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The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology

Kevin W. McCabe
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. (Washington, D.C.)

THE JANUARY 1999 REVIEW OF ARTICLE 27 OF THE TRIPS AGREEMENT: DIVERGING VIEWS OF DEVELOPED AND DEVELOPING COUNTRIES TOWARD THE PATENTABILITY OF BIOTECHNOLOGY

*Kevin W. McCabe**

CONTENTS

* Associate, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. (Washington, D.C.). B.S. 1992, University of Richmond; M.S. 1995, University of Maryland; J.D. January 1999, George Washington University. Any views or opinions in this Article are solely those of the author and do not necessarily represent those of Finnegan, Henderson, Farabow, Garrett & Dunner.

I. INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was introduced under the General Agreement of Tariffs and Trade (GATT) in order to set an international minimum standard for the protection of intellectual property.[1] One of the goals of the United States in the Uruguay Round was to ensure that the TRIPS Agreement included a mechanism for the advancement and adjustment of international intellectual property protection.[2] The United States additionally sought broad patent protection for all patentable subject matter, including plants and living organisms.[3] The United States biotechnology industry

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[1] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, *reprinted in* THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS - THE LEGAL TEXTS 1-3 (1994) [hereinafter RESULTS OF THE URUGUAY ROUND]; Marrakesh Agreement Establishing the World Trade Organization, Annex 1C [hereinafter WTO Agreement], *reprinted in* RESULTS OF THE URUGUAY ROUND 6-19, 365-403; Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994 [hereinafter TRIPS Agreement], *reprinted in* RESULTS OF THE URUGUAY ROUND 6-19, 365-403. *See also* Uruguay Round Agreements Act, Pub. L. No. 103-465, §§ 101-103, 108 Stat. 4809 (1994) (regulating international intellectual property). The WIPO and the WTO have entered into a general agreement regarding how the two organizations shall cooperate. *Agreement between the World Intellectual Property Organization and the World Trade Organizations* (visited Feb. 18, 1998) <http://www.wto.org/wto/intellec/17-wipo.htm>.

At least one commentator, with a pro-developing country viewpoint, has challenged the purpose of the TRIPS Agreement. *See* VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 81 (1997) ("The TRIPs agreement of GATT is not the result of democratic negotiations between the larger public and commercial interests or between industrialized countries and the Third World. It is the imposition of values and interests by Western transnational corporations on the diverse societies and cultures of the world.").

Because the TRIPS Agreement was the product of multilateral negotiations, the TRIPS Agreement represents a compromise between countries with strongly opposing views regarding the value of intellectual property for development. Robert M. Sherwood, *The TRIPS Agreement: Implications for Developing Countries*, 37 IDEA 491, 494 (1997).

[2] Michael L. Doane, *TRIPS and International Intellectual Property Protection in an Age of Advancing Technology*, 9 AM. U. J. INT'L L. & POL'Y 465, 468 (1994) (citing Mark C. Damschroder, *Intellectual Property Rights and the GATT: United States Goals in the Uruguay Round*, 21 VAND. J. TRANSNAT'L L. 367, 391 (1988)).

While the developed countries sought expanded protection for intellectual property, developing countries sought measures that would have weakened the then existing obligations for protecting intellectual property. J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT'L LAW. 345, 351 (1995).

[3] J. Benjamin Bai, Comment, *Protecting Plant Varieties under TRIPS and NAFTA: Should Utility Patents be Available for Plants?*, 32 TEX. INT'L L.J. 139, 141 (1997) (citing GATT Secretariat, *Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights*, pt. 2, art. 33, MTN.GNG/NG11/W/70 (May 11, 1990)). *See also* Klaus Bosselmann,

sought two additional concessions during the negotiations of the TRIPS Agreement. First, the United States biotechnology industry wanted to secure a minimum term of patent protection of twenty years from the date of filing.[4] Second, the industry wanted to secure an expansion on the definition of what constitutes patentable subject matter.[5] The developing countries sought, however, to shorten the term of patent protection, and to narrow the definition of patentable subject matter by excluding plants and living organisms from the definition of patentable subject matter.[6]

While the United States successfully lobbied for a minimum term of patent protection of twenty years from the date of filing,[7] the provision governing the patentability of living organisms and biological processes, which encompassed micro-organisms, seeds, plants and animals, proved to be more controversial.[8] In order to obtain the support of developing countries, provisions were added

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Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity, 7 COLO. J. INT'L ENVTL. L. & POL'Y 111, 127 (1996) (stating that the U.S. sought protection of biological inventions, including pharmaceutical products and processes).

The developed countries were able to obtain safeguards for the protection of pharmaceuticals and agrochemicals, including a pipeline provision that provides pharmaceutical and agrochemical patents at least five years of exclusive rights in countries that previously did not grant patents in these areas. TRIPS Agreement, *supra* note 1, art. 70(8), (9). *See also* Reichman, *supra* note 2, at 353 (citing the TRIPS Agreement at art. 70(8), (9)).

[4] *General Agreement on Tariffs and Trade (GATT): Intellectual Property Provisions: Hearing on H.R. 4894 Before the Subcomm. on Intellectual Property and Judicial Admin. of the House Comm. on the Judiciary and S. 2368 Before the Subcomm. on Patents, Copyrights, and Trademarks of the Senate Comm. on the Judiciary*, 103d Cong. 403 (1994) (statement of Genentech, Inc.).

[5] *Id.*

[6] Bosselmann, *supra* note 3, at 127; Bai, *supra* note 3, at 141-42 (citing GATT Secretariat, *Communication from Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay*, pt. 2, art. 4(1)(ii), MTN.GNG/NG11/W/71 (May 15, 1990)).

For example, Brazil, India and Peru strongly resisted the establishment of a minimum term of patent protection. Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, *in* FROM GATT TO TRIPS - THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 161, 198 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996). *See also* Vandana Date, *Global "Development" and its Environmental Ramifications - The Interlinking of Ecologically Sustainable Development and Intellectual Property Rights*, 27 GOLDEN GATE U. L. REV. 631, 655 (1997) ("[D]eveloped and developing nations have different goals for preservation of biodiversity and protection of [intellectual property rights].").

[7] TRIPS Agreement, *supra* note 1, art. 33.

[8] *See* David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 114 (1995) (noting the need to make concessions in these provisions).

to the TRIPS allowing for preclusion from patentability methods for the treatment of humans or animals, essentially biological processes for the production of plants and animals, and plants and animals themselves.[9] As a final concession, however, all parties agreed to review these provisions four years after the implementation of the TRIPS Agreement.[10] This review is scheduled to begin in January 1999, and no deadline has been set for completing the review.[11] The World Trade Organization (WTO) will constitute the forum for these additional negotiations.[12]

This Article explores the present provisions on the patentability of biotechnology inventions under the TRIPS Agreement and the divergent positions of developed and developing countries toward this issue. Specifically, Part I of this Article discusses the relationship between the biotechnology industry and a strong intellectual property regime. Part II reviews the provisions on the patentability of biotechnology subject matter under the TRIPS Agreement. Part III explores the different viewpoints of developed countries and developing countries (including less developed countries) with respect to patent protection of biotechnology. Part IV discusses potential ways of bridging the gap between the viewpoints of the developed and developing countries regarding patent protection for biotechnology. Part V discusses the possible ramifications of inadequate intellectual property protection on the developing countries.

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[9] TRIPS Agreement, *supra* note 1, art. 27, para. 3. *See also* Scalise & Nugent, *supra* note 8, at 115 (describing concessions by supporters to removal of intellectual property protection for micro-organisms, nonbiological, and microbiological processes for the production of plants and animals).

