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Patenting Life: The Potential and the Pitfalls of Using the WTO to Globalize Intellectual Property Rights

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Introduction

Although the concept of intellectual property rights dates back to the fourth century B.C.,¹ the movement toward creating an international standard for protecting innovation is a relatively new development.² The most significant step in this trend is the recent delegation of intellectual property issues to the decision-making and regulatory bodies of the World Trade Organization.³ The adoption of the far-reaching Trade Related Aspects of Intellectual Property Agreement⁴ (hereinafter the TRIPs Agreement) belies both the complexities inherent in achieving a universal standard for intellectual property management⁵ and the significant divergence of interests remaining in the field.⁶ These complexities and divergent interests are exemplified by the controversy


² Karen A. Monroe et al., International Overview of Trademarks and Copyrights, in INTERNATIONAL INTELLECTUAL PROP. LAW: NEW DEVELOPMENTS 5 (Dennis Campbell & Susan Cotter eds., 1995). Intellectual property rights have been the subject of extensive international agreements, beginning with the Paris Convention for the Protection of Industrial Property of 1883 and continuing through the recent, and most rigorous, Trade Related Aspects of Intellectual Property Agreement of 1994. See id. at 6-19.


⁵ See id. at 13-15.

⁶ See id. at 15.
surrounding the patenting of life forms. Stemming from the cultural and economic differences between developing and developed nations, this controversy also draws into sharp focus many of the pitfalls, both real and perceived, of relying on the unique structure of the World Trade Organization to establish uniform trade standards. This comment surveys the landscape of this controversy and assesses the implications of possible developments for both the field of international intellectual property law and the future of the World Trade Organization. Parts I and II briefly explore the general goals and philosophies behind recognizing intellectual property rights, with specific emphasis on the connection to biological entities. Parts III and IV focus on the functioning of the World Trade Organization and the current status of the TRIPs Agreement. Part V outlines the remaining challenges of attempting to establish a global standard for patenting life forms and using the World Trade Organization to do it.

I. The Purpose of Intellectual Property Rights

Genius is one percent inspiration and ninety-nine percent perspiration.

—Thomas Edison

This oft-heard Edison quote reflects the basic philosophy

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8 See id.

9 See World Trade Organization, Seattle: What’s At Stake? A Resource Booklet for the Seattle Ministerial Meeting 27, 33, at http://www.wto.org/english/thewto_e/minist_e/min99_e/english/book_e/stake.pdf (Nov. 1999) [hereinafter Seattle Meeting]. Concerns commonly associated with the World Trade Organization include: whether it is undemocratic and undermines the sovereignty of governments; whether it values the interests and needs of developed nations to the detriment of developing countries; and whether it is indifferent to advocates for the protection of the environment, health and safety. Id; see also Andrew L. Strauss, From GATTzilla to the Green Giant: Winning the Environmental Battle for the Soul of the World Trade Organization, 19 U. PA. J. INT’L ECON. L. 769, 769-75 (1998).

10 See infra notes 13-92 and accompanying text.

11 See infra notes 93-209 and accompanying text.

12 See infra notes 210-75 and accompanying text.
behind traditional intellectual property rights. Intellectual property rights (hereinafter IPRs) are founded on the assumption that inventions are the product of nothing more than individual labor and investment. IPRs create private property rights in developers of new knowledge to compensate them for the labor and resources expended during the creative process. By rewarding research and development, IPRs systems are intended to foster the creation and dissemination of new knowledge, thereby benefiting society in general as well as the individual inventors. Most developed nations adhere to this philosophy and have established extensive protective systems for IPRs.

Although dominant among developed nations, this individualistic philosophy is not globally accepted. Many developing countries regard knowledge as communal rather than private property. These societies value and encourage intergenerational innovation, perceiving inventions not as purely unique personal achievements but as extensions of existing ideas and discoveries. Furthermore, although they are the proprietors of

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13 See Tansey, supra note 1, at 3.
14 See Kate H. Murashige, Harmonization of Patent Laws, 16 Hous. J. Int’l L. 591, 592 (1994). In the United States, this individual reward philosophy was recognized and validated by the United States Supreme Court in Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974) (holding that Ohio’s trade secret law does not contradict the purpose of federal patent laws and is not preempted by them).
15 See McCabe, supra note 7, at 46; Murashige, supra note 14, at 594. Although widely recognized as effective in certain fields such as pharmaceutical development, some commentators have questioned whether IPR systems generally achieve their expected beneficial results. IPR protections can limit the entry of new competitors into a market effectively, stifling rather than fostering innovation. See Tansey, supra note 1, at 4; see also Vandana Shiva, Biopiracy: The Plunder of Nature and Knowledge at 13 (1997) (stating that “[i]there is virtually no evidence that patents actually stimulate invention.”).
17 Id. at 108.
18 Rosemary J. Coombe, Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity, 6 Ind. J. Global Legal Stud. 59, 77, 80 (1998); see also Sarma, supra note 16, at 108 (stating that many developing nations believe inventive processes for which patents are being granted have their foundations in previous knowledge and the utilization of biological plant and food systems).
much of the world's uncultivated natural resources\textsuperscript{19} and the caretakers of extensive indigenous knowledge,\textsuperscript{20} these nations are less technologically advanced than their industrialized counterparts. As a public policy, countries in this position recognize the value of employing copying strategies as a means of catching up technologically.\textsuperscript{21} These cultural and economic forces counsel against strict IPR regimes, and until recently, many developing countries did not adopt or enforce IPRs.\textsuperscript{22}

In addition to differing on the general applicability of IPRs, developed and developing nations clash over the appropriateness of creating private property protection in sensitive subject areas such as biotechnology.\textsuperscript{23} Biotechnology involves both living organisms and non-living biological material.\textsuperscript{24} Biotechnological innovations also encompass the development of processes which create or modify living organisms or biological material, the products of those processes, or the subsequent use of those products.\textsuperscript{25} Despite the widespread use of biotechnology in medicine, energy, and agriculture, there is substantial international variation in the protection afforded these innovations.\textsuperscript{26} These

\textsuperscript{19} Sarma, \textit{supra} note 16, at 111.

\textsuperscript{20} See Coombe, \textit{supra} note 18, at 77. Definitions of indigenous knowledge vary, but the phrase typically refers to folk or popular knowledge that reflects “symbiotic relationships between individuals, communities, generations, the physical environment, and other living creatures and the spiritual relationships of a people.” \textit{Id.} (quoting Howard Mann from an unpublished paper, \textit{Intellectual Property Rights, Biodiversity and Indigenous Knowledge: A Critical Analysis in the Canadian Context} (1997)).

\textsuperscript{21} Abdulqawi A. Yusuf, \textit{TRIPS: Background, Principles and General Provisions}, \textit{in Intellectual Prop. and International Trade: The TRIPS Agreement} 3, 4-5 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998). This practice is not unique to currently developing nations. As a young country, the United States also limited international intellectual property rights in order to further its social and economic development. \textit{Id.}

\textsuperscript{22} \textit{Id.}

\textsuperscript{23} See generally TANSEY, \textit{supra} note 1 (discussing moral and ethical issues tangential to the application of patents to life forms).

\textsuperscript{24} See \textit{World Intellectual Prop. Org., Introduction to Intellectual Prop. Theory and Practice} \textsuperscript{33.20} (1997). “Living organisms” refers to plants, animals, and microorganisms. \textit{Id.} Non-living biological material refers to seeds, cells, enzymes, and plasmids. \textit{Id.}

\textsuperscript{25} \textit{Id.}

\textsuperscript{26} See \textit{id.} \textsuperscript{33.23, 33.25-33.29.} The patent laws of the United States allow for protection of all forms of biotechnological innovation. \textit{Id.} \textsuperscript{33.34.} The laws of many
differences stem primarily from perceptions of this type of innovation as either a scientific discovery or an invention. Additionally, commentators have debated whether biotechnological innovations meet the standard patentability requirements of novelty and non-obviousness and the common registration requirements of describability and reproducability. Thus, differences between nations on IPR issues encompass cultural, economic, and administrative concerns not easily harmonized through one international agreement.


See WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 33.27. Discoveries are generally not protectable, but inventions that require human intervention are. Id.

See Margaret A. Boulware et al., Introduction: Novelty & Non-obviousness, in 16 HOUS. J. INT’L L. 441, 446-49, 465-66 (1994). Most countries require that patentable material be absolutely novel, meaning that there has been no public disclosure or commercial exploitation of the invention prior to the filing of the application. Id. The European definition of novelty mandates that the invention not be “part of the state of the art,” which is a difficult determination to make in the natural world. Id. at 465.

Id. at 466-67. The non-obvious, or inventive step, requirement demands that the invention not be evident to a person of ordinary skill in the relevant technical field. Id. An invention is obvious if an average person in the field would be likely to discover it from information available in the public domain. Id. Although this test is standard in most developed countries, some apply it subjectively to limit protection of biotechnology. Id. The United States applies it objectively to find a broader array of inventions patentable. Id.

See Geertrui Van Overwalle, Patent Protection for Plants: A Comparison of American and European Approaches, 39 IDEA 143, 155-58 (1999). The registration requirements of describability and reproducibility ensure that the invention meets the patentability requirement of being intrinsically useful. Id. The registration requirements also appropriately limit the scope of protection provided and facilitate the significant IPR goal of general knowledge dissemination. Id.

See generally id. at 148-59. Describability limits IPR protections to the characteristics of innovations that can be adequately described through words, thereby differentiating the registered invention from similar products. See id. at 154-56. Reproducibility ensures that only inventions that can be consistently recreated, and thus may be industrially applicable, are provided protection. See id. at 156-57.

