ The CBD refers to 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.”⁶¹ The CBD also

⁵⁸ See Albert Howard & Frances Widdowson, *Traditional Knowledge Advocates Weave a Tangled Web*, OPTIONS POLITIQUES, Apr. 1997, at 46–48.

⁵⁹ Daniel Alexander, *Some Themes in Intellectual Property and the Environment*, 2 REV. OF EURO. COMM. AND INT'L ENVIRON. L. 113, n.2 (1993). See also Riccardo Pavoni, *Brevettabilità Genetica e Protezione Della Biodiversità: la Giurisprudenza Dell'Ufficio Europeo dei Brevetti*, 83 RIVISTA DI DIRITTO INTERNAZIONALE, FASCICOLO 429, fasc. 2 at 430–33 (2000).

⁶⁰ On the question of transfer of technology, it is important to note the compatibility between Article 16 of CBD and the fundamental principle of WTO agreements on the Most Favored Nation in Article 3 and 4 of TRIPS. See Richard Tarasofsky, *The Relationship between TRIPS Agreement and the Convention on Biological Diversity: Towards a Pragmatic Approach*, 6 REV. OF EURO. COMM. AND INT'L ENVIRON. L. 148, n.2 at 150 (1997).

⁶¹ Convention on Biological Diversity, *supra* note 16, at 829. CBD art. 7(c) imposes the duty on States to identify “processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity.” *Id.* at 825. Such activities have to be coherently managed. *Id.* at 825–26. See Richard Tarasofsky, *supra* note 60 at 148.

requires parties to transfer technology to developing countries on “fair and most favorable terms,” including concessional and preferential terms to which there is mutual agreement.⁶² This provision means that where a developing country has provided access to genetic resources, that country should have facilitated access to technology that makes use of those resources. This objective needs corresponding national and international IP law, as well as a sound competition policy to ensure that IPRs are supportive of and do not run counter to the CBD’s objectives.⁶³

Another possible negative impact of IPR protection of living matter lies in the development of environmentally harmful technologies. This concern mainly focuses on the technologies essentially based on the modification of plant, animal, and microorganism genomes with the aim to embody a special characteristic. One example is developing herbicide resistance or the predisposition to avoid certain diseases in order to attain a commercial advantage. Regarding transgenic plants and animals, specified environmental risks are particularly harmful to human health. These risks can concretize into irreversible harms for the global ecosystem and for human welfare after their entry into the environment and market. This holds particularly true for technologies that produce “terminator seeds,”⁶⁴ sterile seeds that require the application of a chemical “switch” before performing certain characteristics like flowering. In this context, national and international bodies should more clearly define the patentability exceptions under Article 27.2 of TRIPS as they are the only readily available defenses against the IP inventions threatening biodiversity.

According to this author, although the chapeau of Article 8 uses vague and uncertain expressions like “as far as possible” and “as appropriate,” the two regimes of protection can be reconciled.

⁶² Convention on Biological Diversity, *supra* note 16, at 829.

⁶³ *Id.* On this point, the CBD secretariat has also noted, “Due to the rapid development of technologies, particularly biotechnology, further consideration of the impacts of intellectual property rights on the achievement of the objectives of the Convention, including in facilitating access to and transfer of technology is urgently needed.” Note by the Executive Secretary, *The Relationship between Intellectual Property Rights and the Relevant Provisions of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Convention on Biological Diversity*, ¶ 23, U.N. Doc. UNEP/CBD/ISOC/5 (May 11, 1999).

⁶⁴ GRAHAM DUTFIELD, *INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY* 51–52 (London 2000).

One of the main purposes of both the CBD and ITPGRFA is to encourage the transfer of technology concerning plant genetic resources from biodiversity-recipient to biodiversity-provider countries with the view of helping the conservation and sustainable use of the same resources.⁶⁵ As a result, benefit sharing should not only denote a form of monetary compensation, but also—if not primarily—a form of technology transfer.

Remarkably, TRIPS contains parallel provisions. Article 66(2) provides that “[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.” In turn, Article 67 refers to “technical and financial cooperation in favor of developing and least developed countries.” This technical and financial cooperation includes assistance in preparing and administering laws and regulations for technology transfers. Additionally, the cooperation should help mediate the challenges connecting IP protection and biodiversity.⁶⁶

These provisions are unsurprising because the WTO did not create TRIPS to enhance IP protection but to achieve the aims described in Article 7. The Article 7 purposes include “the promotion of technological innovation and . . . 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.”⁶⁷ The broad goals considered in this provision, as well as in TRIPS Article 8, should receive special weight when considering issues at the intersection of IP and biodiversity.

Whether or not TRIPS implementation will accomplish the promotion of technological innovation to the mutual advantage of developing and industrialized countries remains open to question

⁶⁵ See Convention on Biological Diversity, *supra* note 16, at 827; ITPGRFA arts. 5.1(e), 7.2(b), 8 and 13.2(b).

⁶⁶ For a thoughtful commentary of these two provisions, see N.A. Odman, *Using TRIPS to Make the Innovation Process Work*, 3(3) J. WORLD INTELL. PROP. 343 (2000).