It has been suggested that the European Community proposal served as the basis for the final wording of this provision. Ana María Pacón, *What will TRIPs do for Developing Countries?*, *in* FROM GATT TO TRIPS - THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 329, 343 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996) (citing van Wijk, *GATT and the Legal Protection of Plants in the Third World*, 10 BIOTECHNOLOGY & DEV. MONITOR 14 (1992)).

[10] TRIPS Agreement, *supra* note 1, art. 27, para. 3.

[11] *WTO Implementation Report: Trade-Related Intellectual Property Rights* (visited Feb. 18, 1998), <http://www.ustr.gov/reports/wto/intellectual_property.html>. Article 71 of the TRIPS Agreement also authorizes the TRIPS Council to "undertake reviews in the light of any relevant new developments which might warrant modification or amendment of the Agreement." TRIPS Agreement, *supra* note 1, art. 71, para. 1. It is likely, however, that this review will not occur at its scheduled time.

[12] Adrian Otten & Hannu Wager, *Compliance with TRIPS: The Emerging World View*, 29 VAND. J. TRANSNAT'L L. 391, 413 (1996).

II. RELATIONSHIP BETWEEN THE BIOTECHNOLOGY INDUSTRY AND A STRONG INTELLECTUAL PROPERTY REGIME

A. INTELLECTUAL PROPERTY PROTECTION IN DEVELOPED COUNTRIES

In developed countries, the exclusive rights provided by patent protection[13] act "as an incentive to inventors to risk the often enormous costs of invention in terms of time, research and development."[14] It has been suggested that the patent system stimulates investment by reducing the risk of innovation.[15] Because the patent system vests in an inventor this exclusive right, the patent holder or its licensees may be able to obtain an enhanced return in the subject invention.[16] Any exclusive right,

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[13] It has been argued that the intellectual property systems of developed countries rest on three basic premises. These premises are as follows:

1. that "development," defined at least in part as including economic growth, is a desirable goal for all modern societies;
2. that technological innovation contributes in some beneficial way to economic growth; and,
3. that the existence of a legal framework that protects inventions from theft or copying by others stimulates technological innovation.

David Silverstein, *Intellectual Property Rights, Trading Patterns and Practices, Wealth Distribution, Development and Standards of Living: A North-South Perspective on Patent Law Harmonization, in* INTERNATIONAL TRADE AND INTELLECTUAL PROPERTY: THE SEARCH FOR A BALANCED SYSTEM 155, 158 (George R. Stewart et al. eds., 1994).

[14] Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974). *See also* 35 U.S.C. § 271 (1994 & Supp. II 1996) (describing conditions upon which an inventor may base an infringement action).

[15] Sherwood, *supra* note 1, at 492. *See also* Kevin W. McCabe, Note, *Implications of the* CellPro *Determination on Inventions Made with Federal Assistance: Will the Government Ever Exercise Its March-In Right?*, 27 PUB. CONT. L.J. 645, 648 (1998) ("The market exclusivity provided by patent protection affords patent owners the opportunity to realize a return on their investment."). However, this concept has been challenged by some commentators. *See, e.g.*, SHIVA, *supra* note 1, at 13 ("There is virtually no evidence that patents actually stimulate invention.").

[16] PHILIP AREEDA & LOUIS KAPLOW, ANTITRUST ANALYSIS § 336 (1997). *See also* David R. Marsh, *The Preclusive Effect of Foreign Country Patent Judgements in the United States*, N.Y.U. J. INT'L L. & POL. 469, 471 (1995) (describing the ability of patentees to recoup research and development costs by charging "a price reflective of their ability to exclude others from the market"); Evan Ackiron, *Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145, 167, 173 (1991) (noting that Burroughs Welcome purportedly spent $80 million developing the drug AZT but earned an estimated $25 million to $100 million in net profits from the drug in 1989 when sales reached $220 million); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024-25 (1989) (noting that inventions will not be made in the absence

however, is available only for a limited time.[17]

In developed countries, it has been suggested that enhanced intellectual property protection stimulates economic growth and enhances social welfare.[18] Furthermore, it has been argued that the benefits that enhanced intellectual property protection provide are not limited to developed countries.[19]

B. SPECIAL CHARACTERISTICS OF THE BIOTECHNOLOGY INDUSTRY

The biotechnology industry[20] in particular depends on the safeguards provided by the patent laws because of the high costs of research, development, and commercialization associated with biotechnology inventions.[21] It has been suggested that high-tech

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of patent protection "because inventions once made are easily appropriated by competitors of the original inventor who have not shared in the costs of the invention"). Alternatively, it has been argued that patent protection stimulates investment "because it offers assurance that others cannot immediately copy a successful product or use a successful process." Sherwood, *supra* note 1, at 500.

[17] The present term of a patent is twenty years from the date of filing. TRIPS Agreement, *supra* note 1, art. 33; 35 U.S.C. § 154(a)(2) (1994). In other words, society balances two competing social objectives: "the need to encourage technical innovation and the need to disperse the benefits of that innovation throughout society." David Hurlbut, *Fixing the Biodiversity Convention: Toward a Special Protocol for Related Intellectual Property*, 34 NAT. RESOURCES J. 379, 383 (1994), *reprinted in* INTERNATIONAL INTELLECTUAL PROPERTY ANTHOLOGY 32 (Anthony D'Amato & Doris E. Long eds., 1996).

[18] Sherwood, *supra* note 1, at 492.

[19] Sherwood, *supra* note 1, at 493 ("[T]he same general observations probably hold true for developing countries.").

[20] In this Article, the phrase "biotechnology industry" is used broadly to encompass industries that utilize methods, processes, or compositions of matter employing biological molecules, biological systems, or living organisms.

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. *Pharmaceuticals*, 4 No. 7 MEX. TRADE & L. REP. 24 (July 1994). *See also Hearings on Technical Innovations in Health Care Before the House Joint Econ. Comm.*, 103d Cong. (1994) (statement of Roger C. Herdman, director, Office of Technology Assessment), *available in* LEXIS, Legis library, CNGTST file (estimating that by 1995, 1300 biotechnology firms existed in the United States); Gail Dutton, *Biotech: Risky Business*, 84 MGMT. REV. Jan. 1995 at 36 (stating that 1,025 of the firms in the biotechnology industry were formed after 1980).

[21] *See* S. REP. NO. 96-480, at 19 (1979) ("It has been estimated by many experts that the cost of taking a new invention from basic research through development and commercialization costs 10 times as much as did the basic research itself."); WENDY H. SCHACHT, CONGRESSIONAL RESEARCH SERV., THE LIBRARY OF CONGRESS, REPORT FOR CONGRESS: THE BAYH-DOLE ACT: PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY, 4 (1994)

industries, such as the biotechnology industry, could not exist without a strong and effective patent law system.[22]

Billions of dollars are invested in developing new medical technologies,[23] and yet it is estimated that only one in five thousand pharmaceutical compounds[24] ever reaches the commercial market.[25] The costs of bringing a biotechnology product to market are compounded by the complex hurdles imposed by regulatory agencies before a new product is approved for sale.[26] Furthermore, biological inventions are particularly susceptible to piracy because, while they typically require substantial expenditures to develop, they are often simple to replicate.[27]

The biotechnology industry, as all industries, is regulated by two fundamental economic theories.[28] First, as rational actors biotech-

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("Studies have shown that research funding only accounts for approximately 25 percent of the costs associated with bringing a new product to market."); *Biopharmaceuticals Increase Their Share of the Market*, MFG. CHEMIST, Feb. 1997, at 28 (stating that it takes an average of 12 years and $360 million to bring a biopharmaceutical drug to market); *General Agreement on Tariffs and Trade (GATT): Intellectual Property Provisions Before the Joint Subcomm. on Intellectual Property and Judicial Admin. and the Subcomm. on Patents, Copyrights, and Trademarks, Comm. on the Judiciary*, 103d Cong. 295 (1994) [hereinafter Mossinghoff Statement] (statement of Gerald J. Mossinghoff, president, Pharmaceutical Research and Manufacturers of America) (estimating that it takes 10 to 12 years and over $350 million to bring a single pharmaceutical product to market).

