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Abstract

International patent harmonization is far from complete. In the field of biotechnology, the patchwork of standards governing patentable subject matter is a growing cause for concern. Divergent international standards harm patent holders who lack the certainty of knowing where and to what extent their patents will be valid. Divergent standards also harm patients who face restricted access or prohibitively high costs for genetic testing. While many solutions have been proposed, neither a new substantive treaty nor use of compulsory licensing are likely to provide long-term solutions. Independent licensing coordinated by the WTO or WIPO is a far better solution from the perspective of both patent right integrity and international public health.

Table of Contents

I. Introduction ................................................................................................................. 690
II. The Gene Patent Debate ............................................................................................... 692
   A. Primer on Gene Patents and Genes ........................................................................ 693
   B. International Expansion of Gene Patentability ....................................................... 694
   C. Increased Challenges to Gene Patents .................................................................... 695
III. The International Trend towards Harmonization ...................................................... 700
   A. The Trend towards Uniformity of Patent Protection ............................................... 700
   B. The WTO and the TRIPS Agreement ..................................................................... 701
   C. The Role of WIPO ................................................................................................. 703
IV. Concerns with Differing Patentability Standards ..................................................... 704
   A. International Concern over Divergent Policies ..................................................... 705

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1. Private business and patent holder concerns........................................... 705
2. Government and state concerns............................................................. 706
3. International access concerns............................................................... 708

B. Specific Concerns with Biotechnology and Gene Patents........................ 709

V. Resolving the Differing International Approaches to Gene Patents .......... 710

A. Potential Solutions Currently Available through International Organizations .......................................................................................................................... 711

1. Use international organizations for substantive patent uniformity.......... 712
2. Rely on the flexibilities inherent in TRIPS to ensure access to diagnostic tests covered by gene patents............................................................... 713

B. A Pragmatic Approach to Gene Patent Harmonization............................ 715

1. Promote the use of independent licensing agreements......................... 716
2. International organizations intervene to coordinate licensing agreements. .......................................................................................................................... 717

VI. Conclusion.................................................................................................. 720
I. INTRODUCTION

Intellectual property (IP) is a growing component of both global trade and government policy decisions. As the world marketplace becomes increasingly integrated, patent holders seek ways to maintain their exclusive rights.¹ There has been progress towards international harmonization over the years in the form of coordinating procedural requirements and ensuring minimum standards of protection. The World Trade Organization’s (WTO) adoption of the Trade-Related Aspects of Intellectual Property Rights agreement (TRIPS)² was particularly important to the growing harmonization of patent regimes internationally. However, large disparities remain in substantive patent rights, including in standards of patentability, that lead to a fragmented international intellectual property regime.

The field of biotechnology may be especially sensitive to the fragmented nature of international standards of patentability. After the international biotechnology industry’s rapid expansion in the 1980s and 1990s, both the number of biotechnology patents and the scope of patentable subject matter increased significantly. During this time, gene patents were widely available in multiple countries, resulting in thousands of human gene patents.³ Despite efforts to harmonize international patent regimes, recent legal challenges to the validity of gene patents highlight the uneven nature of international policy regarding the patentability of human gene sequences.

The patentability of genes has been questioned in a number of countries, including the United States, Australia, and Canada, as well as in the European Union (EU).⁴ Several of these challenges arose out of the controversy surrounding the U.S. biotechnology firm Myriad Genetics, which owns patents on the BRCA1 and BRCA2 genes associated with breast and ovarian cancers. Myriad’s overbroad patents, along with the company’s strong enforcement of its IP rights, led to controversies in multiple countries.⁵ The United States Supreme

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⁵ See id.
Court invalidated Myriad's patents on isolated gene sequences.\(^6\) Yet in many other nations, Myriad's gene patents are still valid.

