

COMMENTS

INTELLIGENT TRIPS IMPLEMENTATION: A STRATEGY FOR COUNTRIES ON THE CUSP OF DEVELOPMENT

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1. INTRODUCTION

The wealth of nations rests on the pillars of Labor, Capital, Natural Resources,¹ and more recently, Intellectual Property.² However, intellectual property, at least in the form of patents, has evolved in and is primarily the province of developed, industrialized countries.³ In the last two decades, in order to protect taxpay-

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¹ See 1 ADAM SMITH, *AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS* 1-60 (R.H. Campbell & A.S. Skinner eds., 1981) (1775).

² See, e.g., Gerald J. Mossinghoff, *National Obligations Under Intellectual Property Treaties: The Beginning of a True International Regime*, 9 FED. CIR. B.J. 591, 591 (2000) ("Adam Smith taught us that the wealth of any nation rested on three pillars: Labor, Capital and Natural Resources. Our generation has added a fourth pillar—Intellectual Property in all of its forms."); Gerald J. Mossinghoff & Ralph Oman, *The World Intellectual Property Organization: A United Nations Success Story*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 691, 692 (1997) (discussing intellectual property and the World Intellectual Property Organization).

³ The nature of intellectual property is in some ways distinct from that of tangible property. Only one or a few people can use tangible property at a single time. The location of tangible property is typically determinable and the owner maintains the right to exclude others from using the property. Because of this, the owner can exploit the property as he sees fit to maximize his profitability. Intellectual property is not subject to the same physical limitations. Intellectual property can be used in a non-rivalrous manner, by large numbers of individuals simultaneously. Once intellectual property is made available, in the absence of substantive affirmative law stating otherwise, the owner is essentially dispos-

ers and strong knowledge-based domestic industries,⁴ developed countries, particularly the United States, have strongly encouraged the rest of the world to adopt substantive affirmative standards of intellectual property protection. The U.S. effort began in earnest with the passage of Section 301 of the Omnibus Trade and Competitive Act of 1988 (the "Act").⁵ The Act requires that the U.S. Trade Representative annually review the intellectual property regimes of the United States' trading partners⁶ and place countries whose regimes are below acceptable standards on a priority watch list. Inclusion on the watch list typically results in bilateral discussions between the United States and the offending country. Failure to achieve resolution through bilateral discussions can result, for grievous violators of U.S. intellectual property rights ("IPRs"), in unilateral sanctions against the offending nation.⁷ This strategy has been particularly effective when used against countries that rely heavily on exports to the United States.⁸

Perhaps because bilateral methods of encouraging change in the intellectual property policies of U.S. trading partners were inefficient,⁹ U.S. business people and government representatives began calling for the creation of a new international intellectual prop-

sessed of the right to exclude, and often, of any profits. Since resources involved *ex ante* in the creation of intellectual property are often very high, the incentive for the creation and disclosure of new ideas requires that the creator be able to recover the initial investment of time and money, as well as some profit. Absent protection, the creation of intellectual property, a widely recognized public good, would be retarded.

⁴ In the case of the U.S. biotechnology and pharmaceutical industries, much of the research resulting in the creation of new products stands on the shoulders of basic research financed by the taxpayer through the National Institutes of Health and performed at domestic universities and hospitals.

⁵ See 19 U.S.C.A. §§ 2411-2420 (1999) (authorizing the U.S. Trade Representative to act to eliminate counter-policies deemed harmful to trade).

⁶ See Inti Linkletter Knapp, Comment, *The Software Piracy Battle in Latin America: Should the United States Pursue its Aggressive Bilateral Trade Policy Despite the Multilateral TRIPs Enforcement Framework?*, 21 U. PA. J. INT'L ECON. L. 173, 174 (2000) (discussing U.S. involvement in combating software piracy in Latin America).

⁷ See BÉNÉDICTE CALLAN, COUNCIL ON FOREIGN RELATIONS, *PIRATES ON THE HIGH SEAS: THE UNITED STATES AND GLOBAL INTELLECTUAL PROPERTY RIGHTS* 11-12 (1998) (discussing the positive effects of U.S. pressure on nations who fail to protect IPRs).

⁸ See *id.* at 12 (noting that countries that rely on exports to the United States are vulnerable to unilateral sanctions).

⁹ See *id.* at 16 (suggesting such reasoning).

erty law.¹⁰ Predictably, developing countries wanted little part of this, suggesting that promulgation of effective international intellectual property standards through the World Intellectual Property Organization ("WIPO") would not be forthcoming.¹¹ To overcome this resistance, negotiators from developed countries engaged the issue of international intellectual property standards at the General Agreement on Tariffs and Trade ("GATT") Uruguay Round that opened in 1986.¹² Negotiating the issue in the GATT forum allowed participants to engage in linkage bargaining.¹³ The linking of international intellectual property standards to trade,¹⁴ combined with U.S. economic pressure,¹⁵ resulted, in 1994, in the pas-

¹⁰ See *id.* at 8-15 (highlighting the competing needs of these countries calling for new international intellectual property law). See also Michael P. Ryan, *The Function-Specific and Linkage-Bargain Diplomacy of International Intellectual Property Lawmaking*, 19 U. PA. J. INT'L ECON. L. 535, 536-37 (1998) (noting the desire of U.S. business people for the establishment of international intellectual property law).

¹¹ WIPO administered the Paris Convention and at the time was viewed as the most likely forum for international intellectual property law negotiations. Developing countries preferred the WIPO forum because it provided one-nation, one-vote decision-making. Since more than half of the members were considered developing countries, and developing countries typically viewed strong intellectual property policies as contrary to their interests, it appeared unlikely substantive affirmative changes in international intellectual property law could be achieved in WIPO. See Ryan, *supra* note 10, at 541; C. O'Neal Taylor, *Linkage and Rule-Making: Observations on Trade and Investment, and Trade and Labor*, 19 U. PA. J. INT'L ECON. L. 639, 668 (1998).

¹² See CALLAN, *supra* note 7, at 16 (emphasizing the opportunity presented by the GATT Uruguay Round negotiations to establish international intellectual property standards).

¹³ Linkage-bargain diplomacy is a theory of trade negotiations that suggests the key to reaching an agreement is getting the correct mix of issues into negotiations. In other words, issues previously unrelated may be "linked" for the purposes of bargaining. In the GATT Uruguay Round, international intellectual property standards were linked to trade concessions, a linkage that would have been unlikely in a WIPO negotiation, since WIPO does not deal with broad aspects of trade, but with intellectual property alone. See, e.g., Mossinghoff, *supra* note 2, at 598 (discussing how the Uruguay Round negotiations allowed for "creative bargaining" that allowed an agreement linking trade and intellectual property, although there was no precedent); Ryan, *supra* note 10, at 541 (reviewing the change from function-specific to linkage-bargain rulemaking); Taylor, *supra* note 11, at 668 (noting the differences in objectives between developing and developed countries).

¹⁴ See, e.g., Mossinghoff, *supra* note 2, at 598 (noting that the GATT negotiations included textiles, apparel, agriculture, services, foreign direct investment, and government procurement and that developing countries had much to gain from liberalized trade in textiles apparel and agricultural products).

sage of the Trade-Related Aspects of Intellectual Property Agreement ("TRIPs" or "TRIPs Agreement" or the "Agreement").¹⁶

The TRIPs Agreement¹⁷ is an attempt to harmonize national standards for intellectual property protection into an international norm based primarily on the one currently used by developed countries. TRIPs requires compliance with the substantive provisions of existing international intellectual property treaties,¹⁸ specifies categories of intellectual property that are subject to international standards,¹⁹ and mandates both national treatment²⁰ and most favored nation treatment.²¹ TRIPs also includes a dispute resolution mechanism²² that includes compulsory third-party arbitration, final rulings, and enforcement procedures.²³ Since TRIPs

¹⁵ See Ryan, *supra* note 10, at 542 ("USTR pursued an aggressive Special 301 diplomacy throughout the eight years of the Uruguay Round to keep countries at the table.").

¹⁶ See, e.g., Mossinghoff, *supra* note 2, at 598-99 (discussing the events that led to the passage of TRIPs); Ryan, *supra* note 10, at 537 (indicating that both function-specific and linkage-bargain lawmaking continue in the post-TRIPs Agreement era); Taylor, *supra* note 11, at 667-69 (examining the history of the TRIPs Agreement); Knapp, *supra* note 6, at 189-90 (describing the passage of the TRIPs Agreement).

¹⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPs Agreement].

¹⁸ See e.g., TRIPs Agreement, *supra* note 17, art. 1; J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 15 n.10 (1997) (addressing the requirements of the TRIPs Agreement); J. H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, 29 INT'L LAW. 345, 347-51 (1995) [hereinafter Reichman, *Universal Minimum Standards*] (discussing the TRIPs mandate).

¹⁹ See TRIPs Agreement, *supra* note 17, part I, arts. 3, 4, part II §§ 1-7; Reichman, *Universal Minimum Standards*, *supra* note 18, at 348 ("These include (1) copyrights and related rights; (2) trademarks and (3) geographical indications; (4) industrial designs; (5) patents; (6) integrated circuit designs and (7) trade secrets or confidential information.").

²⁰ TRIPs Agreement, *supra* note 17, art. 3.

²¹ *Id.* art. 4.

²² *Id.* arts. 63, 64.

²³ See Mossinghoff, *supra* note 2, at 596 (explaining history behind why TRIPs requires "compulsory third-party arbitration, final rulings and enforcement procedures"). See generally Tuan N. Samahon, Note, *Trips Copyright Dispute Settlement after the Transition and Moratorium: Nonviolation and Situation Complaints Against Developing Countries*, 31 LAW & POL'Y INT'L BUS. 1051 (2000) (focusing on copyrights, this article discusses anticipated issues that hypothetically surround dispute resolution).

calls for the adoption of substantive affirmative law, it contains "transitional arrangements"²⁴ that establish finite periods of time for developed,²⁵ developing,²⁶ and least developed countries ("LDCs")²⁷ to ratify and enact TRIPs requirements.