Doris Estelle Long, Underlying Theories: Harmonization, in INTERNATIONAL INTELLECTUAL PROP. LAW 82, 82-83 (Anthony D’Amato & Doris Estelle Long eds., 1997).
A. The International Treatment of IPRs Related to Life Forms

Historically, the substantive aspects of IPR laws have been determined nationally rather than internationally, and thus have reflected each country’s unique stand on the relevant philosophical and policy issues. IPR systems may vary according to the types of innovations protected, the forms of protection offered, the length of protection, and the terms of enforcement. Traditionally, fundamental differences between nations in the substantive and procedural protections of intellectual property systems have been an accepted part of international IPR agreements. Prior to the adoption of the revolutionary TRIPs agreement, the multinational agreements most relevant to the controversy surrounding the protection of biotechnological inventions were the Paris Convention for the Protection of Industrial Property (hereinafter Paris Convention), the International Union for the Protection of New Varieties of Plants (hereinafter UPOV Acts), and the Convention on Biological Diversity (hereinafter Biodiversity Convention). An

33 Id.

34 Doris Estelle Long & Anthony D’Amato, Introduction: Forms of Intellectual Property, in INTERNATIONAL INTELLECTUAL PROP. LAW, supra note 32, at 3-6 (Anthony D’Amato & Doris Estelle Long eds., 1997). For example, patents generally protect “novel and non-obvious functional aspects of useful articles or processes.” Boulware et. al., supra note 27, at 16. Contrary to the preference of the United States, which would like to expand the definition of patentable subject matter, many countries’ patent laws interpret this broad definition to include the processes used to make pharmaceutical products, but not the products themselves. Long & D’Amato, supra note 32, at 3-4; McCabe, supra note 7, at 43.

35 Long & D’Amato, supra note 32, at 3-6. The five basic types of intellectual property are patents, copyrights, trademarks, trade secrets and industrial designs. Id. In addition to these standard forms of protection, countries may also offer utility models, plant breeders’ rights, droit de suites, and neighboring rights. See generally Doris Estelle Long et al., Introduction, in INTERNATIONAL INTELLECTUAL PROP. LAW 1, supra note 32, at 1-24. Patents and plant breeders’ rights will be explained more fully in Part IV. See infra notes147-209 and accompanying text.

36 Long & D’Amato, supra note 32, at 3-6.


39 Boulware et al., supra note 28, at 17-18; TANSEY, supra note 1, at 9, 14.
understanding of the basic provisions of these agreements is necessary to comprehend recent developments in this area.

B. The Paris Convention

The Paris Convention, the first international union on IPRs, focuses on industrial property. This agreement was founded on the principle of national treatment, which ensures the consistent application of the IPR laws of all signatories, but does not define their substance in any significant way. The Paris Convention dictates that signatories provide foreigners the same IPR protections given to their own citizens. Although the Paris Convention also establishes minimum protective standards to be incorporated into domestic laws, its main objective is to eradicate discrimination rather than to normalize IPR regimes. A chief concern about the current effectiveness of the Paris Convention is that the latitude afforded by the national treatment principle accommodates consistently weak protection of IPRs. Additional concerns with the Paris Convention stem from its failure to specify minimum terms for the length of patents and its lack of meaningful dispute settlement mechanisms. The World

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40 Paris Convention for Protection of Industrial Property, March 20, 1883, last revised at Stockholm, July 14, 1967, art. 1(2), 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention]. The Paris Convention protects industrial property, including patents, utility models, industrial designs, trademarks, service marks, trade names, and indications of source or appellations of origins. It also guards against unfair trade practices. Id.

41 Robert J. Gutowski, The Marriage of Intellectual Property and International Trade in the TRIPS Agreement: Strange Bedfellows or a Match Made in Heaven?, 47 BUFF. L. REV. 713, 717-18 (1999). By 1887, Belgium, Brazil, France, Ecuador, Guatemala, Italy, the Netherlands, Portugal, Salvador, Serbia, Spain, Switzerland, Tunisia, the United Kingdom, and the United States had acceded to the convention. Id. Prior to the ratification of the Paris Convention, the only protection for IPRs came from limited bilateral agreements. Id.

42 See id. at 718-19.

43 Paris Convention, supra note 40, art. 2(1).

44 Gutowski, supra note 41, at 719.

45 See id. at 719-20. Under the national treatment principle, a nation with minimal IPR laws for its own citizens may offer similarly weak protection to foreigners. Id. at 720. The Paris Convention ensures consistency in application, but creates no incentive to enhance the degree of protection provided. See id.

46 Abbott, supra note 38, at 13.
Intellectual Property Organization (WIPO), a specialized agency of the United Nations, currently administers the terms of the Paris Convention. WIPO’s role as an observer during the negotiation of the TRIPs Agreement evidences the continued vitality of the Paris Convention, and despite its limitations, the Paris Convention continues to serve as the foundation for subsequent international IPR agreements.

C. The UPOV Acts

The UPOV Acts represent more focused agreements that foster the establishment of sui generis IPR systems to protect the rights of plant breeders. Designed as an alternative to offering patents on plant genera and species, the UPOV Acts protect new

47 WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 3.1.
48 Doris Estelle Long & Anthony D’Amato, WIPO’s Future After TRIPs, in INTERNATIONAL INTELLECTUAL PROP. LAW, supra note 32, at 282. Provisions of the Paris Convention were specifically incorporated into the TRIPs Agreement, supra note 4.
49 The first convention of the International Union for the Protection of New Varieties of Plants was adopted by various European states in 1961. TANSEY, supra note 1, at 9. There have been three subsequent revisions to the original document, completed in 1972, 1978 and 1991; the 1978 revision was the last one put into force. Id. The modifications made in 1991 have not been fully enacted. WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 27.80. As of October 1996, 31 states were parties to the UPOV 1978 Act and 16 states had signed, though not yet ratified, the UPOV 1991 Act. See id. ¶¶ 27.31, 27.80.
50 TANSEY, supra note 1, at 25. An alternative to traditional IPR regimes, a sui generis system is a “unique form of protection tailored to a country’s particular needs.” Id. Rather than implementing a standard form of protection, i.e. a copyright or patent system, a sui generis system allows a country to develop its own rules to protect a specific subject matter such as plant varieties. Id. at 8.
51 WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 27.4. See also TANSEY, supra note 1, at 8-9 (discussing the effectiveness of the UPOV as a sui generis system developed to protect plant breeders’ rights).
52 TANSEY, supra note 1, at 9. The 1978 Act specifically prohibits the patenting of any materials protected by breeders’ rights, ensuring that a country that recognizes breeders’ rights in plant varieties cannot also offer patents on those materials. WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 27.21. This provision limits the extent of IPR protection available for plant varieties and ensures against double protection by the patent and breeder’s rights systems. Id. The prohibition on double protection was reinforced by the European Patent Office, whose case law specifically assumed that the subject matter excluded from patent protection was identical to materials covered by the UPOV. Van Overwalle, supra note 30, at 169. The 1991 Act is silent on the question of whether double protection is acceptable, suggesting that the issue may be resolved on a
varieties of plants which are novel, distinct, and stable and whose particular propagation features have sufficient uniformity.\textsuperscript{53} The terms of the UPOV Acts are further tailored to the unique demands of protecting plant varieties by allowing for farmers' privileges and exemptions for further breeding,\textsuperscript{55} thus effectively limiting the scope of protection to plant varieties used for commercial purposes.\textsuperscript{56} Like the Paris Convention, the UPOV Acts operate on the principle of national treatment.\textsuperscript{57} The UPOV Acts are administered by the UPOV body, an international intergovernmental organization that works closely with the World Intellectual Property Organization.\textsuperscript{58} Although widely accepted as an effective convention, the UPOV Acts have needed to be revised multiple times to keep pace with the changing demands of the biotechnology industries.\textsuperscript{59}

\begin{thebibliography}{99}
\bibitem{note1} TANSEY, supra note 1, at 9.
\bibitem{note2} WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 27.10. The requirement of novelty ensures that the plant variety has not previously been commercialized. TANSEY, supra note 1, at 9. Distinctness mandates that the plant variety be sufficiently distinguishable from other material. WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 27.10. Uniformity requires that protected plant varieties do not deviate significantly from their standard description. \textit{Id}. Stability demands that the plant variety retain its distinguishing features from one generation to the next. \textit{Id}.
\bibitem{note3} WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 27.14. “Farmer’s privileges allow production of reproductive material, without obligation to the original breeder, so long as the subsequent product is not commercially marketed. Thus, a farmer may produce seed on his own farm for the purpose of resowing his farm.” \textit{Id}. The UPOV 1978 Act specifically allows for farmers’ privileges, while the UPOV 1991 Act leaves determination of the privileges up to each member nation. TANSEY, supra note 1, at 9.
\bibitem{note4} WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 27.17. A fundamental principle of the UPOV 1978 Act is the permissibility of unauthorized use of a protected plant variety as an initial source in creating other varieties. \textit{Id}. The UPOV 1991 Act limited the scope of this exemption; by its terms, essentially derived varieties, which are varieties created by the addition of a single gene to existing varieties, must be authorized by the breeder of the original plant variety. \textit{Id}. ¶ 27.65.
\bibitem{note5} TANSEY, supra note 1, at 9.
\bibitem{note6} WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 27.22. National treatment ensures that signatories provide the same level of protection to foreigners as to their own citizens. \textit{Id}.
\bibitem{note7} \textit{Id}. ¶ 27.6.
\bibitem{note8} TANSEY, supra note 1, at 9. The impact of these revisions remains to be seen, but critics are concerned with the loss of breeders’ exemptions and the removal of the prohibition on patenting UPOV protected material that occurred in the 1991 revisions. \textit{Id}. at 9-10.
\end{thebibliography}
D. The Convention on Biological Diversity