⁶⁷ For a “global constitutional” reading of WTO and TRIPS beyond the narrow “traditional export interests” that may have shaped it, see Ernst-Ulrich Petersmann, *From Negative to Positive Integration in the WTO: The TRIPs Agreement and the WTO Constitution*, 3 INTELL. PROP., COMPETITION AND SUSTAINABLE DEV. 32–35 (Th. Cottier & Mavroidis eds., 2000).

because the granting of patents innately benefits patent holders in industrialized countries. Empirical research on this matter is inconclusive given the complexity of relations between industrialized and developing countries. However, in the field of pharmaceutical technology, which depends on genetic resources, approximately ten corporations hold 36% of the pharmaceutical market, 40% of the seed market, and 82% of the agrochemical market.⁶⁸ In countries that grant overly broad biotechnology patents that cover crop species and other categories, IPR holders may raise prices, impose restrictive licensing conditions, and limit further research, thus undermining their competitors and ultimately hindering the diffusion of technology.⁶⁹ Therefore, the international exercise of patent rights promoted by TRIPS has strongly contributed to the empowerment of industrialized country patent holders over developing countries.

Table 2. Synopsis of the points of conflict between CBD and TRIPS from the developing countries standpoint.⁷⁰

CBD	TRIPS	The Conflict
Nation States have sovereign public rights over their biological resources (<i>Preamble, Article 15.1</i>).	Biological resources should be subject to private IPRs. Compulsory licensing, in the national interest, should be restricted (<i>Article 27, Article 31</i>).	National sovereignty implies that countries have the right to prohibit IPRs on life forms (biological resources). TRIPS requires the provision of IPRs on micro-organisms, non-biological and microbiological processes, as well as patents and/or <i>sui generis</i> protection on plant varieties.

⁶⁸ RAFI, *The Gene Giants: Mastery of the Universe?*, (Mar. 30, 1999), <http://www.etcgroup.org/article.asp?newsid=180>.

⁶⁹ See MICHAEL BLAKENEY, *LEGAL ASPECTS OF THE TRANSFER OF TECHNOLOGY TO DEVELOPING COUNTRIES* (Oxford ESC Publishing 1989).

⁷⁰ This synopsis has been inspired by the one effectuated by GRAIN. For convenience, it has been modified to illustrate the relations between the two conventions.

CBD	TRIPS	The Conflict
<p>The use or exploitation of traditional knowledge, innovations, and practices relevant to the use of biodiversity must give rise to equitably shared benefits (<i>Preamble, Article 18.4, Article 8.j</i>).</p>	<p>States must provide patents for all fields of technology; therefore, IPR must protect the use or exploitation of biological resources. There is no mechanism for sharing benefits between a patent holder in one country and the donor of material in another country where the invention is derived (<i>Article 27.1</i>).</p>	<p>The CBD gives developing countries a legal basis to demand a share of benefits. TRIPS does not mention such legal authority.</p>
<p>Nation States have sovereign public rights over their biological resources (<i>Preamble, Article 15.1</i>).</p>	<p>Biological resources should be subject to private IPRs. Compulsory licensing, in the national interest, should be restricted (<i>Article 27, Article 31</i>).</p>	<p>National sovereignty implies that countries have the right to prohibit IPRs on life forms (biological resources). TRIPS requires the provision of IPRs on micro-organisms, non-biological and microbiological processes, as well as patents and/or <i>sui generis</i> protection on plant varieties.</p>
<p>States should promote the conservation and sustainable use of biodiversity as a common concern of humankind while taking into account all rights over biological resources.</p>	<p>States should safeguard public health and nutrition and public interest in general.</p>	<p>The CBD places the public interest and common good over private property and vested interests. TRIPS grants private rights on the same subject matter.</p>

IV. THE WTO DEBATE ON THE REVISION OF ARTICLE 27.3(b) OF TRIPS FROM DOHA TO HONG KONG

The various arguments of authors, NGO representatives, corporate associations, etc., have largely influenced the positions held by WTO Member States during the revision process of Article 27.3(b) in the TRIPS Council. The revision intends to make TRIPS more compatible with the CBD obligations.

Before the Doha Declaration, there were three major options under discussion in WIPO and the WTO for the revision of Article 27.3(b). The majority position advocated the revision of Article 27.3(b) to exclude life forms altogether from the ambit of TRIPS (option I). A variant to this position argued for allowing full discretion to the States to exclude any life form from patentability (option II). Finally, an intermediate position (option III) supported the *status quo* of the existing text, which became the outcome of the negotiations. By remaining with the *status quo*, patentable subject matter neither strengthens nor extends at the multilateral level. Accordingly, States continue exploit the present textual ambiguities in the implementation process. They also continue to utilize bilateral treaties containing stronger IP standards than TRIPS requires.⁷¹

A. No Patents on Life

The first option reflects the extreme position, which seeks to exclude all life forms from the ambit of the TRIPS Agreement altogether. In particular, the African countries in the WTO proposed amending Article 27.3(b) to clarify that plants, animals, micro-organisms, all other living organisms, and their parts cannot be patented. The prohibition against patenting parts of plants and animals would include protection of genes, gene sequences, cells, seeds, etc., which are an integral part of the particular plant or

⁷¹ Some of these proposals can be found in *Relations Entre les Droits de Propriété Intellectuelle et les Dispositions Pertinentes de l'Accord sur les Aspects des Droits de Propriété Intellectuelle qui Touchent au Commerce et la Convention sur la Diversité Biologique*, UICN/Réunion Intersessions sur le Fonctionnement de la Convention, Montréal, Canada, 28–30 juin 1999, Union Mondiale pour la Nature, available at <http://www.iprsonline.org/resources/biodiversity1994-1999.htm> (last visited Nov. 28, 2005).

animal. A number of other developing countries in the WTO have supported this position.⁷²

B. Full Discretion to Exclude Life Forms from Patentability

The second option stopped short of excluding life forms from the ambit of the TRIPS Agreement. It used the words “may exclude” to denote the discretion of national governments to determine the patenting of life issue. Under this formulation, WTO Member States will retain the right to exclude patentability of plants and animals without the condition of providing protection for microorganisms, microbiological processes, non-biological processes, and plant varieties.⁷³ Advocates for this option believe that TRIPS Article 27 should incorporate the CBD requirements concerning government control over access to genetic resources.⁷⁴ Proponents of this