This Comment will discuss international intellectual property standards in the context of the Life Sciences industry.²⁸ It will show how developing countries can intelligently implement TRIPs and use internal administrative and judicial policy to set the bar for patentability at a level that will maximize economic benefits under the Agreement. Therefore, rather than evaluating the effectiveness or non-effectiveness of TRIPs provisions that allow the exclusion of Life Sciences (and other) subject matter from protection,²⁹ this Comment argues that it may be a much more effective strategy for certain developing nations to embrace international intellectual property standards for such subject matter. By implementing and enforcing substantive intellectual property standards, developing countries faithfully adhere to TRIPs. Intelligently implementing TRIPs, by cooperatively using internal administrative and judicial policy to set the bar for patentability higher than it presently is in developed countries, will allow certain developing countries a comparative competitive advantage in the Life Sciences industry. In certain developing countries, the result may be the creation of a superior research and development ("R&D") climate culminating in a shift in R&D investment from developed to developing countries.

The Comment will provide background, in Section 2, on what makes intellectual property, particularly patents, of critical importance to Life Sciences industries. Section 3 will examine the consequences to developed countries, developing countries, and LDCs of protecting Life Sciences intellectual property with substantive international standards. Section 4 will examine the standards promulgated by the TRIPs Agreement. Realizing that the TRIPs Agreement provides significant loopholes for developing countries to exclude Life Sciences products and processes from protection,

²⁴ TRIPs Agreement, *supra* note 17, arts. 65-67.

²⁵ *Id.* art. 65 (1 year).

²⁶ *See id.* (5 years).

²⁷ *Id.* art. 66 (10 years).

²⁸ In this Comment, the Author uses "Life Sciences" to describe both the pharmaceutical and biotechnology industries.

²⁹ TRIPs Agreement, *supra* note 17, arts. 27, 30, 31.

Section 5 will examine how developing countries might utilize administrative and judicial policy in cooperation with intelligent TRIPs implementation to gain an advantage over developed countries. Section 6 of the Comment will conclude that as developed countries attempt to harmonize international intellectual property standards, they should be wary of requiring too little. The result will be not only a surrender of the moral high ground in international intellectual property disputes, but very possibly, a significant negative economic effect in the Life Sciences industry. This negative economic effect includes a loss of R&D investment and jobs, as well as a surrender of technical leadership in an industry previously dominated by developed countries' concerns.

2. LIFE SCIENCES INTELLECTUAL PROPERTY

The role of patents³⁰ in creating new products in Life Sciences industries is of critical importance.³¹ One reason for this is an unparalleled up-front R&D commitment.³² The result of this massive up-front commitment is that typical drug innovation in the United States costs domestic companies between three hundred and five hundred million dollars.³³ The process typically requires over a decade of research, testing, and Food and Drug Administration ("FDA") approval before marketability.³⁴ Since the cost of copying new compounds is typically dramatically less than their original

³⁰ Patents are open letters from sovereign authority that grant a property right. BLACK'S LAW DICTIONARY 1125 (6th ed. 1990).

³¹ See, e.g., Robin Beck Skarstad, Comment, *The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning*, 20 U. PA. J. INT'L ECON. L. 353 (1999) (providing a good account of the European Union's failure to rationally apply patent law to achieve a competitive stance in the biotechnology industry).

³² See Harvey E. Bale, Jr., *Patent Protection and Pharmaceutical Innovation*, 29 N.Y.U. J. INT'L L. & POL'Y 95, 95 (1997) ("In 1996, U.S. research-based pharmaceutical companies [spent] \$16 billion on pharmaceutical R&D, representing nineteen percent of sales—a ratio higher than any other sector . . . and five times the U.S. industry average of less than four percent.").

³³ See *id.* at 95 (emphasizing the cost of drug innovation).

³⁴ See *id.* (noting the lengthy process required in order to gain FDA approval). It is also interesting to note the rigors of invention, by analogy to technology transfer from universities to industry. See, e.g., Peter D. Blumberg, Comment, *From "Publish or Perish" to "Profit or Perish": Revenues from University Technology Transfer and the § 501(c)(3) Tax Exemption*, 145 U. PA. L. REV. 89, 97 (1996) (citing the one in ten rule: "of ten laboratory inventions, only one will receive a patent; only one in ten patents will be licensed by a company, and only one in ten licenses results in more than \$25,000 per year in income").

creation,³⁵ it appears contrary to investors' interests to invest money in new drug discovery and development if foreign competitors are allowed to make, use, and sell identical products for less than the company that exhausted vast R&D expenditures.³⁶ Since industry is responsible for most drug discoveries and also for developing, clearing administrative hurdles, and marketing new drugs,³⁷ it is reasonable to conclude that there will be fewer new drugs absent substantive intellectual property protection. Indeed, Professor Edwin Mansfield concluded that in the pharmaceutical industry, absent patent protection, sixty-five percent of the products introduced would not have been introduced.³⁸

3. CONSEQUENCES TO DEVELOPED COUNTRIES, DEVELOPING COUNTRIES, AND LDCs OF PROTECTING LIFE SCIENCES INTELLECTUAL PROPERTY: THE CONFLICTS

Globalization of economies, combined with a significant polarity in the technical capabilities between LDCs, developing countries, and developed countries, has brought to light a tension between encouraging progress by granting IPRs to deserving inventive enterprises and the resulting restrictions that granting IPRs has on making, using, and selling protected goods in developing countries and LDCs.

Under the TRIPs Agreement, the owner of a patent has the right to exclude others from making, using, and selling the inven-

³⁵ See CALLAN, *supra* note 7, at 29 (noting the low cost of copying); Bale, *supra* note 32, at 95 (discussing the expenses of R&D).

³⁶ The high price of patented products derived from the Biotechnology industry is often justified. The investment to be recouped comes not only from the R&D surrounding the patented product, but also from the many failed attempts at inventing/discovering a new product. See Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPs Agreement: Diverging views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 48 (1998) ("[O]nly one in five thousand pharmaceutical compounds ever reaches the commercial market").

³⁷ See *id.* at 64-65 (discussing the effects of inadequate intellectual property protection on free trade).

³⁸ Edwin Mansfield, *Patents and Innovation: an Empirical Study*, 32 MANAGEMENT SCIENCE 173, 175 (1986) (noting that, of the industries studied, the next closest in importance of patents was the chemical industry, where thirty percent of products would not have been introduced—a testament to the significant importance of patents in the pharmaceutical industry).

tion.³⁹ The owner also typically retains the right to license others to make, use, and sell the invention.⁴⁰ The "winner-take-all"⁴¹ mentality underlying the patent grant provides the patentee with what is, in essence, a time-limited monopoly through which the grantee may recoup investment dollars by cooperatively restricting competition and regulating the price of protected goods.

3.1. *Developed Countries*

The consequences to developed countries, the present home of R&D investment and strong intellectual property protection, of low or negligible international levels of protection, are the loss of profits and an added economic burden⁴² on taxpayers, investors, and patients in developed countries.⁴³ Lower levels of protection are believed to result in less innovative activity because fewer individuals or groups will take on the risk of developing novel ideas.⁴⁴

Higher levels of protection are traditionally believed to have the effect of increasing profitability as well as maximizing the creation of new drugs.⁴⁵ However, patent laws can overprotect. When patent laws overprotect a particular technology, they make it too easy to obtain a patent and remove too much important information from the public domain. When this happens, innovation cannot go forward because investors cannot be reasonably certain that innovations resulting from their investments will not infringe

³⁹ See TRIPs Agreement, *supra* note 17, art. 28 (explaining owners' right to prevent others from "making, using, offering for sale, selling, or importing" patented products or methods).

⁴⁰ See BLACK'S LAW DICTIONARY 1125 (6th ed. 1990) (defining the characteristics of patent ownership).

⁴¹ See Skarstad, *supra* note 31, at 359.

⁴² Eduardo Buscaglia, *Can Intellectual Property in Latin America Be Protected?*, in INTELLECTUAL PROPERTY RIGHTS IN EMERGING MARKETS 96, 104 (Clarisa Long ed., 2000) (estimating U.S. pharmaceutical losses due to infringement and counterfeiting in Latin America in 1995 at \$1,686,000,000).

⁴³ This results because taxpayers, investors, and patients in developed countries are supporting the cost of R&D for much of the rest of the world.

⁴⁴ FRANK P. PORCELLI & JOHN A. DRAGSETH, PATENTS: A HISTORICAL PERSPECTIVE 10 (forthcoming) (on file with author) ("Modern technologies, such as pharmaceuticals . . . require enormous up-front costs . . . [W]ithout some sort of protection, it is unlikely anyone would take the risk of developing breakthrough ideas."); Bale, *supra* note 32, at 98 ("On a global plane, there is very little debate today about *whether* there should be strong intellectual property protection for pharmaceutical products.").

⁴⁵ Bale, *supra* note 32, at 98.

the patents of another. For developed nations, the major task regarding the granting of patent rights is to set a level of protection high enough to encourage innovation, and the public good that accompanies it, without making it too easy to obtain a patent, thus overprotecting and interfering with innovation.

3.2. *Developing Countries*

The consequence to developing countries, some of which are home to very sophisticated Life Sciences infrastructures,⁴⁶ of low or negligible international intellectual property protection, is the ability to pirate, inexpensively,⁴⁷ new Life Sciences products created by developed countries. The lack of an R&D outlay allows industry in developing countries to make drugs at a fraction of the cost required in developed countries.⁴⁸ Low levels of international protection permit Life Sciences companies operating in developing countries to sell their products in third countries at cheaper rates than manufacturers from developed countries. While this is very profitable for companies in developing countries,⁴⁹ the ability of pirates in developing countries to reach third countries enhances the

⁴⁶ See Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507, 525-26 (1996) (discussing the rapid growth of the pharmaceutical industry in India, which is currently one of the most competitive manufacturers of drugs in the world); Bale, *supra* note 32, at 97 (identifying India and Argentina as developing countries with "highly evolved" pharmaceutical industries). For a discussion regarding China, see Leslie Cataldo, Note, *A Dynasty Weaned From Biotechnology: The Emerging Face of China*, 26 SYRACUSE J. INT'L L. & COM. 151 (1998). For a discussion regarding Brazil, see Christopher S. Mayer, Note, *The Brazilian Pharmaceutical Industry goes walking from Ipanema to Prosperity: Will New Intellectual Property Law Spur Domestic Investment?*, 12 TEMP. INT'L & COMP. L.J. 377 (1998).