Resolving the international inconsistencies in gene patentability presents a difficult problem. Inconsistent patent regimes can result in uncertainty among biotechnology firms, as well as unequal access to genetic testing and health care for patients. Due to the global nature of biotechnology, a solution will likely need to come from international organizations. Some nations have argued for amending TRIPS to ban patents on life forms.\(^7\) But previous attempts at this have failed, and it seems unlikely, given the WTO's "law-making deficit,"\(^8\) that any substantive response will occur in the future. Other individuals have advocated state use of the compulsory licensing provisions in Article 31 of TRIPS, which would allow countries to circumvent patent holders' right to restrict access to their inventions.\(^9\) However, reliance on compulsory licenses is not a viable solution in the long run, given that developed nations have criticized developing nations for "abuse" of these provisions and, by threatening economic sanctions, effectively limited compulsory licensing.\(^10\)

There are viable alternative solutions. Compared to compulsory licenses, private licensing agreements negotiated between biotechnology firms increase the favorability of terms for both sides and improve their ability to respond quickly to dynamic innovations.\(^11\) Because of the potential for firms to engage in restrictive licensing, the WTO and the World Intellectual Property Organization (WIPO) are in the best position to intervene in an administrative capacity to ensure coordination and access.

This Comment discusses the international response to divergent patent standards with a focus on the example of gene patents. Section II provides a

\(^6\) See Ass'n for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al., 133 S. Ct. 2107, 2109 (2013) [hereinafter Myriad Genetics].


brief overview of the gene patent debate and international standards on patentable subject matter. Section III then explores more recent international efforts at coordination, including the WTO and WIPO, and measures their relative success. Section IV describes some of the concerns with differing patent standards, focusing particularly on the field of biotechnology. Finally, Section V offers potential solutions to increase coordination between countries in order to encourage greater harmonization within the field of gene patents.

II. THE GENE PATENT DEBATE

The decision to permit patenting of certain subject matter, such as genetic sequences or genetic tests, "generally rests with the national patent authorities." Each national authority must decide the scope of patentability based on public policy and an analysis of whether allowing the patenting of a given subject matter would be "beneficial or detrimental to the advancement of science and human knowledge." In the U.S., Congress broadly determines what constitutes patentable subject matter. However, the U.S. Patent and Trademark Office (USPTO) and the Federal Circuit largely interpret what technologies and innovations are patentable. In contrast, the European Patent Office can issue directives within the EU, but individual nations retain the ability to decide issues of patentability and patent enforcement within their territory regardless of other European nations' policies.

The debate over gene patentability follows the traditional arguments for and against patents as a whole. Generally, the benefits of patents accrue privately (via incentives to further invention) and publicly (via the publication of findings that increase public knowledge). Yet the issuance of broad patents may actually hinder research when their scope and number limit researchers' access to necessary technology. Patents may also limit public access to new innovations and raise the cost of diagnostic tests for patients. Human gene patents implicate additional ethical concerns about the commodification of public health. Because of this conflict, gene patents have proven controversial since they were first issued in the 1980s. For decades, scholars, human rights activists, and international organizations have argued for and against allowing patents of human genes. The recent U.S. Supreme Court decision in *Myriad Genetics* reflects the ongoing debate.

13 Id.
A. Primer on Gene Patents and Genes

When referring to gene patents, it is important first to distinguish between the human genome, which is not patentable, and genes, which are patentable. The human genome refers to the entirety of deoxyribonucleic acid (DNA) present in each human cell, whereas genes are particular sections of DNA. Gene patents typically issue in one of four categories: (1) genes, in whole or in part, including claims to isolated nucleotide sequences; (2) proteins that the genes encode and their function in organisms; (3) vectors used for the transfer of genes from one organism to another; and (4) genetically modified cells or organisms, processes used for the making of genetically modified products, and the uses of genetic sequences or proteins for genetic tests. These categories are not distinct, and there are frequent overlaps. For example, a company may hold patents on the gene sequence itself as well as patents on the proteins encoded by those genes. Because of the potentially broad coverage of gene patents, ownership of the rights to a single gene sequence can result in a "near monopoly on diagnostic tests and treatments for widespread and serious ailments." This creates the opportunity to "extract rents" from researchers and scientists who are interested in developing further diagnostic tests, resulting in both higher medical costs and decreased availability to patients.