⁷² Communication from Kenya on Behalf of the African Group, *The TRIPS Agreement*, Aug. 6, 1999, WT/GC/W/302, available at <http://docsonline.wto.org/DDFDocuments/t/WT/GC/W302.DOC> [hereinafter Communication from Kenya]; Communication from Mauritius on Behalf of the African Group, *Review of the Provisions of Article 27.3(b)*, Sept. 20, 2000, IP/C/W/206, available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W206.doc> [hereinafter Communication from Mauritius]. India proposes to exclude patents on all life forms, or at least to exclude patents based on traditional/indigenous knowledge and products and processes essentially derived from such knowledge. There must be disclosure of the biological resource's country of origin and associated knowledge, and proof of the provider's consent in order to ensure equitable benefit sharing. National policy should decide what patentable micro-organisms are in light of Article 27.2 (morality and *ordre public*). Developing countries like India cannot accept any further strengthening of the protection presently provided to life forms. Communication from Sri Lanka on behalf of the SAARC Member States of the WTO, *Joint Statement by the SAARC Commerce Ministers on the Forthcoming Third WTO Ministerial Conference (Seattle)*, Oct. 22, 1999, WT/L/326, available at <http://docsonline.wto.org/DDFDocuments/t/WT/L/326.DOC>.

⁷³ TRIPS, *supra* note 2, art. 27.3(b). It has been suggested that since Article 27.3(b) refers to “plants and animals” and not to any particular class thereof (such as “varieties”, “races” or “species”), this reference should be read to include both naturally occurring plants and animals and parts thereof, as well as those which have been genetically modified (i.e. transgenic).

⁷⁴ The African group proposes that the review of TRIPS Art. 27.3 should clarify that plants, animals, micro-organisms, and their parts and natural processes cannot be patented. TRIPS should contain provisions to promote, not undermine, the conservation and sustainable use of genetic material. Finally, TRIPS should contain provisions to prevent “biopiracy.” Communication from Kenya, *supra* note 72; (Aug. 6, 1999); Communication from Mauritius, *supra* note 72. Southern Africa

measure argued that this would ensure that patent applicants would respect source countries' laws on access, benefit sharing, and facilitate protection of traditional knowledge. This revision would also prevent abusive patenting of traditional knowledge by parties other than the holders of the traditional knowledge. Of course, Member States will not accept this option since it

Development Cooperation (SADC) maintains that the exclusion for essentially biological processes should extend to microbiological processes. Communication from South Africa, *SADC Ministers' Agreed Negotiating Objectives for the Third WTO Ministerial Conference*, Oct. 1, 1999, WT/L/317, available at <http://docsonline.wto.org/DDFDocuments/t/WT/L/317.doc>. Brazil proposes that it should retain the flexibility for members to exclude plants and animals. Article 27.3(b) should be amended to allow members to require further conditions for patentability through (i) identification of source of genetic material, (ii) traditional knowledge used to obtain that material, (iii) evidence of fair and equitable benefit-sharing, and (iv) evidence of PIC for the exploitation of the patent. Article 27.3(b) should bear an interpretative note clarifying that discoveries or naturally occurring materials are not patentable. Communication from Brazil, *Review of Article 27.3(b)*, Nov. 24, 2000, IP/C/W/228, available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W228.doc>. This is also the position of Venezuela, Communication from Venezuela, *Proposals Regarding the TRIPS Agreement (Paragraph 9(a)(ii) of the Geneva Ministerial Declaration)*, Aug. 6, 1999, WT/GC/W/282, available at <http://docsonline.wto.org/DDFDocuments/t/WT/GC/W282.DOC>. Zambia, Jamaica, Kenya, Pakistan, Sri Lanka, Tanzania, Uganda and Zimbabwe, JOB(99)/3169. The Least Developed Countries Group affirms that there should be a formal clarification that naturally-occurring plants and animals, as well as their parts (gene sequences) plus essentially biological processes, are not patentable. The group also advocates the incorporation of a provision that patents must not be granted without PIC of the country of origin. Patents inconsistent with Article 15 of the CBD should not be granted. Communication from Bangladesh, *The Challenge of Integrating LDCs into the Multilateral Trading System*, July 13, 1999, WT/GC/W/251, available at <http://docsonline.wto.org/DDFDocuments/t/WT/GC/W251.DOC>. Cuba, The Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka, and Uganda add that the review should also clarify the artificial distinction between biological and microbiological organisms and processes; ensure the continuation of traditional farming practices, including the right to save and exchange seeds and sell their harvests; and prevent anti-competitive practices that will threaten food sovereignty of people in developing countries. Communication from Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka, and Uganda, *Implementation Issues to be Addressed Before/at Seattle*, Oct. 11, 1999, WT/GC/W/354, available at <http://docsonline.wto.org/DDFDocuments/t/WT/GC/W354.DOC>; Communication from Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka, and Uganda, *Implementation Issues to be Addressed in the First Year of Negotiations*, Oct. 11, 1999, WT/GC/W/355, available at <http://docsonline.wto.org/DDFDocuments/t/WT/GC/W355.DOC>. See also F. Seuret and R. Ali Brac De LaPerreire, *L'Afrique Refuse le Brevetage du Vivant*, 556 LE MONDE DIPLOMATIQUE 24 (2000).

undermines the very *raison d'être* of Article 27.3(b), which is to create a minimum protection for biotechnology patent rights.