Although primarily an agreement on environmental policy, not intellectual property, the Convention on Biological Diversity includes many provisions relevant to the debate concerning protection of rights in biotechnology. The agreement also highlights conflicts between developing and developed countries and their divergent interests in regulating biotechnology. The aims of the Biodiversity Convention are to conserve biological diversity, sustain the use of biological resources for current and future generations, and promote the equitable sharing of the benefits resulting from the use of such resources. The agreement specifically recognizes member states’ sovereign rights over their biological resources and their concomitant authority to determine who has access to those resources. It demands protection for the rights of communities and indigenous people to customary use of biological resources and knowledge systems. It recognizes the interdependence among developing countries, which have control of vast genetic resources, and developed nations, which have dominion over most advances in technology. In recognition of these competing interests, the Biodiversity Convention requires

60 David Hurlburt, The Cultural Impact of Intellectual Property Forms: Biodiversity, in INTERNATIONAL INTELLECTUAL PROP. LAW, supra note 32, at 85.
61 Id.
62 Id. The Biodiversity Convention recognizes the interest of developing countries in protecting their natural resources, preserving the rights of indigenous cultures, and encouraging the transfer of technology; these interests clash with those of developed nations intent on ensuring easy access to such resources and limited sharing of technological innovations. Sarma, supra note 16, at 120-21. The acknowledgement of these differences led to reluctance by at least one developed nation to sign the Convention. Murashige, supra note 14, at 596-97. As of early 1999, 175 countries had signed the Biodiversity Convention, although seven, including the United States, had not ratified it. TANSEY, supra note 1, at 14.
64 Id. arts. 3, 15.
65 Id. arts. 8 (j), 10.
signatories to facilitate environmentally sound use of their resources by other members, assuming adequate compensation is provided.\footnote{Biodiversity Convention, supra note 63, arts. 15.2, 15.7.} Signatories must also assist in the transfer of technology that enables countries to capitalize on their own natural resources, even if it requires sharing innovations protected by intellectual property rights.\footnote{Id. art. 16.3. "In other words, if there is any conflict between protection of intellectual property rights and the objectives of the treaty, then intellectual property rights must give way." Hurlburt, supra note 60, at 87-88.} The intention is to encourage countries to recognize intellectual property type rights in biological resources, which will in turn create incentive to preserve biodiversity and promote sustainable development.\footnote{Murashige, supra note 14, at 596-97. For example, recognition of IPRs in species rapidly becoming extinct in the rainforest creates a commercial incentive to preserve them. Id.} Despite these lofty goals, the Biodiversity Convention's overly broad standards and lack of enforcement mechanisms have significantly limited its effectiveness.\footnote{Sarma, supra note 16, at 120; see also Hurlburt, supra note 60, at 85 (referring to the treaty as "an impotent desideratum"). The Biodiversity Convention establishes a general framework for international interaction on issues affecting domestic environments, economies and IPR laws. Sarma, supra note 16, at 120; see Hurlburt, supra note 60, at 85. The Biodiversity Convention established no vehicle for implementation of these broad goals. Sarma, supra note 16, at 120.}

\section*{II. IPRs and Biotechnology}

The Biodiversity Convention and the 1991 UPOV Act revisions, precursors to the revolutionary TRIPs Agreement, reflect the international climate at the time of their promulgation. The early 1990s saw increased emphasis on expanding intellectual property rights governing biotechnology.\footnote{See Cheryl D. Hardy, Comment, Patent Protection and Raw Materials: The Convention on Biological Diversity and Its Implications for U.S. Policy Development and Commercialization of Biotechnology, 15 U. Pa. J. Int'l Bus. L. 299, 303, 308 (1994).} This growing interest was due in large part to the impact of biotechnological developments in the fields of pharmaceuticals and agriculture.\footnote{WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶¶ 33.19, 33.23. For example, in 1996, Monsanto, a U.S.-based company, marketed a cotton variety engineered to be resistant to the bollworm. In one year, the company collected $51 million dollars from this innovation. Shiva, supra note 15, at 36.}
The rapid pace of these developments led to an explosion of biotechnology firms, especially in the United States. In a trend unique to the biotechnology industry, most of the emerging participants were small companies dedicated completely to research and development. In addition to there being many independent competitors in the field, the industry's lengthy research process and high manufacturing and scale-up costs have made the field particularly capital-intensive. The costs and risks of putting a biotech product on the market are compounded by the complex regulations with which such products must comply. Furthermore, although they are initially difficult to develop and successfully commercialize, many biotechnological innovations are easily duplicated in their final stages. This makes such products unusually susceptible to piracy by competitors. Demands for increased IPR protection for new biotech developments emerged in response to the unique characteristics of this high risk, high investment, and highly competitive industry.

Though responsive to the needs of the commercial

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73 Hardy, supra note 70, at 301-02. “The biotechnology industry, in the United States alone, comprised over 1000 small to medium companies in 1994, employed over 184,000 persons in 1992, and had revenues in excess of $52 billion in 1991.” McCabe, supra note 7, at 47.

74 Dan L. Burk, Misappropriation of Trade Secrets in Biotechnology Licensing, 4 ALB. L.J. SCI. & TECH. 121, 136-37 (1994). These companies are frequently called DBCs, short for dedicated biotechnology companies. Id.

75 McCabe, supra note 7, at 48. It is estimated that it takes ten to twelve years to bring a biopharmaceutical drug to market. See id. This extended timeline typically causes “a long delay between the start-up of a biotechnology firm and the marketing of its first commercial product. Burk, supra note 73, at 138.

76 Burk, supra note 74, at 137-38; McCabe, supra note 7, at 48. It is estimated that it takes $350-360 million to bring a biopharmaceutical drug to market. McCabe, supra note 7, at 48 n.21. This figure does not take into account the extensive costs most DBCs incur from failed products. Id. at 49.

77 Burk, supra note 74, at 137. Traditionally, most research in biotechnology was done through universities, but as the profit potential of the field has increased, funding from the private sector has become more common. Id. at 136-37.

78 McCabe, supra note 7, at 48. Estimates suggest the odds that a biopharmaceutical compound will reach the market are one in five thousand. Id. These numbers are comparable for other biotech products. Id. at n.24.

79 Id. at 48.

80 Id.

81 Id. at 50.
competitors, the demand for increased IPR protection for biotechnology has also generated significant alarm. Biotechnology products are expected to contribute to advancements in curing disease, increasing agricultural output, minimizing environmental hazards, and obtaining energy. Achievements in these areas are essential to improving the quality of life in the world’s developing countries. IPR protection generally increases the immediate cost of utilizing such innovations, and many developing nations are leery of imposing this added cost on their impoverished citizens.

Additionally, IPR protection, lauded as a means to foster research and development, tends to focus on what will ultimately be commercially marketable. These market-based priorities may not coincide with the innovations most needed by small farmers and other participants in less developed economies. Concerns have also been raised over the safety of the many new biotechnology products reaching consumers, as well as the use of biotech innovations to create captive markets in formerly self-sufficient areas.

The increased profitability and commercialization of biotechnology has also led to heightened awareness concerning issues of biopiracy and biotechnology’s potential ramifications.

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82 WORLD INTELLECTUAL PROP. ORG., supra note 24, ¶ 33.23.
83 See TANSEY, supra note 1, at 19-20.
84 Id. at 20.
85 Id. One expert believes that “‘miracle’ technologies are not needed to solve the global food security problem” and that focusing energy and investments on such innovations diverts resources from efforts likely to have widespread, beneficial impact on agricultural development. Id. at 20. This diversion of resources may restrict the opportunity for constituencies other than individual inventors to profit from stronger IPR regimes. Id.
86 Id. at 21. These concerns have focused primarily on the possible health risks of genetically modified foods and have been particularly pronounced in Europe. See Terence P. Stewart & David S. Johnson, Policy in Flux: The European Union’s Laws on Agricultural Biotechnology and Their Effects on International Trade, 4 DRAKE J. AGRIC. L. 243, 246 (1999).
87 TANSEY, supra note 1, at 21. Concerns in this area focus on the effect of technological developments on subsistence farming, particularly through the propagation of non-replicating seeds. Id.
88 Valentina Tejera, Tripping Over Property Rights: Is It Possible to Reconcile the Convention on Biological Diversity with Article 27 of the TRIPs Agreement?, 33 NEW ENG. L. REV. 967, 971 (1999). Biopiracy is the use of traditional knowledge and resources without authorization by or compensation to its native communal caretakers.
on resource drain and disruption of the environment. Although curbed by the emergence of prospecting agreements between the governments of biologically rich countries and private corporations seeking use of those resources, these concerns still exist. The demand for enhanced IPR protections for the booming, yet controversial, biotechnology industry was a significant factor in the overall development of the 1994 TRIPs Agreement and directly influenced specific provisions of that agreement.

III. The TRIPs Agreement

The TRIPs Agreement was adopted within the framework of the Uruguay Round of Multilateral Trade Negotiations, incorporating, for the first time, IPR protection into the General Agreement on Tariffs and Trades (GATT). The TRIPs Agreement was one component of the Uruguay Round’s development of the Agreement Establishing the World Trade
The incorporation of IPR issues into GATT discussions and ultimately into the framework of the World Trade Organization was most strongly advocated by developed nations. They argued that the inclusion of IPR issues would help to liberalize international trade, provide for more effective enforcement of IPRs, and allow for negotiated benefits and concessions across trade areas. Initially resisted by developing countries, incorporation of IPR provisions became more appealing to them as they adopted more free market policies and began to feel pressured by isolated bilateral agreements.