[22] Gerald J. Mossinghoff & Ralph Oman, *The World Intellectual Property Organization: A United Nations Success Story*, 160 WORLD AFF. 104, 105 (1997) (stating that according to a study by the World Bank, "65 percent of modern pharmaceutical products would not have been developed or introduced in the absence of adequate intellectual property protection").

[23] Elizabeth Corcoran, *Patent Medicine*, 259 SCI. AM. 128 (1988). *See also* Robert Pear, *U.S. Will Tighten Health-Lab Goals*, N.Y. TIMES, Aug. 24, 1992 at A1 (stating that the government plans to channel $9 billion to critical public health areas).

[24] Although these statistics apply to pharmaceutical compounds, biotechnology products undergo the same rigorous research and development procedures as pharmaceutical compounds. Biotechnology products therefore would have a similar likelihood of reaching the commercial market. Kenneth B. Lee, Jr. & Lilly S. Hu, *Biotechnology: Past, Present, Future*, 1996 CHEMISTRY & INDUSTRY 334.

[25] Mossinghoff Statement, *supra* note 21. Other commentators have estimated that the probability of a newly synthesized compound reaching the marketplace is less than one in twelve thousand. *See, e.g.*, Brian H. Vickery, *Cost of Research and Patent Considerations*, 8 J. ANDROLOGY S-27 (1987) (calculating that the "overall probability of a . . . newly synthesized compound reaching the market place reaches the vanishingly small figure of less than 1:12,000 (0.008%)").

[26] *See, e.g.*, S. REP. NO. 96-480, at 19 (1979) ("Additionally, a medical discovery faces lengthy, expensive regulatory procedures before any new medicine can be marketed.").

[27] William D. Noonan, *Patenting Medical Technology*, 11 J. LEG. MED. 263, 264 (1990).

[28] McCabe, *supra* note 15, at 661-62.

nology companies will seek to maximize their investment return.[29] Second, because investors are risk averse, they would be less willing to invest in biotechnology if they are not guaranteed adequate patent protection.[30] Although the aim of the biotechnology industry is to alleviate the world's health problems, "[w]e need to remember that health care, at least in the United States, is part of our society's free-market economic system,"[31] and therefore it is motivated by profit.[32]

The biotechnology company's desire to price its patented products above competitive levels might seem excessive, but such prices are often justified as allowing the company that sponsored the research leading to a product to recover the research and development costs, not only for that product, but also for its many failed experiments.[33] Furthermore, the seemingly excessive prices for biomedical products often pale in comparison to the costs that untreated ailments can impose on society.[34]

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[29] RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 6 (Richard A. Epstein et al. eds., 4th ed. 1992).

[30] C. Owen Paepke, *An Economic Interpretation of the Misappropriation Doctrine: Common Law Protection for Investments in Innovation*, 2 HIGH TECH. L.J. 55, 60 n.26 (1987); POSNER, *supra* note 29, at 12.

[31] Michael Montagne, *Drug Advertising and Promotion: An Introduction*, 22 J. DRUG ISSUES 195, 202 (1992). *See also* Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 302 (1994) ("According to economic theory, companies in the industry will focus their research and development efforts on finding products that will eventually become profitable."); Thomas P. Dillon, Note, *Source Compensation for Tissues and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628, 639 (1989) (discussing the role of profit-making in healthcare).

[32] Montagne, *supra* note 31, at 202.

[33] By many estimates, only one in ten thousand compounds ever reaches the commercial marketplace. *See supra* notes 23-27 and accompanying text (discussing the costs of developing and marketing a successful biotechnology product). Therefore, the one successful commercial product needs to provide the biotechnology company with sufficient profits to allow that company to recover the research and development costs of, not only that product, but also the remaining 9,999 products that failed to reach the marketplace. Fisch, *supra* note 31, at 303.

[34] It has been estimated that

> [i]n 1990 alone, for example, the projected cost of cardiovascular disease and stroke to the U.S. economy was $95 billion, including the costs of hospital days, disability days, and $33 billion in medical expenditures, not to mention the countless potential years of life lost before the age of 65; for acquired immunodeficiency syndrome (AIDS) including the loss of productivity, the estimated 1990 cost was $26 billion. In 1989 cancer cost the nation $100

Biotechnology companies rely on the exclusive rights provided by the patent system because of the astronomical costs of research and development associated with the biotechnology industry.[35] Furthermore, because of the "competitive and imitative" nature of the biotechnology industry, companies will hesitate to enter into research and development agreements or technology transfer and licensing agreements with respect to their biotechnology inventions unless they are guaranteed exclusive rights.[36]

III. PATENTABLE SUBJECT MATTER UNDER THE TRIPS AGREEMENT

The TRIPS Agreement provides that "patents shall be available . . . without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[37] The TRIPS Agreement defines patentable subject matter as any new invention that involves an inventive step and has a potential industrial application.[38]

A Member country may, however, exclude certain subject matter from patentability.[39] The TRIPS Agreement provides that Member countries may exclude inventions from patentability in order to "protect *ordre public* or morality, including to protect human,

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billion, and Alzheimer's disease cost $80 billion.
P. Roy Vagelos, *Are Prescription Drug Prices High?*, 252 SCIENCE 1080, 1081 (1991) (citations omitted).

[35] *See supra* notes 23-27 and accompanying text (discussing the biotechnology industry).

[36] Paepke, *supra* note 30, at 60 n.26. *See also* Ajay K. Sharma, *The Global Loss of Biodiversity: A Perspective in the Context of the Controversy Over Intellectual Property Rights*, 4 U. BALT. INTELL. PROP. L.J. 1, 15 (1995) (noting that pharmaceutical corporations in the U.S. would be "somewhat hesitant to enter into technology transfer or licensing agreements in the developing world"). *But see* Linda R. Judge, Comment, *Issues Surrounding the Patenting of Medical Procedures*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 181, 203 (1997) ("Intellectual property protection tends to eliminate conventional scientific interaction where information is freely disseminated, and therefore, conflicts with incentives provided to scientists to achieve advancements in science and medicine.") (citing Aryeh S. Friedman, *Law and the Innovative Process: Preliminary Reflections*, 1986 COLUM. BUS. L. REV. 1, 7 (1986)).

[37] TRIPS Agreement, *supra* note 1, art. 27(1).

[38] TRIPS Agreement, *supra* note 1, art. 27. It has been suggested that international protection of biotechnology inventions has been substantially weakened in subsequent agreements. Doane, *supra* note 2, at 489 (citations omitted).