16 See Gitter, supra note 9, at 1628–29.
17 See, for example, "DNA," THE HUMAN BODY BOOK: AN ILLUSTRATED GUIDE TO ITS STRUCTURE, FUNCTION, AND DISORDERS (Steve Parker ed., 2009), available at http://search.credoreference.com/content/entry/dkbody/dna/0.
18 These patents are most often the cause of controversy. Consider, for example, patent 5,622,829, previously held by Myriad Genetics, which claims complementary DNA (cDNA) forms of BRCA1 alleles. See Report of the Secretary's Advisory Committee on Genetics, Health, and Society, Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests, DEPT OF HEALTH AND HUMAN SERVICES (April 2010), available at http://osp.od.nih.gov/sites/default/files/SACGHS_patents_report_2010.pdf.
20 Myriad held U.S. patents on the BRCA1 and BRCA2 genes as well as genetic byproducts and various mutations of these genes. As a result, Myriad was the sole U.S. provider of genetic diagnostic tests for breast and ovarian cancer risk. See Robert Cook-Deegan et al., Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer Comparing Breast and Ovarian Cancers with Colon Cancers, 12(4) GENET. MED. 15, 15 (Supp. 2010).
22 See id. at 308–09.
B. International Expansion of Gene Patentability

The growth of the biotechnology (biotech) industry is "closely linked to the expansion of patent law into the protection of life forms."23 In the U.S. and the EU, the trend of increased patent protection reflects a concerted effort of legislatures, courts, and patent offices—potentially the result of governmental pressure to attract biotechnology investment through more liberal patent standards.24 Biotech companies use patents "as a signaling device to stock markets that they have control of vital or fundamental technologies."25 Patent offices and courts, especially those in many developed countries, are more inclined to grant patents liberally in order to attract biotech investment.26

Industrialized nations have successfully attracted biotechnology firms; entities from developed nations currently hold 97% of all patents worldwide.27 In the field of biotechnology, the divide between developed and developing nations is especially pronounced.28 Gene patents follow this trend, with U.S. inventors filing more international patents on DNA sequences than any others, including the combined total of all inventors in the EU.29

24 See Gitter, supra note 9, at 1636 (citing Peter Drahos, Biotechnology Patents, Markets and Morality, 21 EUR. INTELL. PROP. REV. 441, 442–43 (1999), for the proposition that governments have increased the number of patents granted without considering the "broader public ethic").
25 Drahos, supra note 24, at 446.
27 See WHO HUMAN GENETICS PROGRAMME, GENETICS, GENOMICS AND THE PATENTING OF DNA: REVIEW OF POTENTIAL IMPLICATIONS FOR HEALTH IN DEVELOPING COUNTRIES 20 (2005), available at http://www.who.int/genomics/FullReport.pdf (noting that "[m]ore than 80% of the patents granted in developing countries belong to residents of industrialized countries, usually multinational corporations from the most advanced economies").
28 A large proportion of the biotech industry is centered in the U.S., including most of the venture capital, most of the scientific activities, and a large percentage of the consumer market. See Timothy Caulfield, Gene Patents, Human Clones and Biotechnology Policy: The Challenges Created by Globalization, 41 ALTA. L. REV. 713, 718 (2003); Elisa M. Bucuaron, Globalization of Biotechnology, 20 NEW GENETICS AND SOCIETY 25, 26 (2001) ("[A]lthough the flow of biotechnologies across national borders has grown increasingly in recent years, there is a tendency for this to agglomerate in developed countries, particularly the US, where the socio-economic and politico-institutional environments facilitate their development and commercial exploitation.").
29 See GENETICS, GENOMICS AND THE PATENTING OF DNA, supra note 27, at 20.
An important change in law facilitated this expansion in biotechnology. In 1980, *Diamond v. Chakrabarty*[^30] opened the possibility of patenting isolated gene sequences in the U.S. In overturning the USPTO’s previous decision, *Chakrabarty* allowed the patenting of a genetically modified bacterium for the bioremediation of oil spills.[^31] This decision significantly influenced the intellectual property regimes of other nations, as many began allowing patents on genes.[^32] Around the same time, legislation that allowed public universities to patent their discoveries further encouraged the commercialization of gene-related products.[^33] Public institutions in the EU and the U.S. now own approximately 30% of the patents on DNA filed between 1996 and 1999.[^34] This move towards patent harmonization in international agreements, including the TRIPS agreement and the North American Free Trade Agreement (NAFTA), further contributed to broader acceptance of gene patents, even in nations whose economies do not feature large biotechnology industries.[^35]

C. Increased Challenges to Gene Patents

In the 1980s and 1990s, the standards governing patentable subject matter expanded, particularly in the field of biotechnology, and the issuance of biotech patents, including gene patents, increased. In the U.S., the annual number of biotechnology patents peaked in 1998 with the issuance of 5,977 biotech patents.[^36] After 2000, biotech patent issuance declined and then leveled off.[^37] There are multiple explanations for the leveling off of biotech patents, but it is notable that, after 2000, a growing number of parties challenged the validity of gene patents in courts and legislatures. The shift in policy seems to have been "largely stimulated by a convergence of a general social unease, the emergence of