In 1990, a “Group of 14” developing nations submitted a GATT proposal concerning regulation of counterfeit goods as well as uniform substantive provisions for IPR protections. This break-through proposal accomplished the three following objectives: (1) it emphasized the importance of public policy objectives underlying national IPR systems; (2) it insisted on the necessity of respect for both national legal tradition regarding IPRs and the diverse needs of the countries participating in the negotiations; and (3) it attempted to minimize the actual substantive IPR standards being considered. The “Group of 14” proposal established the framework for the agreement ultimately adopted in 1994, and many of the developing nations’ concerns are reflected in the text of the TRIPs Agreement.
A. General Provisions of the TRIPs Agreement

According to its terms, the objective of the TRIPs Agreement is that:

[...]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.103

This objective reflects the harmonizing of interests between developed and developing nations, and specific provisions in the agreement further reflect this balancing act. The TRIPs Agreement adopts the substantive provisions of the existing intellectual property conventions, including most of the Paris Convention.104 The principle of national treatment is also expressly incorporated into the TRIPs Agreement.105 The benefits of being a TRIPs member are guaranteed through the incorporation of most-favored-nation treatment.106 Most-favored-nation treatment requires signatories to afford to all other members any privileges their national IPR system gives to foreigners.107 Most-favored-nation treatment is a common feature of GATT agreements, but a new development for international IPR regimes.108 The TRIPs Agreement also establishes enhanced substantive and procedural enforcement mechanisms, designed to give it more teeth than previous IPR treaties.109

In addition to these general provisions, the TRIPs Agreement establishes minimum national standards for IPR protection; however, it does provide an exception permitting members to

103 TRIPs Agreement, supra note 4, art. 7.
104 See id. art. 2.1. The TRIPs Agreement is intended to coexist with prior conventions without derogating any of the obligations of those agreements. Id. art. 2.2.
105 Id. art. 3.
106 Id. art. 4.
107 Id.
108 Yusuf, supra note 21, at 16.
109 German Cavelier, Enforcement of Intellectual Property Rights, in INTELLECTUAL PROP. & INTERNATIONAL TRADE: A GUIDE TO THE URUGUAY ROUND TRIPs AGREEMENT, supra note 3, at 65. The TRIPs Agreement’s enforcement mechanisms are discussed in depth in Part IV.
"adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development." This public policy exception allows member nations to retain a considerable degree of legislative flexibility, subject to the caveat that "such measures are consistent with the provisions of this Agreement." It is likely that this provision will allow nations to take steps that conflict with individual TRIPs provisions, so long as they are consistent with the Agreement as a whole. The specific terms of the Agreement set broad boundaries for the protection of biotechnological inventions, with much ambiguity remaining because of the liberal public interest exception, as well as the incorporation of intentionally vague terms.

B. Specific TRIPs Provisions Relating to Biotechnology

Article 27 of the TRIPs Agreement addresses IPR protection through patents. It states that "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." Member states must offer this protection on a non-discriminatory basis, regardless of

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10 TRIPs Agreement, supra note 4, art. 8.1.
11 Id. See also Yusuf, supra note 21, at 13 (stating that the only restriction imposed upon legislation on IPRs by member states to the TRIPS Agreement is that such legislation is consistent with the Agreement's provisions). This seemingly broad principle is a reflection of the Agreement's objective of balancing the diverse needs of member countries. See id.
12 Yusuf, supra note 21, at 13.
13 See generally TANSEY, supra note 1 (stating that the resulting TRIPs Agreement was born from intense debate and a compromise between various national interests). Article 27.3 (b) of the TRIPs Agreement most directly relates to the patenting of biotechnological innovations. It includes nine words that are subject to interpretation. These vague terms were purposefully incorporated to achieve a temporary compromise on the thorny issues of recognizing IPR protection in biotechnology. See id. at 7.
14 See generally TRIPs Agreement, supra note 4 (defining patentable subject matter). Other forms of IPR protection, including copyrights, trademarks, geographical indications, industrial designs, layout-designs of integrated circuits, protection of undisclosed information, and control of anti-competitive practices in contractual licenses, are dealt with elsewhere in the agreement. See id.
15 TRIPs Agreement, supra note 4, art. 27.1. The terms "inventive step" and "capable of industrial application" are considered synonymous with the requirements of non-obviousness and usefulness. Id. n.5.
the location of invention, the field of technology, or whether a product is imported or locally produced.\textsuperscript{116} In addition to this general requirement, Article 70.8 outlines the application of this protection to pharmaceutical and agricultural chemical products.\textsuperscript{117} This Article requires that intermediate steps be taken to ensure protection of these products.\textsuperscript{118} Protection is granted even during the transitional period incorporated into the TRIPs Agreement that allows less developed nations time to acquire appropriate infrastructure to support compliant IPR regimes.\textsuperscript{119} This specialized treatment is a reflection of the social and economic significance of pharmaceutical and agricultural chemical products, as well as a recognition of the need for IPR protection of these products. It is noteworthy that this treatment is limited to the final product being marketed and does not encompass the creative processes or component parts of these products.\textsuperscript{120} Rather than mandating protection, the TRIPs Agreement specifically exempts these more controversial innovations from its general patent requirements.\textsuperscript{121}

Article 27.2 allows members to exclude from patentability inventions whose commercial use would jeopardize the “ordre public or morality” of their state.\textsuperscript{122} This broad provision explicitly

\textsuperscript{116} See id. art. 27.1. This provision reiterates the generally accepted principle of national treatment. Id.

\textsuperscript{117} Id. art. 70.8.

\textsuperscript{118} See id. art. 70.8. Intermediate protection is obtained by allowing exclusive marketing rights for a product to be granted to the applicant while a patent is pending. Id. art. 70.9. Exclusive marketing rights extend five years or until the patent is granted or rejected, whichever period is shorter. Id. These protections are only afforded to products that have been patented and marketed in at least one other member country since the implementation of the TRIPs Agreement. Id.

\textsuperscript{119} Article 65 sets forth the timeline according to which the original parties to the TRIPs Agreement must comply with its minimum standards. Developed countries had to implement the Agreement within one year of its entry into force; developing countries had an extra four years (until January 2000). Economies in transition from centrally planned to market-based economies also had until January 2000 to comply. The least developed countries have at least a ten-year transition period (until January 2006), with the option to apply for additional extensions. Id. arts. 65.1-65.3, 66.1.

\textsuperscript{120} See Carlos M. Correa, Patent Rights, in INTELLECTUAL PROP. AND INTERNATIONAL TRADE: THE TRIPs AGREEMENT, supra note 21, at 220-221.

\textsuperscript{121} TRIPs Agreement, supra note 4, arts. 27.2-27.3.

\textsuperscript{122} TANSEY, supra note 1, at 6. “Ordre public” is a nebulous term that refers to the fundamentals of a society that cannot be derogated from without endangering the society’s basic institutions. Id.
authorizes the exclusion of certain inventions from patentability in order to “protect human, animal or plant life or health or to avoid serious prejudice to the environment.” The only limitation to this broad exception is that simply having a domestic law prohibiting the exploitation of an invention will not by itself sufficiently implicate the ordre public to qualify under these terms. In addition to the potentially far-reaching ordre public exception created by Article 27.2, Article 27.3(a) specifically allows members to exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals.” This exception reflects the acknowledged public interest in stimulating widespread dispersion of therapeutic innovations.

Although numerous provisions of the TRIPs Agreement implicate the use of IPRs in relation to biological entities, the article most relevant is Article 27.3(b). This Article expands the types of subject matter that may be excluded from patentability to include “plants and animals other than microorganisms.” This sweeping language creates an exception to patentability broader in scope than that adopted by European nations and other legislative bodies adopting a European stance. Under Article 27.3(b), members may also exclude from patentability “essentially

123 TRIPs Agreement, supra note 4, art. 27.2.
124 Id.
125 Id. art. 27.3(a).
126 See Group of Negotiations on Goods (GATT) Negotiating Group on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods, Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay & Pakistan, MTN.GNG/NG11/W/71, ch. 2, arts. 4(1)-4(2) (1990), in INTELLECTUAL PROP. AND INTERNATIONAL TRADE: THE TRIPs AGREEMENT, supra note 21, at 441, 446.
127 TANSEY, supra note 1, at 6-7.
128 TRIPs Agreement, supra note 4, art. 27.3(b).
129 Correa, supra note 120, at 194. According to European law, “only plant varieties and animal races are not patentable.” Id. This more limited exclusion, unlike the TRIPs Agreement, allows for protection of specifically altered organisms. Id. The United States does not exclude from patentability any form of subject matter that meets the statutory definition of being a “new and useful process, article of manufacture, machine or composition of matter.” 35 U.S.C. § 101 (1994); see also Murashige, supra note 14, at 601 (stating that some countries have excluded particular processes and/or products from patentability).
biological processes for the production of plants or animals. This exception, derived from European law, is generally thought to turn on the degree of technical intervention involved in creating the process. The greater the need for intervention, the less likely the process is to be classified as "essentially biological" and the more likely it is to be patentable. In contrast non-biological and microbiological processes related to the production of plants or animals are patentable under the text of Article 27.3(b). A non-biological process refers primarily to a therapeutic treatment of plants that is generally recognized as patentable in Europe. Microbiological processes are harder to define; generally, they are thought to involve the use of microorganisms such as "viruses, algae, bacteria and even cells or cell lines," although the definition of a microorganism may vary by country. Additionally, it is not clear how processes involving only "microbiological" steps are to be treated. These terms and others used in Article 27.3(b) are not defined in the TRIPs Agreement; they are thus subject to national interpretation.

While Article 27.3(b) primarily creates exceptions to patentability, it also provides for a minimum level of protection for plant varieties. Its terms require that "members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

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130 TRIPs Agreement, supra note 4, art. 27.3(b).
131 Correa, supra note 120, at 195.
132 Id. According to this notion, "classical breeding methods are not patentable," but genetic engineering methods are patentable. Id.
133 TRIPs Agreement, supra note 4, art. 27.3(b).
134 Correa, supra note 120, at 196. Non-biological processes would also include cultivation methods. Id.
135 Id.
136 See id. European law generally considers such limited incorporation of a microbiological step sufficient to deem the process patentable; other countries may take a more restrictive view. Id.
137 TANSEY, supra note 1, at 7.
138 TRIPs Agreement, supra note 4, art. 27.3(b). "The reference to a sui generis system may be interpreted as alluding to breeders' rights as developed within UPOV and in the domestic law of many countries." Correa, supra note 120, at 197; see also TANSEY, supra note 1, at 7 (explaining that the meaning of sui generis is not explicitly defined in the TRIPs Agreement thus member nations will their own interpretations of the term).
Like many of the terms in this provision, this flexible standard reflects the international divergence of views on protecting plant varieties. The different systems currently in use allow for a range in both “scope and extent of protection.” Article 27.3(b) also permits members to combine patent systems with other forms of IPRs, further expanding the possible range and methods of protection.