[39] TRIPS Agreement, *supra* note 1, art. 27(2)-(3).

animal or plant life or health or to avoid serious prejudice to the environment."[40] Thus, Member countries may exclude an invention from patentability only if the commercial exploitation of the invention is not permitted in the Member country and such a prohibition is necessary in order to protect the interests outlined in Article 27(2).[41]

The TRIPS Agreement also provides that Member countries may exclude from patentability:

> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.[42]

These exclusions do "not cover apparatus and products for diagnostic and therapeutic methods, such as 'kits for application in a diagnostic method.' "[43]

If a Member country excludes plant varieties from patent protection, however, it must provide protection for plant varieties by an effective *sui generis* system.[44] The TRIPS Agreement does not define what is meant by "an effective *sui generis* system," however, most commentators believe that this reference is intended to refer to a system modeled after the International Convention for the Protection of New Varieties of Plants (UPOV).[45]

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[40] TRIPS Agreement, *supra* note 1, art. 27(2) (emphasis in original). A Member country, however, cannot exclude such subject matter "merely because the exploitation is prohibited by their law." *Id.*

[41] *Id.*; Straus, *supra* note 6, at 182.

[42] TRIPS Agreement, *supra* note 1, art. 27(3)(a)-(b).

[43] Pacón, *supra* note 9, at 339 (citations omitted).

[44] Article 27(3)(b) provides 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." TRIPS Agreement, *supra* note 1, art. 27(3)(b).

[45] Bosselmann, *supra* note 3, at 124 ("[T]he nations of Europe adopted sui generis plant-variety protection schemes under UPOV rather than patent-based protection schemes."). *See also* Bai, *supra* note 3, at 140 (suggesting that the UPOV is a suitable system of protection on the international level).

The TRIPS Agreement additionally allows developing countries to postpone the implementation of most of the intellectual standards provided by the TRIPS Agreement for a period of at least five years, and up to ten years with respect to technology fields that were previously excluded from patent protection under their domestic laws.[46]

IV. DEVELOPING COUNTRIES' CONCERNS OVER PATENT PROTECTION FOR BIOTECHNOLOGY INVENTIONS

Developing countries have expressed several concerns over the TRIPS Agreement.[47] Some of the concerns stem from the different view that non-Western cultures have toward individual liberty.[48] Other concerns stem from a view that strong intellectual property protection only serves the developed countries' interests.

A. A STRONG INTELLECTUAL PROPERTY PROTECTION REGIME ONLY BENEFITS DEVELOPED COUNTRIES

First, developing countries view the strong intellectual property protection advanced by the developed countries as only benefiting the industrialized, developed countries that export intellectual property.[49] Developing countries tend to regard patents as a way

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[46] TRIPS Agreement, *supra* note 1, art. 65(1), (2), (4).

[47] *See* SHIVA, *supra* note 1, at 56 ("If the regimen of rights being demanded by the United States is implemented, the transfer of funds from poor to rich countries will exacerbate the Third World crisis 10 times over.") (citation omitted).

[48] *See* Hurlbut, *supra* note 17, at 385 ("Islamic and some African cultures go so far as to define self-identity not according to individual liberty but according to the individual's relationship with and contribution to society . . . . [I]f individual liberty is not the basis for self identity, then the moral foundations of property must rest somewhere else."); Carlos Alberto Primo Braga, *The Economics of Intellectual Property Rights and the GATT: A View from the South*, 22 VAND. J. TRANSNAT'L L. 243 (1989), *excerpt reprinted in* INTERNATIONAL INTELLECTUAL PROPERTY ANTHOLOGY 42, 43 (Anthony D'Amato & Doris Estelle Long eds., 1996) ("[T]he Least Developed Countries tend to assign a higher weight to 'social' interests (often loosely defined) than to private interests.").

[49] *See* U.N. CONFERENCE ON TRADE & DEV., THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES § 25, U.N. Doc. UNCTAD/ITE/1, U.N. Sales No. 96.II.D.10 (1996) [hereinafter U.N. Doc. UNCTAD/ITE/1] (stating that developed countries will reap most of the immediate benefits of the TRIPS intellectual property treaty and listing ways for them to assist the developing countries in implementing and benefitting from the system); Silverstein, *supra* note 13, at 157 (stating that less developed countries feel that "Western science and

for the developed countries "to maintain their head start in technology and deny a transfer of technology so that [the developing countries] can begin their own research and development industries."[50] Developing countries also view the TRIPS Agreement as an impediment to the development of self-sustaining pharmaceutical industries in the developing countries.[51]

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technological innovation typically favor Western needs."); Braga, *supra* note 48, at 252-53 ("In most Third World countries, a reform of intellectual property laws perceived to favor foreign capital would be highly controversial."); Otto A. Stamm, *GATT Negotiations for the Protection of New Technologies*, 73 J. PAT. & TRADEMARK OFF. SOC'Y 680, 689 (1991) (stating that the GATT rules for efficient protection of inventions only benefit the industrial countries that export intellectual property).

It has been estimated that over eighty percent of all unexpired patents in developing countries are owned by foreign corporations or individuals. Mark Ritchie et al., *Intellectual Property Rights and Biodiversity: The Industrialization of Natural Resources and Traditional Knowledge*, 11 ST. JOHN'S J. LEGAL COMMENT. 431, 439 (1996). According to another study, over ninety percent of all unexpired patents in developing countries were owned by foreign corporations or individuals. Silverstein, *supra* note 13, at 170 (citing Shoii Matsui, *The Transfer of Technology to Developing Countries: Some Proposals to Solve Current Problems*, 59 J. PAT. & TRADEMARK OFF. SOC'Y 612, 614 (1977)). Even more troubling from the developing country's perspective, however, is that over ninety-five percent of foreign owned patents are not commercialized in these countries. Ritchie et al., *supra*, at 439 (citing CHAKARARAVARTHI RAGHAVAN, RECOLONIZATION: GATT, THE URUGUAY ROUND & THE THIRD WORLD 123 (1990)). However, even in the United States only a fraction of patents are ever commercialized. Ritchie et al., *supra*, at 439.

[50] Bosselmann, *supra* note 3, at 127. *See also*, SHIVA, *supra* note 1, at 5 ("Through patents and genetic engineering, new colonies are being carved out.").

Developing countries want technology transfer mechanisms and believe that technology is a common asset that should be shared freely. *See* Date, *supra* note 6, at 650 (noting that developed countries consider technology to be a valuable property right and therefore support efforts to protect it); James O. Odek, *Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. INTELL. PROP. L. 141, 150 (1994) (stating that developing countries believe that genetic resources, as the common heritage of mankind, should be freely available). However, in the typical technology transfer agreement, the parent company from the developed country retains control over the technology and the subsidiary established in the developing country. David M. Haug, *The International Transfer of Technology: Lessons that East Europe Can Learn from the Failed Third World Experience*, 5 HARV. J.L. & TECH. 209, 214 (1992).

Developing countries have likened the position of the developed countries on intellectual property rights to imperialism. Marci A. Hamilton, *The TRIPS Agreement: Imperialistic, Outdated, and Overprotective*, 29 VAND. J. TRANSNAT'L L. 613, 614-20 (1996).

[51] Ritchie et al., *supra* note 49, at 437.