[^31]: See id. at 315–17.
[^32]: See Williams-Jones, supra note 4, at 125 ("The 1980 U.S. Supreme Court case of *Diamond v. Chakrabarty* was a landmark decision, and significantly influenced Canadian and international patent law."); Kate M. Mead, *Gene Patents in Australia: A Game Theory Approach*, 22 PAC. RIM L. & Pol'y J. 751, 755 (2013) (noting "that Australian courts often use U.S. court opinions as persuasive authority for determining patent cases").
[^33]: For example, the U.S. Bayh-Dole Act of 1980 introduced incentives for universities and public institutions to patent the products of their research. See *Genetics, Genomics and the Patenting of DNA*, supra note 27, at 20.
[^34]: Id.
[^35]: See Williams-Jones, supra note 4, at 125.
[^37]: See *Genetics, Genomics and the Patenting of DNA*, supra note 27, at 20 (discussing the "notable drop in the past three years in the number of DNA patents granted").
preliminary data and literature on the possible adverse practical ramifications of gene patents, and several high-profile patent protection controversies. Many of these challenges arose out of the controversy surrounding Myriad's strong enforcement of its patent rights. Recent cases, particularly the Myriad Genetics case in the U.S., suggest the pro-patent trend of the 1990s and 2000s may be on the verge of reversing course.

In 2009, the Association for Molecular Pathology, a U.S. nonprofit scientific society of researchers and scientists, challenged Myriad's BRCA1 and BRCA2 gene patents along with their patents on diagnostic testing. Following years of appeals, the Supreme Court granted certiorari in Association for Molecular Pathology v. Myriad Genetics on the question of whether human genes were patentable. The Court held that isolated human genetic sequences were not patentable, effectively invalidating thousands of gene patents in the U.S. This recent decision represents a huge shift in the legal treatment of gene patentability. U.S. courts had allowed gene patents for decades, ever since the decision in Chakrabarty in 1980. The Myriad Genetics case, then, reversed previous U.S. policy. While the full effects of this decision are still unknown, the case has drawn international attention once again to the question of gene patent validity and may influence other countries experiencing similar pending legal challenges.

39 See Williams-Jones, supra note 4, at 139-40 (surveying critical responses in Europe to Myriad's patents).
41 See Myriad Genetics, 133 S. Ct. at 2115.
42 See id. at 2116.
43 See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1355 (Fed. Cir. 2011) (“It is estimated that the PTO has issued 2,645 patents claiming 'isolated DNA' over the past twenty-nine years, and that by 2005, had granted 40,000 DNA-related patents covering, in non-native form, twenty percent of the genes in the human genome.”) (citations omitted).
44 See Chakrabarty, 447 U.S. at 317 (“The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown . . . . [W]e are without competence to entertain [arguments warning against the hazards of gene patenting] . . . .”).
The EU patent regime is comparable to the U.S. system in terms of the standard of patentability as well as in what constitutes patentable subject matter. The 1998 Biotechnology Directive of the European Patent Office (EPO) explicitly discussed gene patents and urged nations to harmonize how each member state protected biotechnological inventions, including gene patents. Unlike American patents, however, European patents issued by the EPO function as a “bundle” of national patents. A patent is subject to judicial decisions on its validity and enforcement by different member states that are controlling only within their jurisdiction. There is currently no court to promulgate an EU-wide determination of a patent’s validity once issued by the EPO. This system can have complicated effects when the validity of a patent is in dispute between countries, with the potential for a patchwork of differing patent decisions among EU members.

Despite the EPO’s explicit acceptance of gene patents, the EU has witnessed challenges over many gene patents, including Myriad’s BRCA1 gene patents. In early 2002, controversy arose over the issuance of patents for the BRCA1 and BRCA2 genes and for a method of diagnosing breast and ovarian cancer to Myriad Genetics. Stakeholders launched an opposition under Article 99 of the European Patent Convention (EPC). The EPO initially invalidated one of Myriad’s BRCA gene patents, and it was reinstated only after the patent was amended and narrowed in scope. Currently, the EU continues to allow patents on isolated gene sequences when a function is identified for the sequence.