C. Maintenance of the Status Quo

European countries,⁷⁵ the United States,⁷⁶ and others⁷⁷ support the *status quo* by relying on the legal grounds that TRIPS and CBD do not deal with the same subject matter. More specifically, CBD objectives concern the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of genetic resource utilization. On the other hand, the TRIPS Agreement aims to set minimum standards of IP protection within the WTO and ensure that its

⁷⁵ Communication from the European Communities, *EC Approach to Trade-Related Aspects of Intellectual Property in the New Round*, June 2, 1999, WT/GC/W/193, available at <http://docsonline.wto.org/DDFDocuments/t/WT/GC/W193.DOC> [hereinafter Communication from the European Communities]; Communication from the European Communities and their Member States, *Review of the Provisions of Article 27.3(b) of the TRIPS Agreement*, June 13, 2001, IP/C/W/254, available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W254.doc>.

⁷⁶ Communication from the United States, *General Council Discussion on Mandated Negotiations and the Built-In Agenda*, Nov. 19, 1998, WT/GC/W/115, available at <http://docsonline.wto.org/DDFDocuments/t/WT/GC/W115.DOC>; Communication from the United States, *Review of the Provisions of Article 27.3(b): Further Views of the United States*, Oct. 3, 2000, IP/C/W/209, available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W209.doc>.

⁷⁷ This is the position of Singapore; TRIPS should not be used to enforce benefit-sharing arrangements or any common approach to benefit sharing. Communication from Japan, *Proposal on Trade-Related Aspects of Intellectual Property*, July 6, 1999, WT/GC/W/242, available at <http://docsonline.wto.org/DDFDocuments/t/WT/GC/W242.DOC>. Norway adds that some consideration should be made as to whether a provision on the disclosure of the origin of genetic resources should be inserted in the TRIPS agreement, thus ensuring a more effective implementation of the CBD. Communication from Norway, *Review of Article 27.3(b) of the TRIPS Agreement: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, June 29, 2001, IP/C/W/293, available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W293.doc>. Switzerland fosters no lowering of protection standards and that the exclusion for plants and animals is a balanced provision that takes into account members' needs and interests. Switzerland also agrees with Singapore that the UPOV system is a useful reference for the basic level of protection of any *sui generis* system for the protection of plant varieties. Nonetheless, Switzerland also agrees that there may be other *sui generis* systems that meet the requirements of Article 27.3(b) besides UPOV and considers the elements listed by the U.S. as helpful in drawing up such systems. Communication from Switzerland, *Review of Article 27.3(b): The View of Switzerland*, June 15, 2001, IP/C/W/284, available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W284.doc>.

Member States make judicial and/or administrative enforcement procedures available to IPR holders.

Although the TRIPS Council maintained the *status quo*, dispute continues to brew regarding the impact of patent legislation on CBD implementation. Many countries argue that IP is only one of the many complicated aspects concerning access to genetic resources and benefit sharing. IPRs aim neither to regulate the access and use of genetic resources nor to set the terms and conditions for bioprospecting and commercialization⁷⁸ of IPR-protected goods and services.⁷⁹ The European Community maintains that patent authorities should only examine whether an invention meets the criteria applicable to that invention.⁸⁰ Alternatively, a majority of countries in the southern hemisphere favor arguments developed in international instruments that support access to genetic resources through benefit sharing and protection of traditional knowledge. Furthermore, they argue that WIPO should act as the negotiation forum to facilitate benefit sharing and protect sovereign access rights. Accordingly, these countries in the southern hemisphere support either a disclosure of origin obligation or extended protection of traditional knowledge.

*D. Bilateral Treaties and the Creation of a “TRIPS Plus” Regime*⁸¹

Notwithstanding the numerous concerns raised by TRIPS, industrialized countries and transnational corporations consider this agreement to be only a minimum standard of protection for IPRs on biological resources; they now seek higher standards through bilateral negotiations. Indeed, an additional minority position to the aforementioned options seeks to include animals and plants among

⁷⁸ Commercialization refers not only to the process of placing products developed from the patented invention on the market, but also to the sale and licensing of patents themselves.

⁷⁹ MARTINE DE KONING, *Biodiversity Prospecting and the Equitable Remuneration of Ethnobiological Knowledge: Reconciling Industry and Indigenous Interests*, in *INTELLECTUAL PROPERTY ASPECTS OF ETHNOBIOLOGY* 23–42 (Michael Blakeley ed., Sweet & Maxwell, 1999).

⁸⁰ See Second Report of the European Community to the Convention on Biological Diversity: Thematic Report on Access and Benefit-Sharing, (Oct. 2002). See generally Communication from the European Communities, *supra* note 76.

⁸¹ For a more in-depth study on this matter, see Peter Drahos, *Bilateralism in Intellectual Property*, http://www.oxfam.org.uk/what_we_do/issues/trade/downloads/bilateralism_ip.rtf (last visited Nov. 21, 2005).

the patentability subject matter and to impose the UPOV Convention as the “effective *sui generis* protection” for plant varieties, as Article 27 TRIPS mandates. This position was likely the unspoken ideal of the U.S. and many EU countries. In the face of the impossibility of achieving these objectives through a multilateral approach, industrialized countries have embarked on bilateral negotiation alternatives with developing countries. In order to achieve much stronger standards of protection, industrialized countries are negotiating a range of bilateral, regional, and sub-regional agreements with individual Southern countries’ governments under the mantra of “national treatment” and “most-favored-nation” principles. This practice may soon make TRIPS obsolete⁸² as the thick network of obligations among WTO Member States combine to achieve a “TRIPS plus agreement,” ultimately providing heightened protections for industrialized countries. Thus, the rights of the IPR holder will have priority over developing countries as users of IP-protected works.