As this brief summary suggests, the language of Article 27.3(b) is both sweeping and vague. It effectuates a temporary compromise among the many competing interests in the protection of biotechnology. The provisional nature of this compromise is evidenced by the inclusion of an early revision date for these provisions (January 1999). This Article is the “only provision in the TRIPs Agreement subject to an early revision, special treatment that again indicates the controversial nature of these issues.” The framers of this Article anticipated a negotiated revision of the terms of Article 27.3(b) as the primary way of resolving this controversy. In addition to lobbying for new agreements favorable to their interests, countries may also seek modification and clarification of these nebulous terms through the use of the World Trade Organization’s administrative committees.

139 Correa, supra note 120, at 197. In Europe, plant varieties are protected under “breeder’s rights” and may not be patented. In both Japan and the United States, however, plant varieties are patentable. Id.

140 Id. For example, patent protection covers particular genes, whereas breeder’s rights protection only applies to specific combinations of genes and not the genes themselves. Id.

141 Id. For example, a system combining patents with other forms of IPR protections might allow for incorporation of “farmer’s rights” which recognize and compensate for the “ancestral contributions” of traditional farmers in developing new plant varieties. Id.

142 See Tansey, supra note 1, at 7. The three-sentence article contains nine terms whose meanings are open to debate: “plants, animals, micro-organisms, essentially biological processes, non-biological, microbiological, plant varieties, effective and sui generis system.” Id.

143 TRIPs Agreement, supra note 4, art. 27.3(b). “The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.” Id. The WTO Agreement entered into force on January 1, 1995. Correa, supra note 120, at 198.

144 Correa, supra note 120, at 198.

145 See McCabe, supra note 7, at 45.
and dispute settlement procedures. In order to understand these options, it is necessary to understand the structure and organization of the WTO.

IV. The Structure and Function of the World Trade Organization

The WTO is a rules-based organization whose primary objective is "to help trade flow smoothly, freely, fairly, and predictably." Its main functions are administration of trade agreements, establishment of a forum for trade negotiations, resolution of trade disputes, review of national trade policies, cooperation with other international organizations, and provision of support for developing countries in trade policy issues. The Ministerial Conference is the top-level decision-making body within the WTO. It is composed of all WTO members, meets at least once every two years, and acts by consensus to affect matters under any of the multilateral trade agreements.

146 See id. at 63.

148 In addition to the TRIPs Agreement, the WTO also administers the Agreement on Trade in Goods and the Agreement on Trade in Services (GATS). World Trade Organization, The Agreements, Overview: A Navigational Guide, at http://www.wto.org/english/thewto_e/whatis_e/inf_m_e/agrms_e.htm (last visited September 9, 2000).

149 For example, one of the provisions of the TRIPs Agreement involves cooperation with the World Intellectual Property Organization, which administers the Paris Convention and other significant treaties. TRIPs Agreement, supra note 4, art. 68.

150 World Trade Organization, supra note 146.
151 Id.
152 Seattle Meeting, supra note 8, at 1. There are 135 member governments in the WTO. Id.
153 Id. The last-scheduled meeting of the Ministerial Conference was to be held in Seattle in November, 1999.
154 World Trade Organization, About the WTO: Whose WTO is it anyway?, at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm (last visited Sept. 9, 2000). In addition to administering the TRIPs Agreement, the WTO monitors the implementation of the General Agreement on Tariffs and Trade—Multilateral Trade Negotiations: Agreements on Trade in Goods, 33 I.L.M. 28 (1994) [hereinafter Agreement on Trade in Goods] and the General Agreement on Tariffs and Trade—Multilateral Trade Negotiations: General Agreement on Trade in Services, 33 I.L.M. 44 (1994) [hereinafter Agreement on Trade in Services]. Id.
Between Ministerial Conference meetings, the General Council supervises the WTO's day-to-day work, which is carried out by committees focused on specific tasks or areas of trade.\(^{155}\) Among these specialized committees, the Council for Trade-Related Aspects of Intellectual Property (TRIPs Council) monitors the operation and implementation of the TRIPs Agreement.\(^5\) The transparency commitments of the TRIPs Agreement facilitate this monitoring process by requiring members to disclosure relevant laws, regulations, final judicial decisions, and administrative rulings.\(^{157}\) Whereas Part III of the TRIPs Agreement provides limited instruction as to requisite domestic enforcement measures,\(^{158}\) the TRIPs Council is more a facilitator of the agreement than an enforcer of its terms.\(^{159}\) The TRIPs Council may recommend changes to or interpretations of the TRIPs Agreement, but only the Ministerial Conference, and at times the General Council, may actually adopt such alterations.\(^{160}\) Thus, any modifications to Article 27.3(b) of the TRIPs Agreement as a result of the early review procedure must be adopted through consensus of the entire WTO membership.\(^{161}\) Additionally, disputes between members are intended to be resolved not by the TRIPs Council, but through the structures created by GATT Article XXIII and the process defined by the Understanding on

\(^{155}\) Id. These focused work groups are also made up of all members of the WTO. Id.

\(^{156}\) See Daphne Yong-d'Herve, Implementation and Administration of TRIPs and Dispute Settlement, in INTELLECTUAL PROP. & INTERNATIONAL TRADE: A GUIDE TO THE URUGUAY ROUND TRIPs AGREEMENT, supra note 3 at 74.

\(^{157}\) TRIPs Agreement, supra note 4, arts. 63.1-63.2.

\(^{158}\) Member states are required to establish fair and equitable civil and administrative procedures and remedies to enforce IPRs. See TRIPs Agreement, supra note 4, arts. 42-49. Members must also ensure adequate provisional measures to avoid irreparable harm to a rights holder while enforcement provisions are being enacted. Id. art. 50. Special provisions are also made for border and criminal procedures; however, none of these requirements creates an obligation for members to establish an enforcement system independent of or in addition to their general law enforcement procedures. Id. arts. 41.5, 51-60, 61.

\(^{159}\) Yong-d'Herve, supra note 156, at 72.

\(^{160}\) Id. at 74.

\(^{161}\) TANSEY, supra note 1, at 13. Contra McCabe, supra note 7, at 64 (suggesting that the TRIPs Council may make interpretations of the vague terms in Article 27.3(b) that would fall short of amendments to the TRIPs Agreement and would not be subject to review by the Ministerial Conference).
Rules and Procedures Governing the Settlement of Disputes (hereinafter DSU). 162 This incorporation of a system for multilateral resolution of intellectual property disputes is one of the most significant features of the TRIPs Agreement. 163

A. The Dispute Settlement Process

In the founding agreement, members of the WTO adopted dispute settlement mechanisms to be administered by the General Council, meeting as the Dispute Settlement Body. 164 These mechanisms, outlined in Article XXIII of the 1994 GATT agreement, were incorporated into all subsequent Uruguay Round agreements, including the TRIPs Agreement. 165 Under this scheme, complaints may be brought for direct violations of or for non-compliance with the terms of the TRIPs Agreement. 166 Beginning in January 2000, members may also bring complaints for the loss of expected benefits under the TRIPs Agreement, whether or not the challenged action directly violates any terms of the treaty. 167

The filing of a written complaint initiates the DSU...
procedure. In that spirit, the first step after the filing of a complaint is consultation between the involved member states, with the possibility of mediation by the WTO Director General, if necessary. If resolution cannot be reached through this consultation process, the complainant party may request that the Dispute Settlement Body (hereinafter DSB) convene an expert panel to hear the dispute. After hearing the dispute, the panel issues a report to the DSB; the DSB then adopts the panel’s recommendation, unless a party appeals or the DSB unanimously rejects the proposed resolution.

After the panel’s or Appellate Body’s report is adopted, the respondent party must comply with the ruling or face sanctions in the form of compensation to the complainant party or withdrawal of concessions. In order to avoid delays in achieving resolution of disputes, there are concrete deadlines set for each phase of the settlement process. According to this timeline, even if an appeal is made, the dispute must be resolved within eighteen months of the filing of the initial written complaint and request for consultation.

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169 Id.

170 Id. arts. 4-5.

171 Id. arts. 6-8.

172 Id. arts. 9-15. In addition to giving each party to the dispute the right to be heard, the DSU also grants that right to any third-party member countries with a substantial interest in the matter. Id. art. 10.

173 Id. Appeals are limited to issues of law and are made to a Standing Appellate Body. The report of the Appellate Body is adopted by the Dispute Settlement Body [hereinafter DSB] , unless there is a consensus decision not to, and must be accepted unconditionally by the parties. Id. art. 17.

174 Id. arts. 16, 20.

175 Id. arts. 21, 22. The parties may independently negotiate appropriate compensatory sanctions, but withdrawal of concessions must be authorized by the DSB. See id. art. 22. Suspension of concessions is meant to serve as a temporary sanction until compliance is achieved. Id. Typically, only concessions or obligations in the same sector as the violation will be affected. Id.