⁴⁷ See Bale, *supra* note 32, at 98 (comparing the costs of pirating with the costs of innovation).

⁴⁸ See *AIDS Epidemic Traps Drug Firms in a Vise: Treatments vs. Profits*, WALL ST. J., Mar. 2, 2001, at A1 (noting that while drug companies have agreed to sell some patented drugs for less in Africa, Cipla, the Indian pharmaceutical company can still sell for less); *A Problem of Patents*, ECONOMIST, Sept. 30, 2000, at 69 (citing the example of Fluconazole, made by Pfizer at U.S. \$10, and made by Cipla (India) for 25 cents a tablet); Michael M. Phillips & Mark Schoofs, *U.N.'s Annan Starts AIDS Drug Campaign*, WALL ST. J., Mar. 2, 2001, at A7 (reporting that Cipla's price for AIDS drugs is forty percent cheaper than discounted prices of drug developers).

⁴⁹ See Donald G. McNeil, Jr., *Selling Cheap 'Generic' Drugs, India's Copycats Irk Industry*, N.Y. TIMES, Dec. 1, 2000, at A12 (citing examples of some of the drugs copied by Cipla, including Erecto, a counterfeit of Viagra, and quoting Cipla's managing director, "I make every Pfizer Product").

economic insult to taxpayers, patients, and investors in developed countries.

It may also be bad for consumers, not just in developed countries, but in all countries. The reason is that copying works against efficiently maximizing drug creation. This occurs because allowing copying reduces investment in drug discovery since investors will be less likely to obtain returns on investments.⁵⁰ In developing countries, a consequence of not efficiently maximizing drug creation is the failure of the international Life Sciences industry to focus on diseases and disorders that are very prevalent in developing countries⁵¹ and LDCs, but less prevalent in developed countries.⁵² So the success of "free-riding" pharmaceutical companies from developing countries, while profitable for the companies themselves, may reduce the "profit" of world citizens as valued by improved pharmaceuticals and the resulting increases in quality of life derived from better medicines.

The effect of higher levels of protection has resulted in considerable debate. On one side, commentators suggest that higher levels of protection will result in maximizing drug creation in coun-

⁵⁰ Evidence suggests that developing countries that have implemented higher standards of intellectual property protection have benefited. See, e.g., Gerald J. Mossinghoff & Thomas Bombelles, *The Importance of Intellectual Property Protection to the American Research-Intensive Pharmaceutical Industry*, 31 COLUM. J. WORLD BUS. 38, 42-48 (1996) (reviewing the increase in R&D investment and patents granted following the implementation of patent laws in Korea, Mexico, Japan, and Italy).

⁵¹ At least one authority suggests this may not be completely accurate. See Arman S. Kirim, *Transnational Corporations and Local Capital: Comparative Conduct and Performance in the Turkish Pharmaceutical Industry*, 14 WORLD DEV. 503, 516-17 (1986) (remarking on spurious product differentiation and the production and promotion of drugs irrelevant to the leading causes of mortality in the country).

⁵² For facts regarding Lymphatic Filariasis, see WHO Information, *Lymphatic Filariasis, Fact Sheet No. 102* (Sept. 2000), at <http://www.who.int/inf-fs/en/fact102.html>.

Lymphatic Filariasis, known as Elephantiasis, puts at risk more than a billion people in more than 80 countries. Over 120 million have already been affected by it, over 40 million of them are seriously incapacitated and disfigured by the disease. One-third of the people infected with the disease live in India, one third are in Africa and most of the remainder are in South Asia, the Pacific and the Americas.

Id. For facts regarding Malaria, see WHO Information, *Malaria, Fact Sheet No. 94* (Oct. 1998), at <http://www.who.int/inf-fs/en/fact094.html> ("Malaria is by far the world's most important tropical parasitic disease, and kills more people than any other communicable disease except tuberculosis. In many developing countries, and in Africa especially, malaria exacts an enormous toll in lives, in medical costs, and in days of labour lost.").

tries that have, to this point, primarily used their industrial Life Sciences infrastructure to pirate.⁵³ Higher levels of protection should result in enhanced international R&D efforts to combat health problems that are more prevalent in developing countries and LDCs than in developed countries. Furthermore, it should enhance international competitiveness by increasing developing countries' technical infrastructures, thus allowing developing countries' Life Sciences industries to effectively compete in developed country markets.

On the other side, commentators have pointed to a slew of wide-ranging negatives that may result from increasing intellectual property protection in developing countries. Many concerns are directed toward Life Sciences industries and a possible increase in the price of pharmaceuticals that might result from higher levels of intellectual property protection.⁵⁴ However, this is a contentious

⁵³ See, e.g., Adelman & Baldia, *supra* note 46, at 525-26 (explaining how India, for example, has a group of bulk drug manufacturers that dominate the Indian market and are considered fierce competitors worldwide).

⁵⁴ See Carlos M. Correa, *Harmonization of Intellectual Property Rights in Latin America: Is There Still Room for Differentiation?*, 29 N.Y.U. J. INT'L L. & POL. 109, 117-19 (1997) (suggesting that moving too rapidly to a high level of intellectual property protection, if such action results in an increase in the price of Life Sciences products, could create domestic resistance to TRIPs implementation in developing countries); Sara M. Ford, Comment, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 948 n.35 (2000) (citing a WTO committee report suggesting TRIPs implementation will result in increases in the cost of pharmaceutical products); Rosemary Sweeney, Comment, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM L. & POL'Y J. 445, 445-48 (2000) (discussing how the Thai people cannot afford the cost of new patented AIDS therapies and how TRIPs implementation will prohibit Thai pharmaceutical companies from copying patented new therapies from developed countries); see also *A Problem of Patents*, *supra* note 46, at 69 (opining that heightened international intellectual property standards will not allow generic manufacturers to sell copies of patented drugs to poor countries); G8 SUMMIT: *Heal first and Pay Later*, BANGKOK POST, Aug. 27, 2000 (opining that the G8 erred when it failed to commit to relaxing international intellectual property standards because the standards have "jacked up the prices of medicine," negatively affecting the poor's access to medicines); "WTO - Shrink or Sink!": *NGOs' Turn-Around Agenda*, ECOLOGIST, Sept. 1, 2000, at 52 ("The TRIPs agreement promotes monopoly by transnational corporations [and] prevents access to essential medicines."); *India Voices Concern Over Including Health Under WTO*, PRESS TRUST OF INDIA LTD., Nov. 2, 2000, available at 2000 WL 27415375 (reporting TRIPs has prevented India from importing raw materials for anti-retrovirals). Not surprisingly, the WTO feels intellectual property rights are an important part of providing the proper balance between incentive and reward for the creation of and access to drugs necessary to treat debilitating diseases in developing and LDCs. See, e.g., Miguel Rodriguez Mendoza, WTO

issue⁵⁵ and proponents of protection argue that not only is innovation maximized, but also that consumers receive the best price when patent protection exists. Other concerns are cultural—the concept of intellectual property and its emphasis on private rights may not be shared by other cultures.⁵⁶ Another concern is that the harmonization of trade is resulting in the homogenization of cultures, an undesirable⁵⁷ result that justifies that a cultural exception be granted to countries facing cultural domination.⁵⁸ Other critics view TRIPs implementation as a “polite form of economic imperialism,”⁵⁹ or as an assertion of a new regime of colonialism.⁶⁰ Still others rail against the phenomenon of “biopiracy”—the exploitation by developed countries of developing country and LDC biore-sources, including the securing of property rights in existing de-

Deputy Director, An ‘Appropriate Balance’ for Public Health, Address Before the European Commission (Sept. 28, 2000) in WTO NEWS, Oct. 11, 2000 (emphasizing the need for IPRs as necessary for improvements in public health and noting that many of the drugs needed to combat disease in developing countries are not presently under patent, allowing generic industries to make and sell such drugs).

⁵⁵ That increased intellectual property protection, in the form of patents, will result in increased prices for pharmaceuticals is a disputed issue. See Bale, *supra* note 32, at 101-02 (explaining how, if enforced, patenting pharmaceuticals can encourage price competition and prevent generic producers from setting high market prices); Mossinghoff & Bombelles, *supra* note 50, at 39 (“The world trading system has recognized the damage caused to the pharmaceutical industry and to the economic development of local industries by the lack of adequate and effective patent protection.”).

⁵⁶ See William P. Alford, *Making the World Safe For What? Intellectual Property Rights, Human Rights and Foreign Economic Policy in the Post-European Cold War World*, 29 N.Y.U. J. INT’L L. & POL. 135, 140-46 (1997) (positing that the Chinese do not have an appreciation for private rights or IPRs similar to that in other countries).

⁵⁷ See Judith Beth Prowda, *U.S. Dominance in the “Marketplace of Culture” and the French “Cultural Exception,”* 29 N.Y.U. J. INT’L L. & POL. 193, 208-10 (1997) (stating that cultural homogenization is a result that no one wants and arguing that when a nation is battling cultural domination, it should be able to restrict free trade).

⁵⁸ See *id.* at 198. A rational extension of the anti-harmonization position extends to international intellectual property standards.

⁵⁹ See A. Samuel Oddi, *TRIPS – Natural Rights and a “Polite Form of Economic Imperialism,”* 29 VAND. J. TRANSNAT’L L. 415, 458-60 (1996) (noting that implementation of TRIPs will continue to force some developing and LDCs to be consumers if they do not have the technical infrastructure and skill base to compete in knowledge-based industries).