B. A STRONG INTELLECTUAL PROPERTY PROTECTION REGIME IS INAPPROPRIATE IN DEVELOPING COUNTRIES

An additional concern is that the patenting of technology is inappropriate to the developing countries' needs and resources and tends to block the development of indigenous technologies that may be better suited to the developing countries' needs.[52] It has been suggested, however, that patent protection does not harm most developing countries because these countries do not have the industrial potential to compete with the developed countries.[53]

The intellectual property standard promoted by the developed countries is premised on the existence of a market-based economy.[54] In other words, strong "intellectual property protection can be expected to produce maximum benefits in markets where private capital and open trade are encouraged."[55] Many developing and less developed countries do not have ready access to private capital and do not encourage open trade.[56] Because many developing countries do not have market-based economies, it has been argued that the model proposed by the developed countries is not readily applicable to developing countries.[57]

C. A STRONG INTELLECTUAL PROPERTY PROTECTION REGIME IS A FINANCIAL BURDEN ON DEVELOPING COUNTRIES

Developing countries have raised concern about the costs associated with developing and maintaining a sophisticated

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[52] Silverstein, *supra* note 13, at 157. *See also* A. Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 1987 DUKE L.J. 831, 848 (1987) (explaining that developing countries may benefit from patent systems because they offer an incentive for development); Haug, *supra* note 50, at 224 ("One of the consistent problems that third world nations have faced in successfully importing technology is that the technology acquired from developed nations is ill-suited to the third world's needs.").

[53] *See* Stamm, *supra* note 49, at 690 (stating that patent protection "interferes with national industry only where the industrial potential for copying exists, i.e. in so-called Newly Industrialized Countries").

[54] Silverstein, *supra* note 13, at 158-59.

[55] Sherwood, *supra* note 1, at 494.

[56] Silverstein, *supra* note 13, at 165-66.

[57] *Id.*

intellectual property system.[58] Developing countries tend to have limited resources that they can expend on a governmental body dedicated to the procurement and protection of intellectual property.[59] Additionally, assuming that the developed countries' arguments are correct and that strengthened intellectual property protection will stimulate growth, the developing country will also need to spend money to develop its infrastructure in order to support the economic growth predicted by the developed countries.[60]

At the very least, the immediate short-term effect of a strengthened intellectual property system will be higher royalty payments from developing countries to developed countries.[61] Developing countries are importers of technology and rely heavily on technologies created by developed countries. The relative cost of royalty payments can be further exacerbated in developing countries because of fluctuations in the foreign currency exchange rates.[62]

Moreover, biotechnology is highly patent sensitive, in that a single patent can dominate a marketed product. As such, patent protection may result in pricing above competitive levels.[63] If the patented technologies become too expensive, developing countries may not be able to afford them. However, according to one commentator, the limited studies performed on this concept suggest that prices as a whole will not rise at a rate significantly greater

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[58] U.N. Doc. UNCTAD/ITE/1, *supra* note 49, § 72. *See also* Tara Kalagher Giunta & Lily H. Shang, *Ownership of Information in a Global Economy*, 27 GEO. WASH. J. INT'L L. & ECON. 327, 331 (1994) (noting that developing countries have scarce government resources and, therefore, resist spending on the enforcement of intellectual property rights); Amy R. Edge, *Preventing Software Piracy Through Regional Trade Agreements: The Mexican Example*, 20 N.C. J. INT'L L. & COM. REG. 175, 190 (1994) (listing types of costs, such as drafting, economic activity costs, and loss of low cost alternatives to legitimate products).

[59] Giunta & Shang, *supra* note 58, at 331.

[60] Edge, *supra* note 58, at 383.

[61] *See* U.N. Doc. UNCTAD/ITE/1, *supra* note 49, § 44 ("[O]ne anticipated consequence of [developing countries] adopting a stronger [intellectual property] regime would be an increase in royalty payments to foreign title holders."). *See also* Giunta & Shang, *supra* note 58, at 330 (discussing the costs); Braga, *supra* note 48, at 256 (discussing the initial consequences of implementing a regime of intellectual property laws).

[62] Braga, *supra* note 48, at 256. The fluctuation in the foreign exchange rates, however, should have only a nominal impact, if any, because there is an equal probability that the exchange rate fluctuations will benefit and harm both sides of the exchange.

[63] Sherwood, *supra* note 1, at 501.

than the consumer price index.[64]

While the developed countries believe that pirating provides no real economic benefit to the pirating country,[65] developing countries tend to believe that pirating intellectual property fuels economic development.[66] Indeed, developing countries are expected to realize an immediate reduction in domestic output and employment rates as pirate corporations move their operations to countries with less restrictive intellectual property protection.[67]

D. A STRONG INTELLECTUAL PROPERTY PROTECTION REGIME DOES NOT PROMOTE DEVELOPING COUNTRIES' AGRICULTURAL BASE

Two main objectives of the developing countries in the Uruguay Round were: (1) to obtain access for their agricultural goods in the markets of the developed countries; and (2) to obtain access for their textiles and apparel goods in those same markets.[68] In light of these goals, one of the arguments that the developing countries have raised against the granting of patents for plants is the concern that public access to the genetic resource of indigenous plant life

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[64] *See* Sherwood, *supra* note 1, at 498-500 (citing Italy as a model, the commentator noted that prices for pharmaceutical products did not increase at a rate greater than the consumer price index over a ten year period after restrictions on pharmaceutical patents were lifted).

[65] *See* J.H. Reichman, *The TRIPS Component of the GATT's Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market*, 4 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 171, 174 (1993) (noting the possible existence of a consensus, which indicates that industrialized societies are better off with established intellectual property regimes than without them).

[66] *See* Ritchie et al., *supra* note 49, at 437 (noting that expanded protection of intellectual property rights for transnational corporations operating in developing countries discourages innovation and economic development in those countries). *See also* Stephan Kirchanski, *Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT'L & COMP. L.J. 569, 577 (1994) ("This inexpensive use of technology stimulates the local economy and provides additional profits . . . .").

However, one commentator has suggested that pirates may not provide as large a benefit as some believe because pirates often enter into price-fixing arrangements amongst themselves, producing goods with prices higher than would be expected for such pirated imitation products. Sherwood, *supra* note 1, at 500.

[67] U.N. Doc. UNCTAD/ITE/1, *supra* note 49, § 7. *See also* Stamm, *supra* note 49, at 690 ("Naturally trade in pirated goods is economically attractive to many so-called developing countries and has advantages.").

[68] Judith H. Bello & Mary E. Footer, *Symposium: Uruguay Round - GATT/WTO*, 29 INT'L LAW. 335, 337 (1995).

would be limited by such patent protection.[69] A similar concern that developing countries have regarding patent protection for plant varieties and biologically engineered organisms is that the prices for this subject matter will rise once it becomes patentable.[70]

It has been suggested that "the value of a patent system to developing countries remains controversial, and single developing countries could suffer hardship because of a growing dependence on foreign patents with few countervailing benefits."[71] Indeed, it is well recognized that the TRIPS Agreement will impact each developing and less developed country differently.[72]

V. HOW DEVELOPED COUNTRIES CAN ADDRESS THE CONCERNS OF THE DEVELOPING COUNTRIES

Several commentators have noted that the TRIPS Agreement fails to adequately protect nontraditional subject matters such as biotechnology and computers.[73] Transnational corporations are lobbying for the deletion of the restrictive language of Article 27 from the TRIPS Agreement.[74] Likewise, the United States is expected to begin lobbying for the deletion of the restrictive

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[69] S.K. Verma, *Trips and Plant Variety Protection in Developing Countries*, 17 EUR. INTELL. PROP. REV. 281, 286 (1995).

[70] U.N. Doc. UNCTAD/ITE/1, *supra* note 49, § 117. *But see* Sherwood, *supra* note 1, at 498 ("When a patent law changes so that subject matter previously excluded from patent protection becomes patentable, the prices of the products already in the market will not change as a result of the newly introduced patent protection. Nor will competing imitation products disappear from the market or change their prices.").