176 See generally id. (describing the deadlines for various phases of arbitration).

177 BANKOLE SODIPO, PIRACY AND COUNTERFEITING: GATT TRIPS AND
As with other facets of the TRIPs Agreement, the DSU reflects the divergent interests of the WTO’s member states. Article 27.2 of the DSU provides for special legal assistance for developing nations involved in dispute settlement procedures.\(^{178}\) Article 24 recognizes the unique situation of the least developed countries and urges members to refrain from using dispute settlement procedures against them.\(^{179}\) Proponents of the DSU mechanism argue that the model balances out the power differential between nations.\(^{180}\) For example, the monitoring process prevents developed countries from unilaterally imposing sanctions against developing nations for alleged violations of the TRIPs Agreement.\(^{181}\) The DSU is designed to limit the possibility of bullying maneuvers by developed nations, while enabling countries dependent upon trade with those wealthier nations to assert their rights under the agreement.\(^{182}\)

The DSU system has generally been successful as a forum for resolving disputes, with about sixty percent of complaints settled through consultation without invoking a dispute panel.\(^{183}\) Additionally, frequent use of the DSU system indicates a high degree of member confidence in it, especially in comparison to the more adversarial and less often utilized enforcement procedures of other international agreements.\(^{184}\) The application of the DSU mechanism to enforcement of the TRIPs Agreement in particular has also met with success, although the process is still in its

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\(^{178}\) DSU, supra note 168, art. 27.2.

\(^{179}\) Id. art. 24.

\(^{180}\) Gutowski, supra note 40, at 735-36.

\(^{181}\) DSU, supra note 168, art. 22.

\(^{182}\) Gutowski, supra note 40, at 735-36. The creation of an enforceable, non-discriminatory multilateral trade system was the stated goal of developing nations throughout the Uruguay Round negotiations. Id. at 736.

\(^{183}\) Id. at 737. These numbers refer to use of the GATT procedure generally, not specifically in enforcement of the TRIPs Agreement. See id. Complainant countries in particular have been satisfied with the procedure, reporting a satisfaction rate of almost ninety percent. Id.

\(^{184}\) Id. The International Court of Justice, the enforcement mechanism for the Paris Convention, heard less than 100 cases in its first fifty years of existence. In contrast, over 400 cases have been taken through the GATT system. See id.
infancy. Thus far, the system has been used almost exclusively by developed nations to ensure compliance with the specific terms of the TRIPs Agreement. The balance of power in the system is likely to even out as the range of possible complaints expands to include non-violations and as more technological developments emerge from developing nations. The strength of these enforcement procedures shapes the impact of the specific terms of the TRIPs Agreement and will likely influence the slated revisions of Article 27.3(b).

B. Review of Article 27.3(b)

The TRIPs Agreement mandated review of Article 27.3(b) beginning in January 1999, but it did not define the procedure or scope for the review. Because of the extended timeframe for transitional arrangements for developing countries, this review is slated to begin before most members will even have attempted to implement the current TRIPs provisions. The lack of data

185 Id. at 737-39. As of 1999, over 100 cases were making their way through the system, indicating significant international confidence in the system. Id. at 743-44.

186 WTO Document Dissemination Facility, at http://www.wto.org/ddf/ep/public .html (last visited Sept. 18, 2000). A review of the documents on intellectual property disputes available through the WTO’s on-line reporting facility listed twenty-one complaints brought to enforce the TRIPs Agreement. All of these complaints were brought by developed countries and over half of them were filed by the United States. Eight of these complaints were filed against developing nations. See id. (These numbers were arrived at by searching the database for all intellectual property dispute documents (search under Dispute Settlement Body Symbol: IP/D). This search produces cites for each IP-related complaint brought to the Dispute Settlement Body, as well as, any resolution that has occurred. The results must be culled to determine which cites indicate new causes of action and which refer to resolutions of previously filed charges. The first party cited on each claim is the defendant to the action, and the party requesting consultation is the complainant.)

187 J.H. Reichman, Universal Minimum Standards of Intellectual Property Protection under the TRIPs Component of the WTO Agreement, in INTELLECTUAL PROP. AND INTERNATIONAL TRADE: THE TRIPs AGREEMENT, supra note 21, at 79. In particular, once GATT Article XXIII 1 (b) applies to the TRIPs Agreement, allowing complaints for nullification of expected benefits, developing countries are likely to seek to hold developed nations accountable for their responsibility to provide technical assistance under Article 67 of the TRIPs Agreement. Id. at 78.

188 Id. at 78.

189 TRIPs Agreement, supra note 4, art. 27.3(b).

190 Id. arts. 65.2-65.4.

191 TANSEY, supra note 1, at 13.
documenting the effects of the first phase of provisions exacerbates the difficulty of redefining the Agreement’s understanding on issues related to patenting biological entities.192 Some members argue that the review should be an examination of the extent to which the current provisions have been implemented.193 Other members favor a more substantive process that might encompass changing the text of the article.194

One possible solution to this difficulty might be to summarily execute a review, postponing any significant substantive or procedural changes until more information is available.195 Such preservation of the status quo would maintain the tentative compromise reached on issues of IPRs in relation to biotechnology and life forms.196 Opponents of this approach focus on the possibility that members may attempt to bypass WTO amendment procedures and define the vague terms of Article 27.3(b) through other means.197

One such avenue is the TRIPs Council, which some commentators suggest has the power to modify the TRIPs Agreement without requiring the approval of the Ministerial Conference.198 This procedural loophole turns on interpretation of the language of Article 71.1 of the agreement, which empowers the TRIPs Council to “undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.”199 Some commentators argue that this broad language gives the TRIPs Council the authority to issue statements of interpretation unreviewable by the Ministerial

192 Id.
193 See id. This is the approach advocated by most developed nations. Although these countries would eventually like to see many of the vague terms of Article 27.3(b) defined or deleted, they are concerned that any immediate attempt to change the terms will lead to a weakening of IPR provisions. See id. at 13-14.
194 See id. at 13. This is the viewpoint espoused by many developing nations unhappy with any delineation of plants and animals as patentable materials. See id. at 13-15.
195 See Doane, supra note 93, at 275.
196 See id.
197 See Reichman, supra note 187, at 78, 91.
198 McCabe, supra note 7, at 63-64.
199 TRIPs Agreement, supra note 4, art. 71.1.
Conference so long as they only modify existing TRIPs terms.\textsuperscript{200} Whether the TRIPs Council has this power under Article 71 is debatable,\textsuperscript{201} as is whether the Council would exercise that power if it were available. It is noteworthy, however, that the potential bypass of the consensus-based decision making of the Ministerial Conference was suggested specifically in relation to revision of Article 27.3(b).\textsuperscript{202}

Another possible means of bypassing the Ministerial Conference is through the WTO’s Dispute Settlement Body, whose panels issue decisions that become binding on the parties involved and set precedents for other members in future disputes.\textsuperscript{203} These panels could be used to define nebulous terms and effectively limit the ability of member countries to determine the precise scope of IPR holders under domestic laws.\textsuperscript{204} The central concern with clarifying terms through case-by-case

\textsuperscript{200} See id.

\textsuperscript{201} Article 71.2 of the TRIPs Agreement outlines the limited situation in which modification actions may be taken by force of recommendation from the TRIPs Council, stating that:

\begin{quote}
[a]mendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPs.
\end{quote}

TRIPs Agreement, supra note 4, art. 71.2. It is unlikely that a more general ability to circumvent the amendment procedure was intended in Article 71.1.

\textsuperscript{202} McCabe, supra note 7, at 63-64. McCabe suggests that the United States, with the help of Japan and the European Union, could lobby the TRIPs Council to issue a statement of interpretation ruling that Article 27.3(b) requires the extension of patent protection to plants or animals made by non-biological and microbiological processes. Id. He advocates this approach as a way to extend the protection available under the TRIPS agreement without having to achieve consensus in the Ministerial Conference. Id.

\textsuperscript{203} Reichman, supra note 187, at 78, 91.

\textsuperscript{204} See Moncayo von Hase, supra note 167, at 141. Article 27.3(b) is not the only provision of the TRIPS Agreement susceptible to interpretation and expansion through the DSU mechanism. See id. For example, Article 41.5 gives member states the right not to augment their judicial and administrative systems in order to provide for TRIPS-required IPR protection. See id. Many developing countries have rudimentary infrastructures and limited resources to administer the requisite IPR framework. See id. Dispute panels are likely to be faced with the challenge of distinguishing between willful non-compliance with the obligations of the agreement and genuine lack of capacity to do so. Reichman, supra note 187, at 77.
decision making is that it will produce shortsighted decisions with unfortunate local and international effects.\footnote{205}{See Reichman, \textit{supra} note 187, at 91.}

As of yet, no complaints have been filed concerning the terms of Article 27.3(b),\footnote{206}{TANSEY, \textit{supra} note 1, at 17.} so no attempts have been made to abuse the DSU process by circumventing the negotiating bodies of the WTO. Despite the lack of direct legal action, the threat of such action may still affect domestic policy decisions regarding interpretation of the terms of the Article.\footnote{207}{\textit{Id.} Governments may refrain from following reasonable and appropriate interpretations of the Article's terms out of fear of opening themselves to costly legal challenges. \textit{See id.}} This potential effect in addition to general dissatisfaction with the Article's current terms make it likely that the review process will attempt to alter the specific provisions of Article 27.3(b).\footnote{208}{\textit{See id.} at 14-15. In September 1999, Kenya, on behalf of many African countries, tabled a proposal to institute a moratorium on implementing Article 27.3(b) of the TRIPs Agreement. This proposal also called for complete exclusion from patentability plants, animals, and microorganisms. Non-governmental organizations also supported this proposal. \textit{Trips, Patents and the WTO Farm Trade Talks, AGRA EUROPE A/3, October 15, 1999, available at LEXIS, Agriculture, Fishing and Tobacco Stories, IAC-ACC-NO: 56914962.}} Attempts at substantive revision of Article 27.3(b) will pose additional challenges arising from the WTO structure.\footnote{209}{\textit{See infra} notes 210-65 and accompanying text.}

V. The Implications of Using the WTO Framework to Establish Global IPRs

\textbf{A. The Difficulty of Action by the WTO}

According to the WTO Agreement,\footnote{210}{\textit{See WTO Agreement, \textit{supra} note 94.}} unanimous action by either the Ministerial Conference or the General Council is required to amend the TRIPs Agreement.\footnote{211}{Yong-d'Herve, \textit{supra} note 156, at 74. Proposals for amendment may be made by any member country or by the TRIPs Council. \textit{Id.}} This requirement of consensus is likely to hamper any attempts to significantly revise the terms of Article 27.3(b) during the early review process. As has been suggested, the issues involved in patenting life forms are
highly controversial. The differences among WTO member countries in philosophy, policy, and priorities concerning IPR protection of biological entities are most pronounced between developing and developed nations.