⁶⁰ See Susan Demske, *Trade Liberalization: De Facto Neocolonialism in West Africa*, 86 GEO. L.J. 155, 157 (1997) (“This subtle yet complex reinforcement of dependency may be described as a de facto neocolonialism . . . Classically, neocolonialism has been defined as a conscious policy of economic domination.”).

veloping country and LDC bioresources to transnational corporations and the selling, or exclusion, as the case may be, of the products and benefits of "pirated" bioresources back to developing nations and LDCs.⁶¹

3.3. *Least Developed Countries*

Often the economies of LDCs lack either the skilled human technical base or the technology infrastructure base to effectively compete with foreign multinational corporations in the research, development, and production of products that may be critical to the health, welfare, and progress of their citizenry. Enforcing high levels of protection of the IPRs of foreign corporations may exacerbate this problem by directly causing important goods to be financially inaccessible to citizens of LDCs. Another result of high levels of protection may be the inhibition of technical development in less developed economies. Without a skill base and any significant technology infrastructure, there may be little incentive for investment in either the Life Sciences industry, a technical industry that requires more investment than most others,⁶² or in LDCs, because they would not have a comparative competitive advantage. LDCs may also be victims of biopiracy and may be vulnerable to the cultural homogenization associated with a reduction in trade barriers.⁶³

⁶¹ This complaint is often linked to existing cultural knowledge and is particularly persuasive when the bioresources obtained by developed countries were identified by observing existing indigenous uses for the biological specimen and enhanced when a Life Sciences company purified away the inactive components. This may reasonably be viewed as the taking of intellectual knowledge of indigenous peoples. See Scott Holowick, *Developing Nations and the Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1999 COLO. J. INT'L ENVTL. L. & POL'Y 49 (2000) (describing examples of patents allowed on substances derived from African plants, the indigenous uses for which were identical to the uses of the patented substance; discussing how TRIPs is detrimental to developing countries and LDCs for ecological and environmental reasons and it asserts that TRIPs undermines the biodiversity of developing countries and LDCs); see also Lakshmi Sarma, Note, *Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 TEMP. INT'L & COMP. L.J. 107, 134-36 (1999) (concluding that patent laws need to be altered to protect indigenous knowledge in developing countries and LDCs from Northern "colonialist ideals").

⁶² See, e.g., Bale, *supra* note 32, at 98 ("[T]he share of total expenditures allotted to R&D by the pharmaceutical/biotechnology industry is much higher than in any other important industrial sector.").

⁶³ See Prowda, *supra* note 57, at 209 (discussing how "closing borders" is not necessarily an action of animosity; rather, it is an act of cultural preservation).

Sometimes LDCs are the consumers, the third countries to whom intellectual property pirating companies from developing countries Life Sciences industries direct their relatively inexpensive products. When an LDC has sufficient resources to be a consumer of pharmaceuticals produced by developing countries and if those pharmaceuticals are under patent and not in the generic market,⁶⁴ the adoption of enforceable international intellectual property standards may make LDCs vulnerable to price increases in critical Life Sciences products. This is because, at least in the short term, they will not be able to purchase pirated goods inexpensively. In that case, revamped international intellectual property protection would likely make it illegal for pirating developing country companies to make and sell the drug to LDCs. This would result in a reduction in availability (probably due to an increase in price) of the drug in question in developing countries.

Since LDCs are not on the cusp of successful R&D and developed countries have not yet found ways to efficiently provide new patented pharmaceuticals to LDCs, high levels of IPR protection could be detrimental to LDCs. However, since LDCs typically do not have well-developed Life Sciences industries, they are consequently unlikely, in the short-term, to suffer from direct competition in the research, production, and distribution of pharmacological agents.

As things stand, there may be several effects of lower levels of protection. First, LDCs suffer the basic problem that weak IPR enforcement discourages innovation. The pirating that results from the lack of IPR enforcement deprives citizens of LDCs (and all of the world's citizens) of access to important drugs, because they are not being made. Thus, the free-riding nature of developing countries Life Sciences industries, as a consequence of weak IPR enforcement, is injuring LDCs. Second, lower levels of protection in a country coincide with poor investment in industries that rely on intellectual property protection to encourage innovation. Thus, lower levels of protection will not work in favor of LDCs obtaining

⁶⁴ Life Sciences products can be viewed as existing in one of two markets: under patent—a period of time when the companies responsible for developing the drug are recouping their investment, and in the generic market—when anyone can legally make, use, and sell the product. After a product enters the generic market, the price of that product typically decreases. See Bale, *supra* note 32, at 101 (discussing the two forms of pharmaceutical price competition that exist in countries where there is patent protection).

investment. This could maintain a domestic environment with little skill base and little technical infrastructure. Thus, in the long run, low levels of protection would be detrimental to LDCs.

As a practical matter, the near-term consequences to LDCs of low or negligible international intellectual property protection may be similar to the consequences of high levels of protection. In other words, these countries may be sufficiently non-competitive as to make them insulated from the positive or negative effects of a strong or weak international intellectual property regime.

For example, higher levels of protection theoretically result in more investment in innovation with a resulting increase in quality of drugs to fight disease. If citizens of LDCs cannot financially afford these drugs, they are not likely to have access to them. So the fact that the drugs exist may mean little. Likewise, if the drugs are never created, because of low levels of international IPR protection, citizens of LDCs will not have access to them. Also, if higher levels of protection result in increased investment in innovation, the fact that LDCs do not have a technical skill or infrastructure base will make them unlikely candidates for R&D investment, even though labor costs might otherwise be less expensive. So the fact that more investment is occurring may simply enlarge the economic polarity between developed and developing countries versus LDCs. In sum, the effect of high levels of international intellectual property protection on LDCs will, in the short term, likely be minimal, and in the long term, may increase the ground needed to be covered by LDCs to become competitive economies in a global market.

4. TRIPS STANDARDS

The TRIPs Agreement acts to protect IPRs in all WTO member countries. Developing countries should have introduced the minimum standards of intellectual property protection, as promulgated under the 1994 Agreement, into their domestic laws by January 1, 2000. LDCs have until 2005 to implement the Agreement.⁶⁵

Implementation of the TRIPs Agreement, in many countries, requires the affirmative act of creating or modifying a substantive

⁶⁵ Extensions are possible. See TRIPs Agreement, *supra* note 17, art. 66 ("The Council shall, upon duly motivated request by a least-developed country [m]ember, accord extensions of this period.").

body of law.⁶⁶ ⁶⁷ Requirements for patentability are articulated in Article 27 of TRIPs.⁶⁸ Article 27 proceeds by stating: "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."⁶⁹ The requirements for patentability, "involve an inventive step," and "are capable of an industrial application" are intended to be viewed as synonymous⁷⁰ with "non-obvious"⁷¹ and "useful"⁷² respectively.⁷³

The TRIPs Agreement has several provisions designed to protect member nations in the event of anti-competitive practices by IPR holders, emergencies, and situations where the public interest mandates obviating or suspending the property right.⁷⁴ TRIPs states: "Member [countries] may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment."⁷⁵ This limitation is itself limited by the condition that the "exclusion is not made merely because the exploitation is prohibited by domestic law."⁷⁶

⁶⁶ See *id.* art. 1 ("Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.").

⁶⁷ Some commentators have suggested that this is a very significant cost, especially due to the introduction and maintenance of the judicial and administrative infrastructures. See Robert M. Sherwood et al., *Promotion of Inventiveness in Developing Countries Through a More Advanced Patent Administration*, 39 IDEA 473 (1999); see also McCabe, *supra*, note 36 at 54-56 (arguing that a strong intellectual property protection regime is inappropriate in developing countries); Robert M. Sherwood, *The TRIPs Agreement: Implications for Developing Countries*, 37 IDEA 491, 522-44 (1996-97) (discussing the kinds of costs and measures needed to implement TRIPs in countries where they did not previously have the infrastructure needed to do so).

⁶⁸ TRIPs Agreement, *supra* note 17, art. 27.

⁶⁹ *Id.*

⁷⁰ See 35 U.S.C. §§ 101-103.

⁷¹ *Id.*

⁷² *Id.*

⁷³ See TRIPs Agreement, *supra* note 17, art. 27 n.5 ("For purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a member [country] to be synonymous with the terms 'non-obvious' and 'useful' respectively.").

⁷⁴ See *id.* art. 27(2).

⁷⁵ *Id.*

⁷⁶ *Id.*

The Agreement further allows member countries to exclude from patentability, "diagnostic, therapeutic, and surgical methods for the treatment of humans or animals"⁷⁷ as well as "plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."⁷⁸

Article 30 of the Agreement allows "limited"⁷⁹ exceptions to the rights conferred⁸⁰ that do not "unreasonably conflict with a normal exploitation of the patent"⁸¹ and do not "unreasonably prejudice the legitimate interests of the patent owner."⁸² Article 31 of the Agreement establishes authorization for compulsory licensing and articulates the requirements that must be met for a member nation to effect compulsory licensing.⁸³

Discussion regarding the prospective effectiveness of the provisions allowing the exclusion of certain subject matter from patentability,⁸⁴ the limitations on the "rights conferred,"⁸⁵ and the compulsory licensing provision⁸⁶ has been significant.⁸⁷ Some commentators believe that the provisions provide a framework for developing countries to manage public health concerns by either excluding important drugs from patent protection or compelling

⁷⁷ TRIPs Agreement, *supra* note 17, art. 27(2).

⁷⁸ *Id.*

⁷⁹ TRIPs Agreement, *supra* note 17, art. 30.

⁸⁰ *See id.* art. 28. The rights conferred to patentees in the Agreement are as follows: (a) to prevent third parties from making, using, offering for sale, selling, or importing a product; and (b) where the subject matter is a process, to prevent third parties from using the process, using, offering for sale, selling or importing the product obtained directly by that process.

⁸¹ *See id.* art. 30.

⁸² *Id.*

⁸³ Note that the drafters expressly state that Article 31 does not displace a member's option to exercise rights under Article 30. *See* TRIPs Agreement, *supra* note 17, art. 31 n.7.