This applies to IPRs dealing with life forms. For instance, one of the biggest novelties introduced by these bilateral agreements is the requirement to provide patent protection on plants and animals. This is true for Jordan,⁸³ Mongolia,⁸⁴ Nicaragua, Sri Lanka,⁸⁵ and Vietnam.⁸⁶ Under another approach, South Africa and the seventy-

⁸² “Using the TRIPS-plus criteria described above, and looking at only a portion of these agreements, GRAIN has, in 2001, identified 23 cases of bilateral or regional treaties between developed and developing countries that should be classed as TRIPS-plus as far as IPR on life forms are concerned. These agreements affect more than 150 developing countries. This means that something serious is occurring; the TRIPS-plus features of these treaties cannot be accidental.” *“Trips-Plus” Through the Back Door: How Bilateral Treaties Impose Much Stronger Rules for IPRs on Life than the WTO*, GRAIN PUBLICATIONS, July 2001, <http://www.grain.org/briefings/?id=6> [hereinafter *Trips-Plus*].

⁸³ Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, U.S.-Jordan, Oct. 24, 2000, DOS No. 02-11, CONSOLIDATED TREATIES AND INT’L AGREEMENTS, 2002, available at http://www.ustr.gov/Trade_Agreements/Bilateral/Jordan/Section_Index.html?ht=jordan%20jordan [hereinafter Jordan Agreement].

⁸⁴ Treaty Between the United States of America and Mongolia Concerning the Encouragement and Reciprocal Protection of Investment, U.S.-Mong., Oct. 6, 1994, <http://www.state.gov/documents/organization/43579.pdf>.

⁸⁵ Treaty Between the United States of America and the Democratic Socialist Republic of Sri Lanka Concerning the Encouragement and Reciprocal Protection of Investment, U.S.-Sri Lanka, Sep. 20, 1991, <http://www.state.gov/documents/organization/43588.pdf>.

⁸⁶ Agreement Between the United States of America and the Socialist Republic of Vietnam on Trade Relations, U.S.-Vietnam, July 13, 2000, <http://www.ustr>.

eight African Caribbean Pacific (ACP) countries are supposed to grant patents on “biotechnological” inventions,⁸⁷ thereby protecting plants, animals, and microorganisms as required by TRIPS.

In the field of microorganisms, TRIPS does not advocate the heightened standard of the Budapest Treaty system for patent protection of microorganisms; however, through bilateral treaties, countries have still entered into this more sophisticated administrative standard. Under bilateral agreements with industrial countries, at least Korea,⁸⁸ Mexico,⁸⁹ Morocco, and Tunisia⁹⁰ have been required to join the Budapest system, while Jordan and other countries must implement their own substantive provisions.⁹¹ These obligations go beyond TRIPS standards because the Budapest treaty obliges parties to recognize the physical deposit of microorganism samples with an international depository authority instead of full written disclosure of the invention.⁹² Under this treaty, a deposit fulfills the requirement for disclosure. Furthermore, this treaty, whose contracting parties are mostly industrialized states, relies on a network of recognized international depository authorities, which operate special rules on access to the biological samples in order to avert potential patent infringement.

gov/assets/World_Regions/Southeast_Asia_Pacific/Vietnam/asset_upload_file804_5101.pdf.

⁸⁷ Partnership Agreement Between the African, Caribbean and Pacific States and the European Community and its Member States, June, 23 2000, 2000 O.J. (L 317) 3, 24, available at http://www.grain.org/brl_files/acp-eu-partnership-agreement-2000.pdf; Agreement on Trade, Development and Cooperation Between the European Community and its Member States, of the One Part, and the Republic of South Africa, of the Other Part, Apr. 12, 1999, 1999 O.J. (L 311) 3, 17–18, available at http://www.grain.org/brl_files/south-africa-eu-trips-plus.pdf.

⁸⁸ Record of Understanding on Intellectual Property Rights art. B(6), U.S.-Korea, Aug. 28, 1986, http://www.bilaterals.org/article.php?id_article=388.

⁸⁹ Economic Partnership, Political Coordination and Cooperation Agreement Between the European Community and its Member States, of the One Part, and the United Mexican States, of the Other Part, Oct. 28, 2000, 2000 O.J. (L 276) 45.

⁹⁰ Euro-Mediterranean Agreement Establishing an Association Between the European Communities and Their Member States, of the One Part, and the Republic of Tunisia, of the Other Part, Mar. 30, 1998, 1998 O.J. (L 97) 2.

⁹¹ Jordan Agreement, *supra* note 83, at 4.

⁹² “Where an invention involves a microorganism or the use of a microorganism, disclosure is not possible in writing but can only be [affected] by the deposit, with a specialized institution, of a sample of the microorganism.” WIPO, *Summary of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977)*, http://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html.

Bilateral treaties increasingly put pressure on developing countries to heighten standards. For example, a substantive provision may require that developing countries implement IPRs “in accordance with the highest international standards.”⁹³ Such ambiguous and lofty standards open the door to new standards generated through investment treaties. This kind of agreement represents only the tip of the iceberg of unrelenting pressure to patent plants and animals. Indeed, the TRIPS-plus phenomenon that once quietly brewed away in the corner has now become rampant.⁹⁴

In a bilateral free-trade agreement text, that has not been made public yet, it is reported that the United States for the first time agreed to language relating to traditional knowledge, according to a Peruvian government source: “the language, which appears in a side letter to the overall agreement, apparently stresses the importance of such practices as informed consent, benefit-sharing, and utilization of contracts with the aim of encouraging the protection of biodiversity.” The agreement facilitates the access by U.S. patent applicants to a database to find eventual evidence of prior art in the form of traditional knowledge related to a genetic resource.⁹⁵

*E. The Debate within the TRIPS Council:
The Road to Hong Kong*

In review of Article 27.3(b), the WTO Ministerial Conference instructed the TRIPS Council “to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant developments raised by members pursuant to Article 71.1.”⁹⁶

Many countries consider this an important step towards the reconciliation between TRIPS and the CBD provisions. Additionally, the TRIPS-plus effect rendered obsolete developing

⁹³ Euro-Mediterranean Interim Association Agreement on Trade and Cooperation Between the European Community, of the One Part, and the Palestine Liberation Organization (PLO) for the Benefit of the Palestinian Authority of the West Bank and the Gaza Strip, of the Other Part, July 16, 1997, 1997 O.J. (L 187) 3.