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45 In order to be patentable material under European law, an invention, paralleling U.S. criteria, must: “(1) comprise patentable subject matter, (2) be new, (3) be ‘susceptible of industrial application,’ and (4) involve an ‘inventive step.’” Gitter, supra note 9, at 1644.

46 Like the US, the EU has been issuing gene patents since the 1990s. See Nicol & Nielsen, supra note 26, at 354.

47 See Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, art. 9, (noting that “exclusion from patentability of plant and animal varieties and of essentially biological process... have created uncertainty” and that “harmonization is necessary to clarify the... uncertainty”).


49 See id.

50 See id. at 321–23.

51 See id. at 322.


53 However, there is an exception for “diagnostic methods practiced on the human body”; diagnostic gene sequencing does not occur within the human body and so would not be excluded
With respect to human gene patents, Australia's official position is that "a DNA or gene sequence that has been isolated may be patentable" so long as "it follows the other statutory rules of patentability." This position has been challenged multiple times throughout the last decade. In 2002, the Attorney General ordered the Australian Reform Commission to "examine the laws and practices governing intellectual property rights over genetic materials and related technologies, with a particular focus on human health issues." In 2011, legislators in Parliament proposed the Patent Amendment (Human Genes and Biological Products) Bill in order to exclude isolated DNA segments from patentability. Although this bill remains under consideration by Parliament, a 2013 case was filed to challenge Myriad Genetics' gene patents. Despite the fact that Australian courts often use U.S. court opinions as persuasive authority, this challenge was unsuccessful. After a subsequent second appeal, Australia's Federal Court upheld the validity of Myriad's gene patents in September 2014.

Canada has taken a different approach to challenging gene patents—one in which public validity of these patents contradicts widespread private circumvention and growing public health concerns. Gene patents are available in Canada. In fact, Myriad continues to hold four gene patents in Canada for the BRCA1 and BRCA2 genes. Despite these patents, multiple private agencies in Canada began using "round about methods' to avoid infringing the patents" while still cutting costs, including brokering patient access to a BRCA research project. Due to the cost of Myriad's licensing agreements for genetic testing, the British Columbia Ministry of Health Services changed its official position in

from patentability.


Mead, supra note 32, at 757.


See Mead, supra note 32, at 755.

See id.

See id.

See id.


See Williams-Jones, supra note 4, at 141.

Id. at 142.
2003 to permit health care facilities to use in-house BRCA testing—in violation of Myriad’s patents. The Ontario Ministry of Health signed on to a report urging the Canadian Patent Act to exclude broad-based genetic patents and include a strong public morality clause.

Because there is “great diversity” among the patent regimes and research capacities of developing nations, it is more difficult to identify a clear approach towards the patentability of genes in these nations. Brazil, China, and India have comparatively well-developed biotechnology industries, but they differ in their approaches to gene patents. Brazil plays an important role in plant genetics but has signed the Convention on Biological Diversity, which excludes genetic resources from patentability. Whether Brazil considers all human genes specifically excluded from patentability is ambiguous. In contrast, China has actively encouraged biotechnology investment by loosening its patentability standards. The State Intellectual Property Office clarified that China does not allow patents on life forms, but it does allow patenting of genes. Similarly, India has allowed patents on genetic materials, but gene patents are controversial and may violate India’s Patent Act.

The international approach to gene patents is fractured and in flux. While some developed nations have been moving towards refusing gene patents, others have not. Developing nations do not have a clear position either, resulting in a patchwork of worldwide patentability standards for human genes.

63 See Williams-Jones, supra note 4, at 143.
64 See id. at 25.
65 See id. at 26. Some argue that Brazil’s approach to the patenting of genetic resources has raised barriers for researchers and prevented new investments in biotechnology. See, for example, Gabriel Di Blasi, Current Barriers to Biotech in Brazil. LIFE SCIENCES INTELL. PROP. REV. (July 31, 2013), available at http://www.lifesciencespreview.com/article/current-barriers-to-biotech-in-brazil.
66 See GENETICS, GENOMICS AND THE PATENTING OF DNA, supra note 27, at 27.
67 See id. at 29 (“Nor does the Indian patent system appear to allow patents on genes or cells.”). It is currently unclear whether human genes are patentable in India. Under India’s Patents Act, signed in 1970, naturally occurring substances are not patentable, yet patents covering genetic material have been granted. See Bhavishyavani Ravi, Gene Patents in India: Gauging Policy by an Analysis of the Grants Made by the Indian Patent Office, 18(4) JIPR 323 (2013).
III. THE INTERNATIONAL TREND TOWARDS HARMONIZATION