⁸⁴ *See id.* art. 27.

⁸⁵ *See id.* art. 30.

⁸⁶ *See id.* art. 31.

⁸⁷ Effectiveness is often measured by the practical effectiveness of these provisions in protecting developing countries from perceived insults resulting from the actions of transnational corporations protecting intellectual property rights. These include price increases in important pharmaceuticals, as well as exclusionary tactics—for instance, the failure of an IPR holder to work an important patent in a particular country. Also, effectiveness is viewed as whether or not these provisions effectively disable what might otherwise be critical IPR grants by allowing developing countries and LDCs to avoid establishing and enforcing protection.

foreign IPR holders to license at affordable rates.⁸⁸ Some have suggested that certain of the provisions may actually expand a member country's opportunity to limit the patentee's grant.⁸⁹ Others commentators view the IPR limiting provisions of TRIPs as serious concerns because they are too broad and may encourage the exclusion from protection of important pharmaceutical products⁹⁰ and discourage the biotechnology industry.⁹¹

This Comment takes a different approach to the evaluation of TRIPs. It does so not with the thought that the exclusionary provisions of TRIPs must be ineffective, but because, for certain developing nations, a much more effective strategy may be to embrace international intellectual property standards.⁹² Therefore, rather than evaluating clauses in the TRIPs Agreement that permit exclusion for subject matter from protection, this Comment will show that by intelligently implementing and enforcing substantive in-

⁸⁸ See, e.g., Robert Weissman, *A Long, Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1116-24 (1996) (describing how developing countries may use some of the provisions to their advantage to restrict drugs prices).

⁸⁹ See Reichman, *Universal Minimum Standards*, *supra* note 18, at 355 (commenting on Article 30: "These and other articles . . . preserve, and may even expand, preexisting grounds for limiting a patentee's exclusive rights."). The same author suggests interpretation of the compulsory licensing provision may be controversial. He notes that the United States has typically required a finding of "anticompetitive practices bordering on antitrust violations" to justify compulsory licensing. *Id.* Many other countries consider it sufficient that a patentee does not work a patent locally, refuses to grant licenses on reasonable terms, does not supply the national market with sufficient quantities of the product, or demands excessive prices for the product. *Id.*

⁹⁰ See 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, 478 (1994) (noting that the subject matter exclusions are very broad and that the biotechnology exclusions substantially limit the biotechnology industry).

⁹¹ See, e.g., Skarstad, *supra* note 31, at 383-84 (noting that exclusion of biotechnology from IPR protection negatively affects the development of Life Sciences industry).

⁹² Excluding subject matter from patentability using the exclusionary clauses of TRIPs prevents the commercial exploitation of the subject matter. Excluding material in this manner preempts compulsory licensing and disallows the use of generic manufacturers to make the drugs in question. It arguably permits only the government of an excluding country to make and, in a non-profit manner, provide the drugs only to its population. This is unlikely to create the Life Sciences Industry infrastructure necessary to promote industry and perhaps even the production and distribution of the products in question. See Weissman, *supra* note 88, at 1100 (discussing the effects of requiring "the denial of patentability to be linked to a denial of commercial exploitation of the invention").

tellectual property standards, particular developing countries can faithfully implement TRIPs and in so doing, utilize internal administrative and judicial policy to maximize their benefits. The result of intelligent TRIPs implementation for these countries could be a comparative competitive advantage in the Life Sciences industry.

5. INTELLIGENT TRIPS IMPLEMENTATION

Throughout this discussion, the reader may consider that a developing country may be able to achieve the results postulated by not entering the TRIPs Agreement at all. This seems unlikely as non-member nations place themselves in the unenviable position of possible multilateral cross-sectoral sanctions for violating member nations' IPRs. In addition, they would not gain from the trade concessions that resulted from the TRIPs negotiations. By implementing TRIPs with an eye to the considerations included in the discussion, a nation can gain the moral and legal high ground of having and enforcing substantive intellectual property standards that comply with those articulated in TRIPs. Absent unilateral action,⁹³ which is unjustified under the Agreement against a complying member nation, member nations are directed to the WTO Dispute Resolution Body ("DSB") to acquire satisfaction in disputes involving IPRs. Because this is an impartial panel, victories in this forum can be very powerful tools in further defining international intellectual property standards.

As noted, TRIPs implementation requires member nations to grant patents for "any inventions,"⁹⁴ whether "products or processes,"⁹⁵ that are new, involve an inventive step (non-obvious), and are capable of industrial application (useful). In the United States there exists over a century and a half of case law defining the meaning of new, useful, and non-obvious. In some countries, forced by TRIPs to implement language synonymous standards, there is no administrative nor judicial definition of the legal meaning of these terms with regards to patentability. In others,

⁹³ The United States is still prepared to utilize Section 301 regarding intellectual property disputes. See, e.g., Section 301 Table of Cases (Aug. 9, 1999), available at <http://www.ustr.gov/reports/301report/act301> (showing the U.S. Trade Representative's initiation of investigation regarding Intellectual Property Laws and Practices of the Government of Paraguay in 1998).

⁹⁴ See TRIPs Agreement, *supra* note 17, art. 27.

⁹⁵ *Id.*

intellectual property laws exist as recent statutory constructions,⁹⁶ created in response to threats of sanctions by the United States and other developed countries, and that have yet to be uniformly enforced. If the United States is any example, determining the meaning of the terms that compose the elements of patentability is no mean feat. Developing countries that intelligently implement TRIPs may seriously consider the ramifications of the legal definition of these terms as they create the legal and administrative infrastructure necessary to grant and enforce patents. Done properly they can set these standards to create a comparative competitive advantage relative to developed countries.

5.1. What is New?

What is new? Examine a hypothetical posited by Ruth Gana.⁹⁷ Imagine that a Life Sciences company observed the native people of a developing country using a particular plant to treat malaria. The native people have limited but observable success. If they have been practicing this behavior for a significant period of time, patenting their use of the plant in such a manner may be barred,⁹⁸ at least in the United States, by the statutory bar.⁹⁹ If the Life Sciences company obtains the biological material and purifies away the active ingredient, or purifies the active ingredient to some substantially purified form, they will likely satisfy the "new" requirement of patentability for what is essentially the same biochemically active ingredient.¹⁰⁰

Although the United States qualifies such a purification step as "new," it does not require another country (or the DSB) to view what is essentially a technical purification as resulting in "new" matter. For developing countries implementing TRIPs, there is

⁹⁶ See, e.g., Cataldo, *supra* note 46, at 151 (noting China's recent renovation of its intellectual property laws).

⁹⁷ See Ruth Gana, *Prospects for Developing Countries Under the TRIPs Agreement*, 29 VAND. J. TRANSNAT'L L. 735, 749-50 (1996) (discussing the "complex application of rules" that is used to define the word "new").

⁹⁸ See *id.*

⁹⁹ 35 U.S.C. § 102(b) (1994).

¹⁰⁰ See *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911). The opinion, written by Learned Hand, stands for the proposition that in the context of the Life Sciences, a substantial purification of an existing biochemical activity, can qualify as a "new" composition of matter. It is also under a similar theory that DNA sequences are patentable—DNA purified away from the surrounding cellular architecture results in a "new" composition of matter.

significant leeway in defining the term "new." If the term is defined broadly, that is, existing matter is given a broad definition,¹⁰¹ the result is a narrowing of the field of patentable subject matter. In our example, if a broad definition of the native people's plant preparation is used, it may no longer be "new" to create some otherwise purified, or more purified, form of the same active ingredient. Alternatively, interpreting the term "new" in the narrowest sense may, by giving existing subject matter a narrow definition, allow even the most trivial changes in purification state to qualify as "new."¹⁰² In our example, this vastly expands the field of patentable subject matter because small changes in the purification state or the use of other purification methodology resulting in actual useful activity and yield, but other inactive ingredients, may become patentable subject matter. A developing country implementing the "new" prong of TRIPs would need to decide what type of definition "new" should receive. This decision would likely be based upon the economic, legal, and political needs of the country in question.

As a practical matter, a country that chooses to allow a very broad description or definition of existing matter will give fewer patents because applicants will have a more difficult time satisfying the "new" requirement. The patentability bar will be higher. Following this reasoning to its natural conclusion, the most sophisticated and innovative individuals will get patents. Few others will. A country that employs a narrow interpretation of the "new" requirement, and thus permits only a narrow definition of existing matter, will grant a large number of patents. They will set the bar for patentability lower. That small differences make a subsequent invention "new" will allow individuals who had very little inventive contribution to obtain patents on what are, for the most part, the inventions of others that are arguably already in the public domain.

¹⁰¹ Depending upon how broad a description existing matter is permitted, the "new" requirement may approach the requirement for nonobviousness.

¹⁰² This is a position favored by commentators concerned about the interests of developing countries in TRIPs implementation; they suggest that the broadening of patentable subject matter will allow for more domestic patents in countries that cannot compete in high-technology Life Sciences industries. *See, e.g.,* Gana, *supra* note 97, at 750 (arguing that a low level of inventiveness is important for the progress of developing countries).

Following our purification example, a country employing a narrow description of existing subject matter may, in the context of a biochemical purification, allow a patent for a pharmaceutical invention that performs an identical function, in an identical or substantially similar way, with an identical or substantially similar result. However, a country giving a broad definition to existing matter would not grant a patent for the above purification because it failed to satisfy the requirement that the invention be new.

5.2. *What is Useful?*

In the past, some countries, including at least one "developed" country, prevented foreign patentees from obtaining a patent unless the patentee established a new industry in that country through the patent.¹⁰³ The TRIPs-mandated national and most favored nation treatments make any such interpretation by developing countries unlikely. Such an interpretation would likely be too restrictive and too far removed from a reasonable definition of "useful." Between "new," "capable of an industrial application," and "involve an inventive step," "capable of an industrial application" as a synonym of "useful" may be the requirement with the least flexibility.