⁹⁴ See *Trips-Plus*, *supra* note 82.

⁹⁵ Martin Vaughan, *US-Peru Deal Includes First-Ever Traditional Knowledge Provisions*, Sept. 12, 2005, INTELL. PROP. WATCH, available at <http://www.ip-watch.org/weblog/index.php?p=173&res=1024&print=0>.

⁹⁶ Ministerial Declaration, *supra* note 31, at 751.

countries' appeals to revise Article 27.3(b) of the TRIPS Agreement to ban the patentability of life forms. Because most developing countries accepted heightened standards and the patenting of living organisms through bilateral trade agreements with industrialized countries, little conflict remains regarding Article 27.3(b).

As a result, the current controversy within the TRIPS Council focuses less on the morality of patenting life and more on the integration of benefit-sharing obligations arising from the IP exploitation of genetic resources mentioned in Article 27. More particularly, developing countries now demand a new patentability requirement: the disclosure of origin as evidence of PIC and benefit sharing. Thus, the road to the Hong Kong Ministerial Conference in 2006 is fraught with more technical issues than moral ones.

Most agree that the vast majority of genetic resources exist in the global South where little possibility of exploitation exists. A large block of developing countries led by India and Brazil argue that the industrialized world's practice of exploiting their resources without equitably sharing the benefits is the equivalent of "biopiracy."⁹⁷ Therefore, the Brazil-India coalition has called for augmented criteria to patent an invention. The current TRIPS regime requires an invention to meet three criteria before issuing a patent: novelty, non-obviousness, and utility. The Brazil-India coalition is currently pushing for the addition of a fourth requirement: proof of PIC. Firms would prove PIC by disclosing the source and origin country of the genetic resources used to make the invention. This added disclosure requirement, developing countries argue, will ensure the equitable sharing of benefits and prevent the erroneous issuance of patents.⁹⁸

While ensuring equitable sharing of benefits and preventing the erroneous issuance of patents are undoubtedly desirable objectives, the United States argues that the introduction of new patent disclosure requirements will not achieve these desirable objectives. They further argue that the proposed requirement may actually have significant negative social and economic consequences. The U.S.

⁹⁷ See generally Submission from Brazil and India, *The Relationship Between the TRIPS agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge: Technical Observations on Issues Raised in a Communication by the United States (IP/C/W/434)*, 18 March 2005, IP/C/W/443, available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W443.doc> [hereinafter *Technical Observation*].

⁹⁸ *Id.* ¶ 3.

proposes an alternative solution; it calls for tailored, national solutions to meet practical concerns and actual needs.⁹⁹ In other words, the U.S. calls for the *status quo* and supports the strengthening of nationally administered and enforced contractual arrangements, as already promoted under the Bonn Guidelines and mandated under the CBD. The U.S. claims this as the most effective manner to achieve the CBD objectives for several reasons.¹⁰⁰

First, the U.S. holds that new patent disclosure requirements cannot guarantee that industrialized countries will obtain PIC before they issue patents, and thus the new requirements will not prevent misappropriation. According to the U.S., “it is the relevant PIC agreement itself (usually constituting a contract between two entities), and not disclosure in a patent application, that manifests prior informed consent.”¹⁰¹ If the goal is to ensure authorized access based on PIC, “only contractual obligations that establish the rights and obligations of the entities involved prior to any access to genetic resources can ensure prior informed consent is achieved.”¹⁰² From this point of view, what all countries need, more than an adjustment in the international patent system, is a clearer delineation of the contractual guidelines for acquiring authorization to exploit genetic resources at the national and local levels. This would facilitate the proliferation of contractual agreements on benefit sharing.

Second, the U.S. declares that patent offices have insufficient resources and capability to examine documentation regarding source and origin, PIC, or equitable benefit sharing. Thus, new patent disclosure requirements would place overpowering administrative burdens on national patent offices. The necessary training and additional resources needed to prepare for such work would be very costly.¹⁰³ Even with these added resources, the U.S. doubts that patent examiners could make legally certain determinations regarding such documentation, particularly when those decisions involve interpreting foreign laws. Accordingly, the U.S. maintains that strengthening national mechanisms for

⁹⁹ See Communication from the United States, *Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, ¶ 6, IP/C/W/434 (Nov. 26, 2004).

¹⁰⁰ *Id.* ¶ 4.

¹⁰¹ *Id.* ¶¶ 7, 18–32.

¹⁰² *Id.* ¶ 7.

¹⁰³ *Id.* ¶ 15.

developing and enforcing contractual arrangements between bioprospecting entities and “owners” of genetic resources and traditional knowledge would do much more to prevent erroneous patents and would do so without unnecessarily burdening patent offices.