For the most part, global patent law has been moving towards harmonization in the past decades. Despite vastly different industries, values, and levels of development among countries, patent regimes have become increasingly uniform. This push towards uniformity is due in large part to the adoption of the TRIPS agreement and other international treaties. Since the Paris Convention for the Protection of Industrial Property (Paris Convention) in 1883, the “pendulum has been swinging towards greater harmonization among countries,” which in turn necessitates greater uniformity in standards for patentable subject matter.

A. The Trend towards Uniformity of Patent Protection

International patent cooperation has been extensive and largely successful in coordinating procedural patent protections. Under the Paris Convention, signatory countries committed to offer “the same opportunity to receive and enforce patent right[s] to other signatories as they offer to their own nationals.” Subsequent treaties have led to the standardization of the form of patent applications, the procedure for applying, and the terms of protection. However, the term “international patent harmonization” was originally understood to mean “uniform patent laws throughout the world,” which would require more uniform substantive, as well as procedural, standards. In the past, multiple sources have called for “true harmonization,” in which patent applicants would complete a single patent application and receive global protection. Advocates for this global patent system emphasize the simplification of the law, ease of application and enforceability, and reduced administrative costs.

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72 Wasserman Rajec, supra note 70, at 155.
74 See id. at 202.
75 Chun, supra note 1, at 137.
76 See id.
While true subject-matter harmonization is further off, more countries have voiced concerns about differing substantive patent laws. Recognizing the benefits of harmonization, WIPO and WTO members have signed a number of treaties designed to coordinate internationally fragmented patent laws. These international organizations serve a particularly important role by allowing members to gain access to global public goods and protection under rules that ensure at least a minimum level of IP protection. International organizations “create the capability for states to cooperate in mutually beneficial ways” and enforce agreements which otherwise would be unlikely to achieve consensus. As such, international organizations are in a unique position to influence and enforce patent standards, including the patentability of genes. The WTO and WIPO have both had a particularly strong role in the development and increased harmonization of patent standards internationally.

B. The WTO and the TRIPS Agreement

Aware of the tension created by IP rights varying throughout international economic relations, the WTO sought to create rules ensuring order and predictability and allowing for systematic dispute resolution. These rules took the form of the TRIPS agreement, which was established in 1994 as part of the General Agreement on Tariffs and Trade. All 159 WTO members have agreed as a “single undertaking” to adhere to TRIPS requirements. These requirements include: minimum levels of IP protection, a requirement to provide effective enforcement procedures permitting action against any infringement of intellectual property rights, and a prohibition on discriminating between different industries by allowing different levels of IP protection. Additionally, WTO members “may, but shall not be obliged to” implement more extensive protections than required.


80 Id.


83 See TRIPS, supra note 2, art. 27.

84 Id. art. 1.1.
Specifically relating to patents, Article 27 of TRIPS requires that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application." The terms "inventive step" and "capable of industrial application" are synonymous with "non-obvious" and "useful" as defined in U.S. law. Consonant with Article 27’s goal of "recogniz[ing] the underlying public policy objectives of national systems for the protection of intellectual property," TRIPS still allows members a degree of flexibility. Members may, for example, "adopt measures necessary to protect public health and nutrition" or "to promote the public interest in sectors of vital importance to their socio-economic and technological development." Members may also exclude any invention that "is necessary to protect ordre public [public policy] or morality, including to protect human, animal, or plant life or health." Article 27.3 also allows explicit exclusions from patentability of "diagnostic therapeutic and surgical methods for treatment" and "plants and animals . . . and essentially biological processes." Even with these flexibilities in the agreement, TRIPS has gone a long way towards harmonizing international patentability through ensuring minimum IP protection and preventing discrimination between industries.