However, the utility of an invention can be a critical component of patentability. In the United States, recent decisions seem to have expanded the definition of useful.¹⁰⁴ This has allowed the patenting of the application of algorithms.¹⁰⁵ The result is that a patent application that recites a practical utility most likely satisfies the utility element of patentable subject matter.

In the realm of the Life Sciences, the patentability of Expressed Sequence Tags ("ESTs") has been of particular concern.¹⁰⁶ ESTs

¹⁰³ See *id.* at 746 ("Prior to the Paris Convention, . . . Spain and Bolivia did not grant patents for inventions unless such [i]nventions, in addition to being new, also established a new industry [i]n the country.").

¹⁰⁴ See *e.g.*, *State St. Bank v. Signature Fin. Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999) (discussing application of the definition of "useful"); *AT&T Corp. v. Excel Communications, Inc.*, No. CIV.A.96-434-SLR, 1999 WL 1050064, at *6 (D. Del. Oct. 25, 1999) (applying standard set by *State St. Bank v. Signature Fin. Group* for the definition of "useful").

¹⁰⁵ See *State St. Bank*, 149 F.3d at 1372 (discussing the "mathematical algorithm" exception).

¹⁰⁶ Most cells in the bodies of higher organisms contain a full complement of the genes of the respective organism. Cells in different tissues and often in different disease states are different because they express different parts of the genome

themselves, while valuable research tools, typically have little other utility. However, ESTs can be used to identify the complete sequence of the underlying gene using well-established experimental methods. Since ESTs typically represent the partial sequence composition of the underlying gene, many individuals have tried to use EST sequences to claim through to the underlying gene. When that is not possible, individuals have tried to claim the sequence itself with the idea that using "comprising" or "consisting essentially of" language will allow them to control the use of the underlying gene once it is ultimately cloned.

At least partly in response to this, the U.S. Patent and Trademark Office has issued new utility standards which require the patentee to assert at least one "well-established utility," i.e., one that is "specific, substantial, and credible."¹⁰⁷ This does not appear to include the use of ESTs as research tools to identify the underlying gene and thus will probably operate to reduce the number of patents granted on ESTs.

A developing country or LDC can modulate the level of utility. The language used by the TRIPs agreement, while claiming to be synonymous with "useful"¹⁰⁸ as it is used in the United States, is actually "capable of an industrial application."¹⁰⁹ Such language could easily be construed as requiring a higher standard than "useful" as it now stands in the United States. Regarding business methods and applications of algorithms, such language is perhaps permissive. Regarding ESTs, whose application is typically as a research tool, such language could easily be viewed as hostile to awarding patents. Indeed, such language might be interpreted as

than other cell types or cells not in a disease state. Differential expression of certain regions of DNA from the human genome occur because different regions of the genome are transcribed from DNA into another nucleic acid, RNA, which is then translated into protein. Techniques exist for identifying and sequencing RNA molecules or portions thereof. These molecules are ESTs. Identifying and sequencing ESTs is important for many reasons, including their ability to identify the genes that they represent. They are very important research tools. However, outside of that use, many of the ESTs do not have a practical utility. Even so, because ESTs can be used to identify the sequence composition of, usually part, but sometimes all, of the underlying genes from which they were transcribed, researchers and corporations have used the sequence information obtained from ESTs to try to claim the underlying gene.

¹⁰⁷ Utility Examination Guidelines, 66 Fed. Reg. 1092, 1097 (Jan. 5, 2001).

¹⁰⁸ See 35 U.S.C. § 101 (1994) (codifying the requirements under which an individual can obtain a patent).

¹⁰⁹ See TRIPS Agreement, *supra* note 17, art. 27.

hostile to a range of gene based biotechnology reagents whose industrial application is only theoretically possible,¹¹⁰ rather than practically possible.

There may be advantages to a country that will disallow the patenting of ESTs as compared to a country that will allow the patenting of ESTs. Since ESTs are not typically valuable for practical applications other than as a research tool, allowing protection of ESTs would result in allowing protection of a research tool. By doing so, the property right holder would be able to prohibit others from *using* the EST to find the underlying gene and perhaps even from *using* the underlying gene. If, as I suggest is possible, using the "capable of an industrial application" requirement, a country can, under TRIPS, exclude ESTs from patentable subject matter, it may create a competitive advantage relative to countries that allow the protection of ESTs.

This scenario is perhaps particularly bad for the country that protects ESTs because the public is not getting significant practical utility from the ESTs even though they have granted a property right to the EST discoverer. Thus, distinct from a pharmaceutical compound, from which, for a price, the public will get a benefit, in the case of EST protection, the public is not getting the near-term benefit of the utility. Rather, the public is expressing the confidence that the party that discovers and patents an EST is somehow the party most motivated and able to eventually turn it into something of value to the public.

A country that does not allow protection of ESTs can allow multiple parties to use the EST to come up with a practical utility. This should be an ideal circumstance because it incentivizes multiple actors to achieve the practical result. After that result is achieved, the winner of that race can obtain a patent. This situation is not the same as weak protection. Neither, I suspect, will it result in companies not identifying and using ESTs. ESTs are not so hard to identify, in fact, they can be obtained in a mechanized manner. Since the economic and public benefit is downstream from the EST anyway, disallowing the protection of ESTs that have

¹¹⁰ This might include a wide array of gene therapy applications. While there is a good basic understanding of what needs to be done and possession of the gene sequences allows their use in therapy, the practical problems of effectively introducing these genes into subjects and getting a sustained or regulable response is a problem that still needs to be refined before these genes can generally be used in humans.

no practical utility should not result in failure to encourage research using EST reagents.

5.3. *Non-obvious*

The non-obvious¹¹¹ ("involve an inventive step") requirement is perhaps the ultimate bar to patentability.¹¹² Considerable jurisprudence has evolved in the United States regarding the term and its application to patent law.¹¹³ In the United States the doctrine of non-obviousness acts to prevent patentability, if, given the prior art, the invention would have been *obvious* to one of ordinary skill in the art.¹¹⁴ The purpose of the non-obviousness requirement is to complement the novelty requirement. From a certain perspective, patentability is all about novelty. Non-obviousness can be understood as a way to "bump-up"¹¹⁵ the novelty requirement so that subject matter for which a patent is granted has a conceptual or inventive newness that could otherwise easily be escaped if new only meant not having existed before. Non-obviousness, because of its conceptual nature, is very difficult to pin down, and thus, has considerable interpretive flexibility.

Because of the relationship between "non-obvious" and "new," the issues that arise in the context of patentability decisions can be similar. Returning to the example of the indigenous use of a plant or plant extract to treat a particular disease,¹¹⁶ it seems clear that at least in some circumstances, making a plant extract by another procedure, so that the resulting extract has different inactive ingredients or a different concentration of biological activity, or both, can reasonably be viewed as obvious.

The language of the TRIPs Agreement, intended to be analogous to "non-obvious" is "involve an inventive step."¹¹⁷ It is cer-

¹¹¹ See 35 U.S.C. § 103 (1994).

¹¹² See generally PORCELLI & DRAGSETH, *supra* note 44, at 138 ("Non-obviousness is really the most significant hurdle an aspiring patentee must clear.").

¹¹³ See, e.g., *Graham v. John Deere Co.*, 383 U.S. 1 (1965) (discussing the nature of the term "nonobvious").

¹¹⁴ See *id.* at 14 ("Patentability is to depend . . . upon the 'non-obvious' nature of the 'subject matter sought to be patented' to a person having ordinary skill in the pertinent art.").

¹¹⁵ Author's quotation.

¹¹⁶ See *supra* Section 5.1.

¹¹⁷ See TRIPs Agreement, *supra* note 17, art. 27.

tainly arguable that there is not a conceptual inventive step in trying purification protocols to obtain what is only a "differently" purified active ingredient. Even if the results of the experimentation are not absolutely predictable, the application of a number of standard purification protocols to determine whether the desired activity can be purified may not "involve an inventive step." Rather, it involves some repetitive work. Work nowadays is often done by machines. Thus, a country implementing TRIPs might decide to mandate that its version of the Patent and Trademark Office find that the results of such purifications do not "involve an inventive step" and are thus not patentable.

In the United States, in the field of biotechnology, it is possible to get a patent on things that are reasonably viewed as obvious,¹¹⁸ for instance, the patenting of a DNA sequence obtained by reverse translation¹¹⁹ of the primary amino acid structure of a protein.¹²⁰ The techniques required to obtain the DNA sequence in this manner are well defined.¹²¹ The genetic code is known.¹²² Yet the Federal Circuit views DNA sequences obtained in this manner as "non-obvious."¹²³

The result of this judicial interpretation of obviousness is that, as a practical matter "any given DNA sequence . . . is obvious only if the prior art actually recites a similar or identical sequence."¹²⁴ This has encouraged Life Sciences companies to seek patents on vast numbers of DNA sequence fragments that they have isolated through routine automated methods.¹²⁵ Employing non-obviousness in such a manner "significantly impoverishes"¹²⁶ the

¹¹⁸ See Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 833 (1999) (discussing the lowered bar for patentability in the context of obviousness).

¹¹⁹ This involves obtaining the amino acid sequence for part of a protein and using the genetic code, which specifies the nucleic acid sequences that could give rise to such an amino acid sequence, along with standard experimental techniques, to obtain the original DNA sequence that encodes the protein.

¹²⁰ See *In re Deuel*, 51 F.3d 1552, 1557-60 (Fed. Cir. 1995).

¹²¹ See Rai, *supra* note 118, at 833 (describing the steps necessary to obtain a DNA sequence).

¹²² See *id.*

¹²³ See *id.* at 834 (discussing why DNA sequences are nonobvious).

¹²⁴ *Id.* at 834.

¹²⁵ See generally Eliot Marshall, *Patent Office Faces 90-Year Backlog*, 272 SCIENCE 643 (1996) (noting that there has been a flood of new patent applications for DNA sequences).

¹²⁶ See Rai, *supra* note 118, at 833.

public domain and suggests that citizens of the United States are paid too little for the "embarrassment"¹²⁷ of granting a patent.