Third, the U.S. believes a new disclosure requirement in the patent system would not ensure that industrialized countries equitably share benefits with the providers of traditional knowledge or genetic resources.¹⁰⁴ If the country of origin in question has no benefit-sharing infrastructure, disclosure would “convey the information requested but would have no mechanism to transfer benefits between parties.”¹⁰⁵ The U.S. indicates that the real problem is the general lack of benefit-sharing infrastructures in developing provider countries rather than an inadequate international patent system.

Finally, the U.S. argues that new patent disclosure requirements would add new uncertainties to the patent system and thereby decrease investment in important drugs.¹⁰⁶ This position relies upon the interests of the economic forces in this field. Pharmaceutical companies spend large sums of money on the research and development of new drugs—those companies then rely on the monopoly rights patent grants to recover their expenditures. Thus, patents promote the public good by providing incentives to innovate.

The question then becomes whether the WTO should amend the TRIPS Agreement as proposed by the Brazil-India camp? The proposed recommendation would still allow any State the right to litigate over patent rights for biotechnological and pharmaceutical goods developed from their country’s resources. The fear of losing a patent through litigation would act as an *ex-ante* tax on pharmaceutical investment. Proponents of the U.S.’s point of view refer to a recent study by Timothy A. Wolfe and Benjamin Zycher of the Pacific Research Institute. This study estimated that the aforementioned uncertainty would reduce biotechnological and pharmaceutical research and development by almost twenty-seven

¹⁰⁴ *Id.* ¶ 9.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* ¶ 14.

percent before 2025. The reduction would result in the loss of 150 to 200 new drugs, and cost a cumulative \$100.6 billion.¹⁰⁷

The Brazil-India camp argues, however, that the U.S. “has not made a sufficient case against the proposed disclosure requirement.”¹⁰⁸ From their point of view, the development of effective national laws that address the goals of transparent patent applications through PIC and access and benefit sharing (ABS) are necessary steps in achieving the goals of the CBD. They assert, however, that this “does not in anyway provide a basis for rejecting the establishment of an international system to support and facilitate the implementation of national systems.”¹⁰⁹ The Brazil-India camp argues that both the PIC and ABS institutions are critical to achieving an equitable result between the right-holders and -users and the provider country and recipients. They maintain that they should be integrated into TRIPS Article 27.

Rebutting the U.S.’s argument that patent disclosure requirements can neither ensure PIC nor prevent misappropriation, Brazil and India claim that a national system alone cannot achieve this either. The proposed international system, they point out, was never intended to be a stand-alone system, but a “vital measure and incentive that would support and ensure the effective operation of national regimes for prior informed consent.”¹¹⁰ Contractual arrangements and similar mechanisms must be enforceable across borders, and the current fragmented national system does not achieve enforceability.

Brazil and India respond in a similar vein to the U.S.’s claim that disclosure cannot ensure benefit sharing. Again, they argue that national systems of the contractual brand are necessary but insufficient alone. International obligations coupled with relevant national regimes would affect the transfer of benefits.¹¹¹

The Brazil-India coalition, however, disagrees with the U.S.’s claim that the proposed changes would overburden patent offices. The coalition asserts that the disclosure requirement in question does not differ from the other disclosure requirements common to

¹⁰⁷ Timothy A. Wolfe & Benjamin Zycher, *Biotechnological and Pharmaceutical Research and Development Investment Under a Patent-Based Access and Benefit-Sharing Regime*, PACIFIC RESEARCH INSTITUTE, May 2005, at 2 [hereinafter Wolfe & Zycher].

¹⁰⁸ *Technical Observation*, *supra* note 97, ¶ 3.

¹⁰⁹ *Id.* ¶ 6.

¹¹⁰ *Id.* ¶ 8.

¹¹¹ *Id.* ¶ 13.

domestic legal systems (i.e. disclosure of information material to patentability requirements in the U.S.). Therefore, the disclosure requirement should not impose any excessive administrative burdens on patent offices or applicants. As for the U.S.'s doubt regarding patent examiners' ability to determine the validity of PIC and ABS, Brazil and India insist that the disclosure requirement will not require patent examiners to determine such validity. "The role of the patent examiner," they claim, "will be limited to confirming that the patent application contains a declaration in the prescribed form indicating that PIC was obtained and that benefits were shared and/or that there exists an arrangement for future benefit-sharing in accordance with the relevant national law."¹¹²

Finally, Brazil and India disagree that the changes would add uncertainty to the international patent system. They believe that rather than taking it away, "the proposed disclosure requirement would in fact introduce much needed certainty ... by establishing clear internationally agreed rules on disclosure, prior informed consent, and benefit-sharing."¹¹³ They add that the requirement would preserve the balance of the patent system by recognizing that States and local communities contribute to innovation by providing genetic resources and traditional knowledge.

The validity of the Wolfe and Zycher analysis on the negative effects of a "patent-destroying ABS regime" is difficult to assess. The circumstances may vary with the creation of a new environment of cooperation in the biological resource exchange. One can also counter the U.S.'s arguments by noting that new ABS laws would build trust between provider communities and industrial bioprospectors. This may explain why no other WTO member supports the extreme position of the U.S.'s proposal even though it claims to offer a "superior way" of achieving the CBD objectives while retaining the purity of the international IP system. The patent system is not clinically isolated from other non-IP issues. However, the developing world would be wise to consider the U.S.'s recommendation to develop systems of benefit sharing outside the patent system. By creating a cooperative system to share the benefits flowing from biotech patent rights, the patent system will acquire legitimacy in the eyes of the public in developing countries. However, the main purpose of this article is to introduce the international legal debate on the solutions *de lege ferenda* in Article

¹¹² *Id.* ¶¶ 21–22.

¹¹³ *Id.* ¶ 4.