[71] Reichman, *supra* note 2, at 354 (citing Oddi, *supra* note 52). *See also* Arvind Subramanian, *The International Economics of Intellectual Property Right Protection: A Welfare-Theoretic Trade Policy Analysis*, 19 WORLD DEV. 945, 947-52 (1991) (noting that the small country might derive very few dynamic benefits from higher levels of intellectual property protection).

[72] U.N. Doc. UNCTAD/ITE/1, *supra* note 49, § 10.

[73] Reichman, *supra* note 2, at 358. *See also* Lisa B. Martin & Susan L. Amster, *International Intellectual Property Protections in the New GATT Accord*, 6 No. 2 J. PROP. RIGHTS 9, 12 (1994) (detailing the concerns of the Pharmaceutical Manufacturers Association that a serious flaw in the TRIPS Agreement is that it removes many biotechnical products from the umbrella of international protection by failing to address the issue of the patentability of plants and animals).

[74] *See* Chakrit Ridmontri, *Patenting of Modified Life Forms: EU's Plan Faces Opposition: Biodiversity Backers Set to Discuss Impact*, BANGKOK POST, Nov. 28, 1997, at 1, *available in* 1997 WL 14431969 (reporting the gathering of forty biodiversity advocates to discuss opposition to the European Union's move to legalize the patenting of living organisms).

language of Article 27.[75] In addition to deleting the restrictive language, the developed countries have alternative avenues which may simultaneously address both the developing and developed countries' concerns.

A. UPOV CONVENTION

The TRIPS Agreement provides that if the contracting state excludes patent protection for plants from its domestic patent laws, the contracting state must protect plant varieties under a *sui generis* legal regime.[76] Several commentators have suggested that an appropriate *sui generis* legal regime could be based on the International Convention for the Protection of New Plant Varieties (UPOV Convention).[77]

The UPOV Convention was created in 1961 in response to complaints regarding the difficulty of obtaining patent protection for cultivated plants.[78] The UPOV Convention established plant breeders' rights that provide protection for new plant varieties that are clearly distinguishable by one or more important characteristic, homogeneous in their sexual reproduction or vegetative propagation, and stable in their essential characteristics.[79] Although the UPOV Convention provides substantial protection for plant

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[75] According to the Office of the United States Trade Representative, "biotechnology is a key area of omission from the TRIPs Agreement's patent obligations [and] U.S. negotiators should strive to remedy this situation." *WTO Implementation Report: Trade-Related Intellectual Property Rights* (visited Oct. 14, 1998) <http://www.ustr.gov/reports/wto/intellectual_property.html>.

[76] TRIPS Agreement, *supra* note 1, art. 27(3)(b).

[77] International Convention for the Protection of New Plant Varieties, Dec. 2, 1961, *revised by* 33 U.S.T. 2703 (1978) *reprinted in* INTERNATIONAL TREATIES ON INTELLECTUAL PROPERTY L. 53 (Marshall A. Leaffer ed., 1990) [hereinafter UPOV Convention]. *See also* Reichman, *supra* note 2, at 358-59 (discussing TRIPS and UPOV); David S. Tillford, *Saving the Blue Prints: The International Regime for Plant Resources*, 30 CASE W. RES. J. INT'L L. 373, 406-7 (1998) (providing a general description of the UPOV Convention and its 1991 Amendment); Naomi Rohy-Arriaza, *Of Seeds and Shamans: The Appropriateness of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L L. 919, 940 (1996) ("The most well known existing sui generis system for plants is the [UPOV convention].").

[78] UPOV Convention, *supra* note 77. *See also* Bosselmann, *supra* note 3, at 123 ("The difficulties of obtaining patent protection for the cultivation of plants . . . led eventually to the adoption of [UPOV].").

[79] UPOV Convention, *supra* note 77, art. 6.

varieties, the scope of its protection is limited. For example, the UPOV Convention does not protect plant parts or plant products. The scope of protection under the UPOV Convention is further limited because of so-called farmer's rights, which allow farmers to reuse the seed from the crops they grow in subsequent seasons.[80] Additionally, the UPOV Convention does not provide a doctrine of equivalence-like protection for plants, and it provides no protection against the use of the protected variety in the making of another plant variety.[81]

The 1991 revision of the UPOV Convention (1991 UPOV Convention) altered the standard of protection from a modified copyright model to a modified patent model.[82] It has been suggested that the scope of protection provided by the 1991 UPOV Convention is best suited toward "traditional 'field' research based on selecting the best and strongest plant and animals for breeding, cross-breeding and hybridization."[83] The 1991 UPOV Convention addresses at least some of the nontraditional methodologies for producing new plant varieties.[84] However, neither convention provides the level of protection provided by a patent system.[85] A major concern of the developing countries is the protection of their

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[80] *See* Bosselmann, *supra* note 3, at 123-25 (citing GOLLINS ET AL., BIOTECHNOLOGY PROSPECTING (1993)) ("[T]he legislative presumption is that farmer's rights are not allowed without the express authorization of the breeder . . . .").

[81] UPOV Convention, *supra* note 77, art. 15(iii). *See also* Bai, *supra* note 3, at 144 (stating that there is no protection under a doctrine of equivalence theory for plant varieties).

[82] International Convention for the Protection of New Varieties of Plants, *opened for signature* Mar. 19, 1991, *reprinted in* 3 EUR. PAT. HANDBOOK (MB) ch. 90 [hereinafter 1991 UPOV Convention]. *See also* Reichman, *supra* note 2, at 359 (stating that the 1991 revision elevated UPOV Convention "standards of protection to a modified patent model"); Bai, *supra* note 3, at 144 (stating that the 1991 UPOV Convention "seems to offer patent-like protection to plant varieties").

[83] Sherwood, *supra* note 1, at 520. *But see* 1991 UPOV Convention, *supra* note 82 (providing stronger protection for genetically modified plants).

[84] Scalise & Nugent, *supra* note 8, at 108-9. *See also* Bosselmann, *supra* note 3, at 125 (citing Natalie M. Derzko, *Plant Breeders Rights in Canada and Abroad: What Are These Rights and How Much Must Society Pay for Them?*, 39 MCGILL L.J. 144, 167 (1992)) (stating that, under the 1991 UPOV revision, the legislative presumption was that farmers must obtain express authorization from plant breeders to take seeds from a harvested crop to grow the next crop).

[85] Bai, *supra* note 3, at 148.

agricultural economies.[86] Therefore, they are generally reluctant to provide patent protection for plants and plant parts.[87] The TRIPS Agreement, however, provides that, at the very least, the contracting states must provide a *sui generis* form of protection for plant varieties. Although the 1991 UPOV Convention does not provide the level of protection that patents do, it may provide a common platform acceptable to both sides of this issue.

B. PRICE CONTROLS

If one concern of developing countries is the higher prices associated with patented subject matter, one course of action would be to install price control mechanisms, rather than imposing outright bans on patent protection. Through price controls, the developing countries could ensure that the patented technologies are not priced at unreasonable levels. If the patentee was able to realize a reasonable return on his investment, technology transfer to developing countries would not be inhibited.

Price controls which are unreasonably restrictive, however, will only act to restrain the importation of patented technologies into the developing country.[88] Without an adequate return on investment, companies will not transfer their latest technologies to a developing country.[89] Given the history of price controls, it is unlikely that any price control mechanism would provide the

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[86] *See supra* Part IV.D (discussing the concern of developing countries with respect to their agricultural base).