A similar and related example is the problem of homologues. Homologues are distinct molecules of substantially the same structure. Due to the similarity in structure, homologues often have substantially the same or similar functional characteristics. A legal interpretation that makes a molecule obvious only if the prior art discloses exactly the same molecule allows for the granting of rights for an invention that, from some perspectives, is reasonably viewed as obvious.

A developing country or an LDC need not adopt such standards of non-obviousness; the TRIPs Agreement does not require it. Instead, it could decide that when an experimental result is a near certainty, the result is obvious. It might then reject patent applications directed to such subject matter as obvious, and, in the parlance of the TRIPs Agreement, not involving an inventive step. Countries that choose to adopt such standards will need to be concerned with how such a choice will affect the economic incentives of Life Sciences companies. However, observed from a global perspective, the patentability of this subject matter in one country (e.g., a developed country) as compared to its unpatentability in another (developing countries and LDCs) may influence the decision of the latter because of the possible ramifications of having a competitive environment where there is a greater amount of sub-patentable information relative to that of a competitor where there is relative overprotection.

This exodus of "obvious" information from the public domain to private coffers is precisely the sort of concern that developing countries and LDCs have regarding the Life Sciences and the ability of developed countries to sew up IPRs before developing countries and LDCs can compete effectively in the Life Sciences industry. TRIPs does not require adhering countries to adopt such a generous view of obviousness in the Life Sciences. A developing nation intelligently implementing TRIPs may rightly and reasonably view such above-mentioned "inventions" as obvious and disallow them within the context of a consistent, TRIPs-legal, and transparent patent policy. The result of such a policy would be to

¹²⁷ ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 199 (2d ed. 2000) (quoting VI WRITINGS OF THOMAS JEFFERSON (H.A. Washington ed.)).

raise the bar for patentability. Fewer patents would be granted and more subject matter could remain in the public domain.

Alternatively, a developing country might adopt standards similar to those of the United States. This would lower the bar for patentability. More patents would be granted on things that could easily have been figured out. In such an environment, second comers (and maybe even third comers) would be able to get patents from the discoveries of the original innovator.

5.4. *Written Description/Enablement*

It is often the goal of those prosecuting patents to get the broadest claims possible allowed. This permits the patentee to lay claim to the greatest amount of subject matter. In the field of Life Sciences, the Federal Circuit has used an interpretation of the written description requirement in an effort to narrow the scope of protection.¹²⁸ The Federal Circuit now requires that an applicant for a patent grant actually isolate and sequence a DNA molecule in order to sufficiently describe it.¹²⁹ Consequently, it is not sufficient to simply describe the amino acid sequences that comprise a gene product, combined with a method for isolating the DNA molecule, to describe the DNA molecule. The specific molecular structure of the molecule must be known and disclosed.

The TRIPs Agreement has a written description requirement,¹³⁰ which uses language similar to that used in the U.S. requirement.¹³¹ Basically, the requirement is that "applicant[s] for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art"¹³² Developing countries intelligently implementing TRIPs may use the written description requirement to raise or lower the bar for patentability by requiring more or less description of the invention in the application. They might also use the written description requirement to narrow or enlarge the scope of protection.

¹²⁸ See Rai, *supra* note 118, at 834 n.48 (discussing the effect of a "written description" requirement).

¹²⁹ See, e.g., *Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) (describing the amino acid sequence for insulin and a method for obtaining the DNA sequence in a claim to the DNA sequence).

¹³⁰ See TRIPs Agreement, *supra* note 17, art. 29.

¹³¹ See 35 U.S.C. § 112 (1994).

¹³² TRIPs Agreement, *supra* note 17, art. 29.

In the Life Sciences realm, one way to treat nucleic acid and amino acid sequence information is to require that the written description include the complete structure (the primary sequence structure) of the claimed molecule. Furthermore, when interpreting the scope of the claim, allow it to cover only the disclosed sequence. By such an interpretation, and by requiring "consisting of" instead of "consisting essentially of" or "comprising"-type language, the patent grant is effectively narrowed.

Alternatively, allowing for substantially similar sequences to be sufficiently described by the disclosure of one specific sequence will allow a broadening of the patent grant. This is a possible interpretation, because as a practical matter, substantially similar sequences often perform substantially similar functions. A country wanting to broaden the grant even more might allow the disclosure of a single specific sequence to cover a broader range of similar sequences.

However, there are good reasons not to allow the description of single sequence to enable many other sequences. While substantially similar sequences do often perform the same functions, small changes in the sequence can make certain specific sequences functionally distinct and functionally superior to an existing or well known sequence. A proper goal of intellectual property policy should be to encourage companies and investigators to identify those special sequences, sometimes different from naturally occurring forms, that might be highly therapeutically valuable to the public.

5.5. The Scope of Protection

When a country construes existing patented subject matter narrowly it decreases the scope of protection. Less scope means less protected matter and therefore theoretically allows for the patenting of new matter that is not anticipated by existing patented subject matter. Alternatively, construing the scope of existing patents broadly, to cover a large amount of subject matter, may reduce the number of patents granted because there is less unpatented matter.

One way to examine the scope of a patent is to examine when a patent is infringed. In the United States, a patent can be infringed literally or under the doctrine of equivalents. Under a theory of literal infringement, in order for a device to be considered infringing, each and every element of the patentee's claim must be present in

the accused device. Therefore, if the accused device differs in insubstantial ways it may not infringe by literal infringement.

In the United States, if an accused device does not literally infringe, it may still infringe under the doctrine of equivalents if it performs substantially the same function in substantially the same way to achieve substantially the same result as the protected device.¹³³ In this manner, the scope of protection for claimed subject matter is broadened because while the accused device does not literally fall under the claims of the patent, we are prepared to find that it infringes anyway. The general policy is that patent protection would be weak, if not nonexistent, if competing parties could make small changes to patented subject matter and not be liable for infringement. If this were possible, the scope of protection would be very narrow, so narrow in fact that it might likely act to reduce the incentive of individuals to invest time and money in inventive behavior.

TRIPs does not contain a "doctrine of equivalents"¹³⁴ provision. Therefore, countries adopting the agreement are not required to enforce patent rights against possibly infringing devices that differ only insubstantially from the patented device. The effect of a lack of a doctrine of equivalents—or of very narrow protection—is a concern distinct from how high or low the bar for patentability is set.

A legal regime that enforced infringement liability only for the literal scope of patent claims with certain Life Sciences subject matter could have a dramatic effect. Sequences can often be changed without significant functional effect. Thus, if claims were directed to the DNA sequence of a gene or EST that had a defined primary (sequence) structure, small changes in that sequence could likely be made that would not cause a significant difference in function, but would make the changed sequence literally different from the claimed one. The biotechnological tools necessary to make such changes are well known and can be used successfully by even relatively unsophisticated parties. Thus, a patent on a

¹³³ See *infra* note 134.

¹³⁴ The doctrine of equivalents exists to prevent the practice of fraud on a patent. It prohibits patenting of minor changes that, while not literally infringing claims, perform substantially the same function, in substantially the same way to achieve substantially the same result. See *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608 (1950) (articulating the function-way-result test for doctrine of equivalents).

particular sequence, in the absence of some sort of equivalents regime is likely to be very narrow protection indeed.

5.6. *How Should a Developing Country Implement TRIPs Patents?*

As noted in the above examples, there are numerous ways that developing nations can apply the standards for patentability promulgated in the TRIPs Agreement to modulate the bar for patentability and the scope of protection. A critical question then, will be how *should* a developing nation implement patentability standards.

Some commentators have suggested that developing countries and LDCs should endeavor to set the bar low, that is, make patentability easy.¹³⁵ One possible result of such a strategy would be to make patents more accessible to domestic enterprises that are less competitive than their foreign counterparts from developed countries. However, an alternative result is that a low bar simply makes patents too easy to get. Transnational pharmaceutical and biotechnology companies are some of the most sophisticated enterprises at obtaining patents. In an environment of easy patentability with a low non-obvious hurdle, a more likely result of a low bar would be that transnational Life Sciences companies would be able to secure vast amounts of intellectual property. This would sequester large amounts of subject matter from the public domain resulting in a comparative competitive disadvantage for developing countries' Life Sciences industries. The competitive disadvantage would arise because they would be excluded from making, using, and selling products, or products of processes made with protected intellectual property. This sequestration of information, then, reduces the subject matter that developing countries' Life Sciences companies can use to pursue R&D.

Rather than setting the bar for patentability low, there are good reasons for developing nations to set the bar higher. If developing countries with a substantial Life Sciences industrial infrastructure and technical skill base¹³⁶ pursue a patent policy, based upon TRIPs, that requires a higher bar for patentability, they may create a comparative competitive advantage for themselves over developed nations.

¹³⁵ See, e.g., Gana *supra* note 97, at 751 (suggesting that a lower innovation requirement may facilitate creative domestic activity).

¹³⁶ For examples, see *supra* Section 3.2.

It is a common premise that not having intellectual property protection in the form of patents is economically inefficient. It is also a common premise that allowing too much protection in the form of patents is economically inefficient. This occurs because too much information is taken from the public domain. The result is a restriction in the flow and utilization of information. When this happens, it limits the number of individuals who can use that information to innovate and create next generation products.¹³⁷ In the context of this model, the Author proposes that developing countries adopt a strategy in which they set the bar for patentability higher than it presently exists in developed countries, rather than lower.

This proposal is obviously subject to the criticism that given the competitive abilities of developed countries, developing nations would be able to get few domestic patents. While this seems true in the short term, the result is not likely to be different if developing countries set a very low bar for patentability. Transnational corporations with sophisticated R&D and patenting abilities would simply get even more patents, to the disadvantage of developing countries industry and economy. The advantage of setting the patentability bar higher relative to developed countries, yet still within TRIPs standards, is that it preserves a wealth of subpatentable information in the public domain in developing countries that has been excluded from the public domain in developed countries.