27.3(b) of the TRIPS Agreement. Thus, solutions in this regard fall outside the scope of this article.

V. CONCLUSIVE OPINIONS

The first conclusive observation about Article 27 of the TRIPS Agreement is that it opened up new commercial opportunities through IP protection of biotechnology in all countries. In spite of its incomplete construction and inherent vagueness, it has powerful implications in the context of international commerce based on biological resources. These implications have started a massive, controversial campaign, mainly organized by non-governmental organizations (NGOs) and indigenous communities in developing countries, to wrest market control over biodiversity through the patent system and to change the system's rules.¹¹⁴ Companies in industrialized countries with sophisticated technologies—such as genetic engineering—that extract value from biodiversity by patenting new genetic “inventions” have aggravated the controversy. However, many of these genetic “inventions” claimed in the North have come primarily from traditional knowledge and genetic resource misappropriations in the South. Through patent protection on life forms, major transnational corporations can take genes from, for instance, a weed in the fields, forests, or coastal waters of developing countries without PIC from provider States.¹¹⁵ A transnational corporation can then manipulate this weed in its labs and obtain patent protection for its “new” discovery. Consequently, the mere transformation of resources in the laboratories of industrialized countries has resulted in a public outcry from developing countries because corporations are paid royalties based on the developing countries' preserved resources and traditional knowledge.

The second observation is that contracting parties to both TRIPS and the CBD encounter hurdles implementing both treaties in national legislation. Because TRIPS only recognizes a patent in the case of novelty, industrial application, and non-obviousness, and the CBD provides pre-existing rights to genetic resources and related traditional knowledge, there is a definite conflict in dual

¹¹⁴ According to WIPO, citizens and corporations of industrialised countries hold 95% of the patents in Africa, almost 85% of those in Latin America and 70% of those in Asia. WIPO, data set IP/STAT/1994/B (*released* Nov. 1996).

¹¹⁵ Convention on Biological Diversity, *supra* note 16, at 828.

implementation. Contrary to TRIPS, national laws implementing the CBD principles must assign the rights of pre-existing genetic resources to local communities or the States. The international exercise of IPRs on biodiversity-related “inventions” becomes dependent upon the prior “rights” of these local and indigenous communities.

Finally, in light of this debate, some considerations and opinions need to be stated. Although to the Brazil-India coalition the TRIPS Agreement seems like the right treaty to achieve reconciliation between the CBD and international patent law, these countries must not forget that they can achieve similar results by amending other patent treaties administered by WIPO. There are serious doubts that the WTO will amend TRIPS to reconcile it with conflicting CBD concepts in the near future. Diplomats and IP policy makers may realize that TRIPS is not the right treaty to reconcile these differences in the most thorough and rapid manner given the opposition by WTO Member States.

Member States hardly expect a revision of TRIPS Article 27 as an outcome of the Hong Kong Ministerial Conference unless other WTO agreements come into the bargaining. Under such circumstances, agreements for agriculture or services may increase the bargaining margin and maneuvering of certain States, which may play a part in the revision of Article 27. As things stand, it would be highly unlikely to expect industrialized countries to give up tariffs and subsidies on agricultural production while burdening their patent system with new CBD-compliant requirements such as PIC and benefit sharing.

Policy makers in industrialized countries know that empirical data supports the fact that patents, no matter how imperfect the granting system, are indeed a necessary tool for innovation. For example, the U.S.’s Bayh Dole Act allowed universities to retain profits flowing from the exercise of patent rights, which resulted in an increase in the number of patent applications by encouraging inventiveness.¹¹⁶ Hence, radically modifying the current patent system in the field of biotechnological innovations by introducing a burdensome system of CBD-compatible benefit sharing in Article 27 may seriously impede the investment flows to biotechnological start-up companies. As seen from the Bayh Dole Act, most industrialized countries prefer to remove as many burdens as possible in order to keep the patent system as neutral and free

¹¹⁶ Wolfe & Zycher, *supra* note 107, at 11–12.

flowing as possible. Other treaties administered by WIPO are more appropriate for a rapid reconciliation between patent law and the CBD principles. For example, the international community could introduce transparency measures, such a certificate of origin for genetic resources on which the patentable invention is based and requiring such certificates for patent applications under the Patent Corporation Treaty and Substantive Patent Law Treaty.¹¹⁷

The complexities inherent to the patentability of biological material may persuade WTO Member States to introduce a higher threshold than what currently occurs in Europe and the United States. Moreover, U.S. patent law is currently watering down patentability requirements, leaving all controversial matters to the scrutiny of courts. Consequently, court proceedings are very complex and the international system follows these proceedings in alleged cases of international misappropriation.

This analysis has been inherently limited to the IP aspects of the important instrument of transparency in patent application. It is apparent that this is just one of many potential measures that countries may consider to facilitate the convergence between CBD objectives and the exercise of IPRs. In fact, the CBD realizes most of its objectives when countries act outside the IP system because many products on the market rely on genetic resources accessed and bioprosected without patents.

Clearly, the legal tensions between TRIPS and the CBD are the source of much debate. In this debate, players must exercise extreme caution when dealing with the delicate question of monopolized private ownership of the building blocks of life. In case WTO Members, also contracting parties to the CBD, do not reach an international level agreement, the PIC, and access and benefit sharing institutions will still bind them when implementing national patent legislation, thus rendering the patent system more fair and equitable.

¹¹⁷ Martin A. Girsberger, *Transparency Measures Under Patent Law Regarding Genetic Resources and Traditional Knowledge—Disclosure of Source and Evidence of Prior Informed Consent and Benefit-Sharing*, 7(4) J. WORLD INTELL. PROP. 451, (2004).