Economically, countries clash over whether to focus on encouraging the cheapest and most widespread use of technology or on preventing piracy and misappropriation of innovations. The increasing privatization of knowledge is a concern for developing countries attempting to expand their domestic economies and technological and scientific resource bases. In addition to a likely immediate increase in the cost of acquiring technological developments, a particular concern for these countries in relation to biotechnology is the trickle-down effect that enhanced IPR protection is likely to have on breeding materials. Studies of the flow of germplasm (breeding materials of plants) indicate that stronger IPRs lead to restricted access to these supplies, which in turn inhibits the development of new plant varieties, especially through publicly funded research.

On the other side of this issue, the economies of many developed countries are becoming increasingly dependent on the products of the mind. Such dependency makes these countries particularly wary of weak IPR regimes that allow for the copying

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212 See supra notes 82-92 and accompanying text; infra notes 214-28 and accompanying text.

213 TANSEY, supra note 1. The marked contrast between the interests of developed and developing countries overshadows the divergence of interests between nations within each of these groupings. Id. at 14-15. Among developed countries, differences primarily focus on the nature and scope of IPR protection. Id. at 14. "The developing countries have a wide range of interest depending on their factors such as: whether they are net food importers or exporters; how extensive their biodiversity is; the nature of their farming economy; the degree of industrialisation [sic]; and whether they have an established biotech industry or not." Id.

214 Carlos Alberto Primo Braga, Conflicting Theories of Economic Value, in INTERNATIONAL INTELLECTUAL PROP. LAW, supra note 32, at 50-51.

215 Tara Kalagher Giunta & Lily H. Shang, Intellectual Property Protection in Developing Countries, in INTERNATIONAL INTELLECTUAL PROP. LAW, supra note 32 at 445-46.

216 TANSEY, supra note 1, at 19.

217 Id. at 19-20. This concern has impacted the seed industry in particular, which has actively sought to ensure an adequate flow of germplasm. Id.

218 Giunta & Shang, supra note 215, at 446.
of valuable advancements, especially in the lucrative, but vulnerable field of biotechnology.\textsuperscript{219} The divergent economic interests between developed and developing countries will make it difficult to reach consensus as to how the terms of Article 27.3(b) should be revised.\textsuperscript{220}

Cultural differences between WTO member nations may also pose challenges to achieving consensus on these issues.\textsuperscript{221} The frameworks for IPR regimes in most developed countries recognize the rights of one inventor to the "'new' knowledge" he has created.\textsuperscript{222} Not only do the cultures of many developing countries fundamentally disagree with this concept,\textsuperscript{223} but they would like to broaden the definition of who can be a holder of an IPR.\textsuperscript{224} Indeed, there is a growing movement to recognize communal rights in intellectual property, particularly for indigenous cultures.\textsuperscript{225}

In light of these concerns, some commentators advocate the incorporation of provisions or concepts from the Biodiversity Convention into the TRIPs Agreement.\textsuperscript{226} Not only does the

\textsuperscript{219} \textit{Id.} Recent studies conducted by the United States government indicate that billions of dollars and thousands of jobs are lost each year due to counterfeiting practices. \textit{Id.}

\textsuperscript{220} \textit{Tansey}, \textit{supra} note 1, at 14-15. For example, the United States would ultimately like to delete the clause allowing plants and animals to be exempted from patentability. \textit{Id.} In contrast, advocates in some developing countries want to maintain the patentability exemptions and delete the requirement of a \textit{sui generis} system of protection for plant varieties. \textit{See id.}

\textsuperscript{221} \textit{See generally David Hurlbut, Hegel, Individual Will and Non-Western Cultures, in INTERNATIONAL INTELLECTUAL PROP. LAW, supra note 32 at 35-39 (discussing the historical and cultural influences that have shaped European, African, and Indian conceptualizations of intellectual property).}

\textsuperscript{222} \textit{Tejera, supra} note 88, at 974. This individual rights concept is the basis for the current form of the TRIPs agreement. \textit{See id.}

\textsuperscript{223} \textit{Tansey, supra} note 1, at 18. Many indigenous "religious and cultural traditions regard the extension of patents to living organisms" as a commodification of life and an attempt to recognize a human stake in what is essentially a divine creation. \textit{Id.} An additional concern of many of these cultures is that the recognition of such IPR rights will ultimately lead to disruption of the interdependence of the natural world. \textit{Id.}

\textsuperscript{224} \textit{See Primo Braga, supra} note 214, at 48-49. This broadened definition is, in part, a reflection of the higher value developing countries generally place on social interests, loosely defined, over public interests. \textit{Id.}

\textsuperscript{225} \textit{Tejera, supra} note 88, at 968-71.

\textsuperscript{226} \textit{Id.} at 980-86; \textit{Sarma, supra} note 16, at 120-22. To this end, representatives from
Biodiversity Convention recognize the right of indigenous cultures to preserve their knowledge and resources, it also places significant value on protecting natural resources and ensuring that their custodians share in the rewards of their commercial use while monitoring their exploitation. These concepts find widespread support in many developing countries, but may also be the reason some developed nations hesitated in signing the Biodiversity Convention.

This clash in cultural values is likely to become more pronounced as each side attempts to alter or do away with the parts of Article 27.3(b) most in conflict with their norms and priorities. The TRIPs Agreement is founded on concepts of intellectual property that are predominant in developed countries, but attempts have been made to incorporate other value systems into the Agreement. The contentious debates that are likely to ensue will make achieving new consensus on these issues challenging at best. Thus, the consensus requirement imposed by the WTO's structure will likely make significant developments in this area difficult.

**B. The Legitimacy of Action by the WTO**

Despite the requirement of consensus action, developing countries distrust the WTO in general, and the TRIPs Agreement

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227 See Tejera, supra note 88, at 982-84.

228 See Sarma, supra note 16, at 121. The United States delayed in joining the Biodiversity Convention in part because it required "compensation for use of biological resources and transfer of technology." Id.

229 Tansey, supra note 1, at 14-15.

230 Sarma, supra note 16, at 121. India is a developing country at the forefront of the fight against the priorities imposed by developed nations; Indian patent law refuses to recognize IPRs in the area of biodiversity. Id. at 132. Furthermore, Indian representatives are lobbying for changes to the current Article 27.3(b) provisions to accommodate this stand. See Tansey, supra note 1, at 16. Additional resistance to the TRIPs terms is evidenced by the fact that WTO dispute and appellate panels were compelled to order the Indian legislature to establish adequate protections for pharmaceutical and agricultural products in compliance with the requirements of Article 70.8. Gutowski, supra note 41, at 741-42.
in particular because they perceive them as a means for developed
countries to assert power and inculcate their value systems.\textsuperscript{231} Decisions concerning IPR protection for biological entities
implicate issues of economics, religion, health, agriculture,
environmentalism, and cultural identity.\textsuperscript{232} Attempts to harmonize
this body of law traditionally governed by individual nations have
great implications for the concept of national sovereignty.\textsuperscript{233}
Although the TRIPs Agreement does not dictate the manner in
which its provisions are incorporated into members' domestic
policies,\textsuperscript{234} the scope and nature of the rights it establishes
represent a significant increase in external influence on substantive
local decisions.\textsuperscript{235} The effect of this influence can be seen in an
analysis of the potential modes of review for Article 27.3(b).

The current text of Article 27.3(b) represents a compromise
among the different policy interests of WTO member states. It
provides greater protection than some countries would prefer and
less than others would like.\textsuperscript{236} Under this scheme, a minimum
standard of patentability is established, although countries are
allowed to provide stronger protection than the terms mandated by
the agreement.\textsuperscript{237} Typically, any advocated changes would lead to
less flexibility and greater substantive harmonization of domestic

\begin{itemize}
\item \textsuperscript{231} Sarma, \textit{supra} note 16, at 125. This distrust exists despite WTO Treaty provisions
asserting that all WTO contracting parties are considered equals and that the outlined
decision-making process is a democratic one. \textit{Id}. One commentator suggests that the
differences in resources between members of the WTO do in fact call into question the
equity of the negotiating parties and the legitimacy of decisions made. TANSEY, \textit{supra}
note 1, at 19.
\item \textsuperscript{232} TANSEY, \textit{supra} note 1, at 18-22.
\item \textsuperscript{233} Gutowski, \textit{supra} note 41, at 744-47.
\item \textsuperscript{234} TRIPs Agreement, \textit{supra} note 4, art. 1.1. This Article specifically provides that
"[m]embers shall be free to determine the appropriate method of implementing the
provisions of this Agreement within their own legal system and practice." \textit{Id}.
\item \textsuperscript{235} Gutowski, \textit{supra} note 41, at 745.
\item \textsuperscript{236} Doane, \textit{supra} note 93, at 275. Developed countries generally see this
compromise as providing insufficient protection for the burgeoning biotechnology
industry. \textit{Id}.
\item \textsuperscript{237} TRIPs Agreement, \textit{supra} note 4, art. 27. A comparison of the language of the
subsections of this Article delineates the basic guidelines that are established and the
flexibility that countries may exercise in raising this floor of protection. \textit{Id}. Article 27.1
uses the language "shall be available" in setting forth the minimum requirements of
patentability, whereas Articles 27.2 and 27.3 use the language "may exclude" in
outlining the possible subject matter exceptions to those requirements. \textit{See id}.
\end{itemize}
In practice, the trend in harmonization of patent laws is to move toward the standards established by developed countries.\textsuperscript{239} With respect to Article 27.3(b), this would mean deleting the patentability exceptions of Article 27.3(b).\textsuperscript{240} As has been indicated, this change would drastically alter the level of IPR protection currently available in most developing nations.\textsuperscript{241} Such a change would not only entail a shift in policy, but would also require a significant bolstering of most countries' infrastructures to adequately enforce such rights.\textsuperscript{242} The questionable wisdom of requiring a developing country to use its limited resources to enforce primarily foreign property rights presents a significant obstacle to establishing more expansive IPRs.\textsuperscript{243} Another hurdle is the symbolic significance of turning over such important decisions to an international body with questionable equity among member governments and little accountability to individual citizens.\textsuperscript{244}

With the increasing interconnectedness of the global community, concerns about loss of individual national identity and sovereign control are not unique to the TRIPs Agreement; however, as it is a component of the WTO, it can be a lightning

\textsuperscript{238} See Reichman, supra note 187, at 29-30, 40-41.