As a consequence, this information is available domestically for R&D toward the end of creation of next-generation products. While it is true that patented products and products of patented processes may not be made abroad and imported back to the United States absent a license, in countries faithfully implementing TRIPs, products and processes may be used for research purposes to attain next generation products and processes. These next generation products and processes will be patentable subject matter and will thus be eligible for protection in both the United States

¹³⁷ Indeed, a helpful analogy may be the difference in Trade Secret laws between the Northeastern United States and California. It has been postulated that the reduced enforceability of restrictive covenants and greater employee flow causes a greater flow of subpatentable information. The result of this has been greater innovation in California, relative to that achieved in the Mid-Atlantic and New England States in recent years. See, e.g., ANNALIE SAXENIAN, *REGIONAL ADVANTAGE: CULTURE AND COMPETITION IN SILICON VALLEY AND ROUTE 128* (1994) (comparing Silicon Valley with Route 128 in Boston because both areas are known as leading centers for electronics).

and other countries. Since in the United States only a limited number of companies may use patented products and processes for R&D purposes,¹³⁸ competition will be reduced relative to the developing country where, because the information is in the public domain, anyone and everyone may use it to develop next generation products. This pro-competitive environment should encourage foreign and domestic investment and may ultimately result in the transfer of R&D operations from developed to developing countries that follow this policy. These countries have an even greater advantage in that while they have the skill base, their human resources are comparatively inexpensive. This further incentivizes the transfer of R&D because in addition to access to more usable information, foreign and domestic companies can do the research at a lower cost.¹³⁹ Cooperatively, the result is a comparative competitive advantage for countries intelligently implementing TRIPs.

5.7. Raising the Bar

If a country is to set the bar higher, how should it do it? What is the best way to do it? What about complementary considerations such as scope of claims as determined by infringement analysis?

Developing countries with a significant Life Sciences infrastructure can use each of the concepts of "new," "capable of an industrial application" (useful), and "involve an inventive step" (nonobvious) to raise the bar for patentability for biotechnological inventions.

As noted in Section 5.1., one way to raise the bar is to utilize the novelty requirement. In the example of the anti-malaria drug, native people used an extract of an indigenous plant for some period of time. If a developing country charged its Patent and Trademark Office to not allow patents for routine and alternative purifications

¹³⁸ This includes the patentee and his licensees.

¹³⁹ See Joseph Straus, *Bargaining Around the TRIPs Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 DUKE J. COMP. & INT'L L. 91, 96 (1998) (noting that globalization offers internationally active enterprises the real choice of locating their R&D and production activities at sites where they can expect the most competitive advantage). The article uses as an example Daimler-Benz's moving of software development to India, where skilled labor exists and is relatively inexpensive. See *id.* Another example is the migration of biotechnological activities from Europe to the United States and Japan. See *id.* at 96-98.

of biologically active agents from known existing sources, what effect would that have?

In this case, where the active ingredient is unknown, yet known to exist within a particular plant, it may well be that not allowing the patenting of the active ingredient as either a product or process is an acceptable approach for a developing country. While the actual active ingredient in a plant preparation may not be known, it is localized to the plant. All a Life Sciences company need do is try any one of a number of established purification protocols to make the active ingredient more pure. While this will require investment on the part of the Life Sciences company, it may not be an investment of hundreds of millions of dollars. Thus, the cost, in the cost versus profit opportunity consideration, is likely to be less than that required for the development of other drugs. After all, some other party, namely an indigenous population, has identified the source of the drug. The Life Sciences company does not have to send scientists and researchers out to screen hundreds of thousands of plants and animals to find this one.

If the up-front cost is reduced, less total profit need be made in order for the developing country's Life Sciences company to recoup its investment. If the purified active ingredient is patentable in a developed country, a developed or developing country's company can obtain a patent on it there. But since the drug will not be patentable in the developing country because it is not "new," neither company should be able to enforce patent rights in that country or any other country that views "new" similarly.

Furthermore, if a developed country granted a patent to the composition that was a purified form of the active ingredient, it could, by enforcing the patent, prevent others who accept the enforceability of that patent from using that composition to make improvements on it. If, as appears to be acceptable under TRIPs, a developing country determined that the composition were unpatentable because it was not "new," research enterprises could operate in the developing country to make improvements using the composition, which, once made, may be patentable in the developed country and possibly the developing country. Thus, having the developing country's patent-issuing body implement "new" in this manner provides a comparative competitive advantage to that developing country.

How would this affect the patenting of ESTs, complete genes, homologues, and amino acid sequences? In the instance of ESTs,

the EST sequence is obtained through a mechanical process, which identifies the underlying gene, homologues, and corresponding amino acid sequences. Perhaps a developing country will find that, like the purification of a biochemical activity, the purification of the DNA or amino acid sequence from an EST does not result in "new" matter because once the initial reagent is identified, the underlying gene and its homologues are in the possession of the public after the application of well-known purification protocols.¹⁴⁰ Such a strategy would make a gene identified in this manner unavailable for patent in a country that decided to find such identification not "new."

In a developed country allowing protection of the gene, only the patent holder and those with the patent holder's permission could use the gene. Compared to such a developed country, a developing country could have a comparative competitive advantage if it would not allow protection of the gene, because companies could perform research in the developing country on the gene to create a practical use for it.

The practical use or utility of using the gene could then be patented in developed countries and developing countries. The practical use (or sometimes a likelihood of practical use) is ultimately what a company needs to make money. More importantly, a practical use is, in large part, how the public obtains its benefit. Attempts to obtain patent protection and exclusionary rights too far in advance of the conception and reduction to practice of a practical utility cheat the public of its part of the patent bargain. In the absence of a practical utility with a commercial value, but with the prospect of one, there is still incentive for companies to do research. Therefore, the incentive to investigate and identify some practical utility for the gene is still strong.

The similarity between "new" and "involve an inventive step" (nonobvious), is such that many of the arguments applicable to using "new" to raise the bar for patentability, are equally or better applied to "involve an inventive step."

The elements of patentability required by the TRIPs agreement can all be subject to modulation by the patent-issuing body of a developing country. In the case of the biotechnology examples given above, "new," "involve an inventive step," and "capable of

¹⁴⁰ If the initial reagent has no utility other than identifying the underlying gene, then perhaps it, too, would be unpatentable.

an industrial application" are all elements of patentability that can be used to effect a higher bar for patentability in developing countries.

One thing that is particularly interesting is that the "capable of an industrial application" (utility) element of patentability, an element that is usually not a significant bar to patentability in the United States, can be reasonably used to reject patents or claims directed to sequences of nucleic acids or proteins. The sequences themselves often have little utility; they are typically most valuable as information. They only become valuable beyond being a research tool when applied to practical situations (e.g., gene therapy, diagnostic tools, transgenic plants, animals, etc.). So a developing country might, under TRIPs, properly reject a claim to a sequence as not "capable of an industrial application." After all, it is perhaps more accurately the use of the sequence in a method or process that provides the utility, not knowledge of the sequence itself. And, if the process is only theoretically very reasonable and not practically possible, then maybe there is not yet a utility.

5.8. What About Scope?

How TRIPs-implementing countries define infringement can act to complement whether a country sets a high or low bar for patentability. For instance, a country affording a very narrow scope of protection may want to set the bar for patentability low. If it does, it may issue a lot of patents, but afford each only literal scope, thus, allowing competitors to make small changes to the patented device and either get a patent on those small changes or at least avoid liability for infringement. In this manner, even though a lot of patents are granted, the scope of protected matter may be so little as to make the granting of the patent not particularly restrictive to competition. Of course, that could also make the property right less valuable and could effect a decrease in incentive to engage and invest in inventive behavior.

Alternatively, a TRIPs-implementing country could set a high bar for patentability and afford only literal scope. Such an approach should have even worse economic effects, because not only will fewer patents be given, but those that are given will not protect the concept giving rise to the patented subject matter very well. The result should be a disincentive to engage and invest in inventive behavior.

A better approach is for a developing country to adopt some protection for equivalents. Defining and interpreting this approach will be an important job for a developing country's judiciary. By raising the bar for patentability higher than in developed countries, a developing country obtains the economic benefit of having a greater amount of subpatentable information. The development of a legal doctrine that protects equivalents affords substantial protection for the patents a developing country does grant. Thus, developing countries that have a Life Sciences infrastructure may have the best of both worlds: a pro-competitive environment relative to developed countries as well as the strong patent policy necessary for encouraging inventive behavior and investment in research and development.

6. CONCLUSION

As we pass the seventh anniversary of the TRIPs Agreement and the one-year anniversary of the deadline for developing countries to pass into law the international intellectual property standards promulgated in the TRIPs Agreement, we are really only beginning the attempt at harmonizing international intellectual property standards. Now that developing countries have laws on the books, the means by which they grant and enforce patents have to develop within their respective national legal and administrative infrastructures. Making intelligent decisions on where to set the bar for patentability is an evolutionary process. After all, it was not that long ago that a United States Supreme Court dissenting Justice complained, "the only patent that is valid is one which this Court has not been able to get its hands on."¹⁴¹ Depending on where a country is situated economically, it may be better or worse to have the bar at a particular level.

There is room within the TRIPs Agreement for developing and LDCs to make substantive decisions about this subject and still be viewed as being reasonably within the TRIPs framework. From that perspective, developed countries may have given up more than they intended. It will be more difficult now for the U.S. Trade Representative to argue the moral high ground when she considers a Section 301 sanction. Under 301, a foreign country had to be violating United States standards to be the subject of sanctions.

¹⁴¹ *Jungersen v. Ostby & Barton Co.*, 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

Under TRIPs, in order to be the subject of World Trade Organization sanctions, a nation must violate TRIPs standards. As this article has hopefully demonstrated, those standards, while written in the Agreement in general terms and sounding similar to the standards used in developed countries, have yet to be digested and interpreted by developing countries, LDCs, and the World Trade Organization DSB. Developing countries can faithfully implement TRIPs and set the bar for patentability higher than where it exists in the United States and other developed countries. Developed countries have now given the DSB the ability to legitimate such action.