[87] *Id.*

[88] *See, e.g.*, Ileana Dominguez-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT'L L.J. 245, 247 n.8 (1997) (suggesting that patent hostility and price controls may "decrease drug availability or cause pharmaceutical companies to withdraw from some particular markets or to engage in less innovative research"). Another commentator has suggested that the existence of price control systems in Europe may be one reason why there is less biotechnology innovation in Europe. Mary T. Griffin, *AIDS Drugs & The Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 407 (1991).

[89] *See supra* Part II.A. (discussing the incentives provided to investors by intellectual property protection). Indeed, one critic commenting on India, has suggested that the phasing out of price controls "would provide an incentive structure necessary to encourage Indian pharmaceutical corporations to increase their research and development expenditures." Suresh Koshy, *The Effect of TRIPS on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B.U. J. SCI. & TECH. L. 4, 55 (1995).

patentee with a sufficient return on his investment. The net effect would be an unwillingness on the part of corporations from developed countries to operate in such markets. Indeed, it would be expected that the developed countries would vigorously oppose price control mechanisms because of the subjective nature of defining what is a "reasonable" price.[90] Therefore, it is unlikely that the developed countries would find acceptable any proposal including price control mechanisms.

C. COMPULSORY LICENSING

Although the TRIPS Agreement permits compulsory licensing of patents, it has placed severe restrictions on the use of such licenses.[91] Some of these restrictions could be relaxed as a concession towards the developing countries in exchange for enhanced patent protection for biotechnology. However, one of the developed countries' main stated goals in negotiating the TRIPS Agreement was to secure a restriction on the application of compulsory licenses.[92] Given the negotiating position of the developed countries, it is unlikely that they would agree to a relaxation of the restrictions on compulsory licenses.[93]

D. WORK REQUIREMENTS

Several developing countries, prior to the TRIPS Agreement, required that a patented invention had to be manufactured domestically in order to receive the full scope of patent protection

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[90] For example, the pharmaceutical industry and other special interest groups, have always been opposed to price controls and compulsory licensing requirements. *See* Griffin, *supra* note 88, at 397 (noting the general opposition to price controls and drug licensing).

[91] TRIPS Agreement, *supra* note 1, art. 31. As a general rule, a compulsory license can only be granted if an attempt has been made to obtain a voluntary license on reasonable terms and conditions, the patentee obtains adequate remuneration, and the reasonable value of the invention has been taken into account. *Id.* In addition, the patentee must be able to subject the compulsory license to judicial or other independent review. Finally, the laws must prohibit discrimination in compulsory licensing with respect to a given field of technology, place of invention, or location of manufacture. *Id.* *See also* Otten & Wager, *supra* note 12, at 401 (noting the existence of multiple restrictions).

[92] Bosselmann, *supra* note 3, at 146.

[93] *Id.*

offered by that country.[94] If a patented invention was not manufactured in the developing country, a third party could petition the government for a license to manufacture the patented invention in the developing country. Obviously, these provisions were extremely unpopular with developed countries.[95]

Article 27(1) of the TRIPS Agreement, which provides that "patent rights [shall be] enjoyable . . . whether [the] products are imported or locally produced," has effectively banned work requirements.[96] From the developed country's perspective, work requirements were highly contentious, and therefore, they would not accept any modification to Article 27 that provided for work requirements.

E. PURSUIT OF ADDITIONAL UNILATERAL, BILATERAL, OR MULTILATERAL AGREEMENTS

The TRIPS Agreement was implemented to establish a minimum standard for the protection of intellectual property.[97] Member countries may, however, provide more extensive protection for intellectual property than that provided for in the TRIPS Agreement.[98] Member countries may also belong to international agreements that promote stronger intellectual property protection, for example the European Community, the North American Free Trade Agreement (NAFTA),[99] and the World Intellectual Property Organization (WIPO).[100]

If the United States is unable to obtain adequate concessions from the TRIPS Council, it could lobby each of the respective

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[94] Countries that provided for work requirements prior to the TRIPS Agreement include Brazil and India. *See also* John Richards, *Recent Patent Law Developments in Asia*, 7 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 599, 603 (1997) (explaining the Turkish system).

[95] The main reason such requirements are unpopular, especially within the biotechnology industry, is that companies from developed countries rarely manufacture the patented invention in a developing country. If such requirements were in place, a given company would be forced to set up a manufacturing facility in every country having such requirements in order to maintain patent rights. Such action would be too burdensome for any company.

[96] TRIPS Agreement, *supra* note 1, art. 27(1).

[97] *Id.*

[98] TRIPS Agreement, *supra* note 1, art. 1(1).

[99] North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 605 (1993).

[100] Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3 (1972).

multilateral and bilateral organizations to alter their positions on the patentability of biotechnology. Alternatively, the United States could pursue new unilateral, bilateral, or multilateral agreements that provide more robust protection for biotechnology. One reason the TRIPS Agreement was enacted, however, was in recognition of the difficulty of negotiating worldwide patent protection through unilateral, bilateral, and multilateral agreements.[101]

F. AMEND OR MODIFY THE TRIPS AGREEMENT

Article 71 of the TRIPS Agreement authorizes the TRIPS Council, established in Article 68, "to undertake reviews in the light of any relevant new developments which might warrant modifications or amendment of this Agreement."[102] Although the TRIPS Council must forward amendments to the TRIPS Agreement to the Ministerial Conference of the WTO for consideration, it appears that the TRIPS Council has the authority to make modifications to the TRIPS Agreement without forwarding such modifications to the full Ministerial Conference of the WTO.[103] If the United States does not think that it will receive adequate consideration for an amendment to Article 27 before a Ministerial Conference, the United States may wish to pursue a modification. This avenue probably represents the United States' best option for obtaining the desired changes to Article 27.

An example of such a modification can be ascertained by an interpretation of the somewhat ambiguous language of Article 27. For example, Article 27(3) provides that Member countries may exclude from patentability "plants and animals."[104] An argument could be made, and further strengthened by a letter of interpreta-

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[101] Paul Katzenberger & Annette Kur, *TRIPS and Intellectual Property, in* FROM GATT TO TRIPS - THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 1-7 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996).

[102] TRIPS Agreement, *supra* note 1, arts. 68, 71(1).

[103] Formal amendments (but not necessarily modifications) appear to require a consensus proposal from the TRIPS Council for action before a Ministerial Conference. TRIPS Agreement, *supra* note 1, art. 71(2); WTO Agreement, *supra* note 1, art. X(2), (3), (6). *See also* Reichman, *supra* note 2, at 384 (noting that the TRIPS Council, under the statute, may review modifications and amendments and in this capacity, may substitute for developed countries trade representatives).

[104] TRIPS Agreement, *supra* note 1, art. 27(3).

tion from the TRIPS Council, that the phrase "plants and animals," as used in Article 27(3), refers only to plants and animals made through traditional breeding techniques. It appears that Article 27(3) provides that "non-biological and microbiological processes" for the production of plants and animals may not be excluded from patentability.[105] "[B]iological processes for the production of plants or animals," however, may be excluded from patentability.[106]

If Article 27(3) does not exclude "non-biological and microbiological processes" for the production of plants or animals from patentability, then it would appear that Article 27(3) would require the extension of patent protection to the plants or animals made by such processes. If the United States were able to persuade the TRIPS Council to issue such a statement of interpretation, the TRIPS Council would not have to forward such a statement to a Ministerial Conference for resolution because it would only be a modification, if anything, of the TRIPS Agreement.[107] As the TRIPS Council is smaller than the Ministerial Conference, the United States should be able to successfully lobby for such a modification, especially if the United States were able to obtain the support of Japan and the European Union.