\textsuperscript{239} Long & D'Amato, supra note 34, at 9.

\textsuperscript{240} TANSEY, supra note 1, at 14. Article 27.3(b) excludes from patentability "plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." TRIPS Agreement, supra note 4, art. 27.3(b). Deleting these exceptions, the stance advocated by the United States, would bring the terms of the TRIPs Agreement into line with American patent laws. TANSEY, supra note 1, at 13-14. This change is generally supported by the agricultural, biotechnology, and pharmaceutical industries and therefore would likely be favored by other developed nations as well. \textit{Id.}

\textsuperscript{241} See supra notes 213-16 and accompanying text; supra notes 220-27 and accompanying text.

\textsuperscript{242} See Reichman, supra note 187, at 87.

\textsuperscript{243} Gutowski, supra note 41, at 749. For example, Disney attempted to enforce its copyright against Chilean Marxists to limit distribution of a book entitled \textit{How to Read Donald Duck}. \textit{Id.} "One might well question the wisdom of countries beleaguered by the challenges and social costs of malnutrition, child prostitution, sex tourism, AIDS, foreign debt, and structural adjustment policies putting scarce resources into tracking down those who would appropriate Looney Tunes characters. \ldots\" \textit{Id.} at 749.

\textsuperscript{244} See TANSEY, supra note 1, at 18-19.
The TRIPs Agreement and the WTO are part of the changing face of international law. Traditionally, international law focused on duties and obligations owed between sovereign states, and affected citizens only through the intermediary of their sovereign. Historically, this area of law focused on issues over which conflicts between nations were likely to arise and domestic policies and interests were typically weak. In this context, conflicts between international law and domestic law were minimal.

In recent years, political and societal trends have converged to increase the interconnectedness of national interests and shrink the realm in which state action can occur without reliance on or repercussions for the interests of other countries. The new international laws that have emerged from this evolving globalization are different in both form and function from their predecessors. The new laws operate through international bodies that promulgate rules constraining individuals fairly directly, and

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247 Id. at 1561. For example, admiralty is an area where international law has historically been active and domestic legislation has been limited. Id.

248 Id.

249 The relevant political trends of the last century are: a recognition of the role international law can play in relation not just between rulers but also between ruler and ruled, see id. at 1569; separation of principles of national self-determination from concepts of pure citizenry and state sovereignty, see id.; and emergence of international institutions from the rubble of the three great conflicts of the twentieth century, World War I, World War II, and the Cold War which have significantly formalized the practice of international law. Id. at 1569-74.

250 The relevant societal trends of the last century are: "(1) [the development of] science and its application in technology; (2) [the] dissemination of information; (3) popular organized action in public affairs; (4) [the] emergence of international environmental organizations; (5) global economic growth; and (6) [the] proliferation of people." Caldwell, supra note 244, at 230.

251 Id. at 228-30.

252 See Stephan, supra note 246, at 1563.
these bodies have a much more formal institutional structure than did their predecessors. Functionally, many of the recent laws promulgated by these international bodies effectively supplant domestic regulations. These changes have led to concerns over the waning importance of the nation state and the increasing influence of global corporations and other non-governmental actors. Notwithstanding the significance of these developments, the weightiest criticism of this new world order is that it brings with it a striking deficit of accountability.

The legitimacy of domestic government is typically gauged by the ability of its citizens to hold lawmakers accountable for their actions. In the planning stages, accountability can be achieved through the people’s influence over the content of the decisions made. As policy decisions are implemented, an individual’s ability to exit, or opt out of, the system also checks the use of the sovereign power. As international organizations begin behaving in ways similar to national governments, questions of the legitimacy of such conduct and the demand for accountability through exit and voice become relevant as well.

One of the most frequently cited concerns about the WTO and its subordinate organizations is that they displace national policymakers and operate through an unrepresentative decision-making process. In response to these accusations, supporters of

253 Id. Examples of these bodies include the WTO, the European Court of Justice, and the International Monetary Fund. See id.

254 Id. at 1561.

255 Id. at 1562; see also Caldwell, supra note 245, at 234-35 (stating that multinational corporations' activities will impact the global environment and promote new provisions in international law in this area).

256 Stephan, supra note 245, at 1562.

257 Id.

258 Id.

259 Id.

260 Id.

261 Seattle Meeting, supra note 9, at 27-29. For example, the TRIPs Agreement establishes essentially global minimum standards of IPR protection. Id. These rights are essentially created in private parties, but can only be redressed through action by national governments. Id. The direct impact on individual citizens who have little ability to influence the decisions being made strikes at the heart of these concerns. Reichman, supra note 187, at 77.
the WTO model emphasize its voluntary membership and operation by consensus.\textsuperscript{262} As one commentator points out, however, emphasizing waiver of sovereign immunity by sovereign states does not address the issue of lack of individual influence over an increasingly powerful standard-setting body.\textsuperscript{263} As the members of the WTO attempt to deal with highly controversial issues such as those implicated by Article 27.3(b), questions surrounding the legitimacy of such decisions are likely to become more pronounced.\textsuperscript{264} Who is involved in making these decisions and whether and how their voices are heard and valued will affect the outcome of the review process.\textsuperscript{265}

VI. Conclusion

Global harmonization of substantive IPR laws arguably offers significant benefit to the world economy, as well as to individual nations.\textsuperscript{266} Over the course of the twentieth century, international agreements on IPRs have slowly moved in the direction of establishing global minimum protective standards.\textsuperscript{267} These standards have tended to emerge from the existing laws and philosophies of developed nations with little accommodation for

\textsuperscript{262} Sara Dillon, Fuji-Kodak, the WTO, and the Death of Domestic Political Constituencies, 8 MINN. J. GLOBAL TRADE 197, 204-06 (1999).

\textsuperscript{263} Id. “Many experts justify the WTO system by noting that individual states have ratified the WTO Agreement. Even so, the state cannot legitimately waive the democratic rights of its citizens to influence the content of national legislation (footnotes omitted).” Id. at 205.

\textsuperscript{264} Id. Article 27.3(b) addresses the level of IPR protection and thus the potential cost of biotechnology products essential to the life and health of the world’s citizens. See id.

\textsuperscript{265} Tansey, supra note 1, at 14. In addition to member states, non-governmental organizations like biotechnology companies are likely to have a significant influence on the outcome of the review process, at least indirectly. Id. There is also a movement to involve indigenous cultures in decisions on biotechnology patenting. Sarma, supra note 16, at 127-29. Only through joining interest groups that petition their national representatives, however, can an average citizen have a role in the process.

\textsuperscript{266} Murashige, supra note 14, at 592-95. The primary benefit of harmonization is the encouragement of research in beneficial areas and the stimulation of the marketing and distribution of the fruits of those labors worldwide. Id. at 594-95. In the short term, these benefits will accrue most directly to developed countries. Id. In the long run, however, developing countries are also expected to reap these benefits and profit from an attendant increase in the transfer of technology. Id.

\textsuperscript{267} Monroe et al., supra note 2, at 6-19.
the divergent cultures and interests of less developed countries.\textsuperscript{268} The apex of this still-emerging trend has been the creation of the WTO and the signing of the TRIPs Agreement.

The TRIPs Agreement combines basic guidelines for IPR protection with significant enforcement mechanisms, effectively revolutionizing international intellectual property law.\textsuperscript{269} Although the TRIPS Agreement signifies a giant step toward globalizing IPRs, this movement has just begun. One of the most significant hurdles will be finding common ground between the many divergent interests affected by IPR standards.\textsuperscript{270} These differences are particularly notable in the area of protection of biotechnology innovations.\textsuperscript{271} The concept of patenting life forms has moral, social, economic, cultural, and religious implications, making mutual agreement on appropriate treatment difficult to achieve.\textsuperscript{272} A tenuous compromise on these issues was reached with the creation of Article 27.3(b) of the TRIPs Agreement.\textsuperscript{273} The scheduled review of the terms of this compromise is likely to produce conflict over the specific standards set, as well as the processes used to establish them.\textsuperscript{274} Proceeding with caution is therefore essential under the circumstances.

Although ostensibly a representative body, the WTO is criticized for having limited accountability and not giving equal weight to the interests of all its members.\textsuperscript{275} In order to produce lasting achievements in establishing the substantive IPR policies many feel are crucial to fostering international trade, the WTO must first ensure that its actions are perceived as legitimate by both its sovereign member states and their citizens. As such, the process of reviewing and revising the terms of Article 27.3(b) will prove just as important as the outcome achieved.

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\textsuperscript{268} Long & D'Amato, supra note 34, at 9.
\textsuperscript{269} Saylor & Beton, supra note 3, at 13-15.
\textsuperscript{270} See supra notes 13-32 and accompanying text.
\textsuperscript{271} See supra notes 209-29 and accompanying text.
\textsuperscript{272} TANSEY, supra note 1, at 18-22.
\textsuperscript{273} Doane, supra note 93, at 275.
\textsuperscript{274} See supra notes 230-64 and accompanying text.
\textsuperscript{275} Dillon, supra note 262, at 204-06.