VI. RAMIFICATIONS OF INADEQUATE PATENT PROTECTION FOR BIOTECHNOLOGY ON DEVELOPING COUNTRIES

Patent protection acts as a stimulus for investment, not necessarily because it offers an expectation of increased profits, but rather because it offers a mechanism to exclude competitors from copying the subject invention.[108] It has been argued that inadequate

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[105] *Id.*

[106] *Id.*

[107] Article 71(2) provides that amendments to the TRIPS Agreement need to be referred to a Ministerial Conference. TRIPS Agreement, *supra* note 1, art. 71(2). Article 71 places no special restriction on modifications. TRIPS Agreement, *supra* note 1, art. 71. Therefore, it would appear that the TRIPS Council would be able to modify the TRIPS Agreement without referring the modification to a Ministerial Conference for consideration. *See supra* note 103 and accompanying text (discussing the inference that a modification, unlike an amendment, may not have to be referred for consideration).

[108] Sherwood, *supra* note 1, at 500.

intellectual property protection undermines free trade.[109]

In order for developing countries to fully benefit from a stronger intellectual property protection regime, corporations in developed countries will have to either increase their direct investments in developing countries or license their technologies to the developing countries.[110] Even under the best of circumstances, however, certain individual countries will be worse off after the implementation of a stronger intellectual property protection regime than others.[111] Specifically, the least industrialized countries have the most to gain from strengthening their intellectual property protection.[112] These countries generally lack the industrial capacity to pirate the intellectual property of others.[113] Additionally, these countries require large infusions of capital investment in order to develop an effective technological base.[114]

One of the ways for the least developed countries to obtain capital investment is to modify their intellectual property protection and their economies.[115] By strengthening their intellectual property protection and reforming their economies to a market-based economy with a free and open trade system, these countries will encourage outside capital investment. Only through indigenous research and development will developing countries achieve real growth and development of their economies.[116] Indigenous research and development, such as external capital investments, will only occur once appropriate intellectual property protection exists.[117]

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[109] Giunta & Shang, *supra* note 58, at 332 (citing *Intellectual Property and Trade: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Admin. of Justice of the House Comm. on the Judiciary*, 99th Cong. 51-53 (1986) (statement of Assistant U.S. Trade Representative for Trade Policy and Analysis, Harvey E. Bale, Jr.)).

[110] Reichman, *supra* note 2, at 354.

[111] *See* Reichman, *supra* note 2, at 354 (discussing hardships faced by some developing companies as a result of reliance on foreign patents).

[112] Sherwood, *supra* note 1, at 493.

[113] *Id.*

[114] *Id.* at 494.

[115] *Id.* at 508 ("[A] country which adopts a robust [intellectual property] system will be able to encourage optimum risk capital activity.").

[116] EDWARD SLAVKO YAMBRUSIC, TRADE-BASED APPROACHES TO THE PROTECTION OF INTELLECTUAL PROPERTY 9 (1992).

[117] However, it has been suggested that there is little conclusive evidence that strengthened intellectual property protection would expand the transfer of technology to developing countries. U.N. Doc. UNCTAD/ITE/1, *supra* note 49, § 61.

In many developing countries, agriculture is an important component of the economy.[118] It has been reported that biotechnology has played, and will continue to play, an important role in the development of new higher-yielding and pathogen resistant forms of commercial food crops.[119] As the world's population continues to grow, it will be necessary to expand the productivity and yield of traditional farming techniques.[120] Genetically modified crop species are expected to represent the future in the growth of farming productivity and crop yields.[121]

Companies will likely refrain from commercializing genetically engineered crops in countries that lack strong patent protection.[122] Indeed, companies may not be willing to either sell or license their patented technologies in markets that lack adequate patent protection.[123] If the developing countries are refused

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[118] Sherwood, *supra* note 1, at 505, 520.

[119] Bosselmann, *supra* note 3, at 118. Indeed, it has been estimated that over fifty percent of the increase in the yield of food crops has been the result of genetic manipulation. *Id.* at 115 (citing Eric Christensen, *Genetic Arc: A Proposal to Preserve Genetic Diversity for Future Generations*, 40 STAN. L. REV. 279, 288 (1987)).

For example, Agracetus, a biotechnology company, has received a patent in the U.S. for genetically engineered cotton. Ann Thayer, *Scope of Agricultural Biotechnology Patents Sparks Debate*, CHEMICAL & ENGINEERING NEWS, Aug. 21, 1995, at 12-13; Seth Shulman, *Patent Medicine*, TECH. REV. Nov./Dec. 1995, at 28, 31.

Other genetically modified crops include Monsanto's Roundup Ready Soybean and Novartis' herbicide- and pest-resistant Maximizer maize. Thomas P. Redick et al., *Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path within the Biosaftey Protocol*, 4 ENVTL. LAW. 1, 14 (1997) (citing Diane Montague, *Genetic Engineering and Food Safety*, MILLING & BAKING NEWS, Feb. 11, 1997, at 26-8; Emma Johnson, *Ciba Faces a Maize of Committees in Europe*, 14 NATURE BIOTECHNOLOGY 1068 (1996)).

[120] John H. Barton, *Biotechnology, the Environment, and International Agricultural Trade*, 9 GEO. INT'L ENVTL. L. REV. 95, 98-99 (1996).

[121] *See* Barton, *supra* note 120, at 98-9 (discussing the advantages of technically engineered agriculture for increasing yield and improving quality).

[122] Sherwood, *supra* note 1, at 506. One commentator has suggested that European biotechnology companies are considering relocating their operations to the United States because of the United States' more expansive protection of biotechnology. Bosselmann, *supra* note 3, at 128. *See also* Edge, *supra* note 58, at 191 ("[W]ithout intellectual property laws to protect their investment, foreign producers will be reluctant to ship their products into the developing country or to invest in the local economy.").

One critic, however, has suggested that "[t]he frantic cry for patent protection in agriculture is really a ruse for control of biological resources in agriculture." SHIVA, *supra* note 1, at 54.

[123] Sherwood, *supra* note 1, at 503.

access to the latest patented, biogenetically engineered plants and animals, the developing countries will be precluded from realizing increases in farming productivity and crop yields. The net effect would be that the countries that are the most dependent on their agricultural base would be unable to take advantage of many of the breakthroughs that are happening today and that are anticipated to occur over the next decade. Therefore, it is in the developing countries' best interests to adopt the developed countries viewpoint toward intellectual property protection. In doing so, they will ensure that they will be able to benefit from the expanding breakthroughs that biotechnology will continue to offer in the future.

VII. CONCLUSION

It has been suggested that "[a]fter the Uruguay Round goes into effect, the terms of protection for biotechnology patents should be a major focus of the United States policy."[124] The United States and the United States biotechnology industry should lobby extensively for an amendment or modification to Article 27 that would mandate the recognition of all biotechnological inventions as patentable subject matter. Not only would such an amendment or modification be vitally important to sustaining the biotechnology revolution that the United States has experienced in the last decade, but such an amendment or modification also would help the long-term economic and social growth of the developing countries.

However, given the current political split between the developed and developing countries, no change in the existing system is entirely possible.[125] In the end, any amendment or modification, if it is to succeed, must be responsive to the different economic and social realties of each country.[126]

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[124] Mossinghoff Statement, *supra* note 21, at 5.

[125] *See* Bosselmann, *supra* note 3, at 141 (discussing the various possible results on intellectual property flowing from the political split between the developed and developing countries).

[126] Silverstein, *supra* note 13, at 156.