There is some contention as to whether the language of TRIPS requires countries to allow patents on DNA sequences. The language of Article 27 would not require countries affirmatively to declare DNA patentable, because a particular subject matter is assumed patentable when it has not been listed among the exceptions from patentability in Article 27.3. Nowhere does 27.3(b) specifically reference genes or DNA. The WTO has remained relatively silent

85 Id. art. 27.1.
86 In this way, TRIPS could be read as analogous to U.S. standards. However, this is not explicit within the agreement. See id. art. 27.1 n.5.
87 TRIPS, supra note 2, art. 27.
88 Id. art. 8.1.
89 Id. art. 27.2.
90 Id. art. 27.3(b).
91 See GENETICS, GENOMICS AND THE PATENTING OF DNA, infra note 27, at 16.
92 These exclusions include “a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological process.” TRIPS, supra note 2, art. 27.3.
93 See GENETICS, GENOMICS AND THE PATENTING OF DNA, supra note 27, at 17.
on the patentability of genes, although more recent conferences have noted some countries' growing concerns regarding access to diagnostic testing.94

C. The Role of WIPO

WIPO is the other major player in international patent regimes. WIPO was established by the WIPO Conference of Stockholm in July 196795 and has been associated with the United Nations since 1974.96 Its main objective is to promote IP protection worldwide.97 Three activities—assisting with applications for intellectual property rights, managing patent information, and promoting new treaties to increase harmonization—facilitate this objective.98 WIPO is responsible for the administration of the Paris Convention, which established minimum standards of IP protection prior to the adoption of TRIPS.99 WIPO also administers other patent agreements, including the Patent Cooperation Treaty of 1970—designed to increase efficiency of international patenting—and the Strasbourg International Patent Classification Agreement of 1971, which was designed to establish global uniformity of classifications in international patenting.100

WIPO is undoubtedly an important player in the international intellectual property regime; however, the absence of enforcement mechanisms or dispute-
settlement procedures limits its efficacy.\textsuperscript{101} Because of this, the WTO and TRIPS, which have the benefit of institutional supremacy and the ability to make international law, are viewed as authoritative over WIPO.\textsuperscript{102}

Despite having limited ability to enforce directives, WIPO has issued many of its own guidelines regarding genetic patents and resources. In the past decade, it made an attempt to streamline and clarify policies as they apply to gene patents: during negotiations for the Substantive Patent Law Treaty, it sought to clarify patent requirements and exceptions, including those on “life forms and public health patents.”\textsuperscript{103} As a testament to the difficulty in coming to a consensus, members were unable to agree, and negotiations were put on hold in 2006.\textsuperscript{104}

Because of an increasing number of voices in the debate over gene patents, WIPO members have struggled to reach agreement regarding the scope of patentable material. The Director General of WIPO, Dr. Francis Gurry, has identified a shift in patent law from a “unimodular” to “interactive” system where a broad range of actors influence patent policy.\textsuperscript{105} Patentability of specific subject matter is no longer governed solely by economic analysis; it is also geared towards ethical concerns and public health.

IV. CONCERNS WITH DIFFERING PATENTABILITY STANDARDS

Both TRIPS and the Paris Convention require a certain degree of uniformity in patent protection internationally, but neither agreement places significant limits on the scope of what subject matter may be patented. While these agreements facilitate procedural harmony, there is a significant lack of

\textsuperscript{101} See Maskus, supra note 96, at 64.


international substantive uniformity of patentability standards. The debate over the patentability of genes highlights this divergence. As some nations, such as the U.S., invalidate patents on isolated gene sequences, others, including the EU and Australia, continue to allow these patents to stand. This divergence has important consequences, both for biotech firms craving predictability for their research and development (R&D) efforts and for public health, as diverging standards can limit access to and increase the costs of genetic testing.

A. International Concern over Divergent Policies

Patent law is inherently diverse for multiple reasons, including territoriality, government use of patent law as a tool for economic growth, and cultural factors that make each patent system unique. These sources of variation have led to differences in how nations define patentable subject matter. Internationally, this can be a concern for individual businesses and patent holders, for governments seeking to increase development, and for patients and consumers who would benefit from access to biotechnology.

1. Private business and patent holder concerns.

A fragmented patent system with delays and unpredictable enforcement is a “grave concern” for many businesses and start-ups for whom access to IP rights is often essential for growth. Jurisdictional uncertainty hinders patent holders who are unclear about the extent of patent protection in a given jurisdiction. Without certainty as to the scope of patent jurisdiction or patentable subject matter, a firm cannot know if it will be able to secure patent rights and may choose to avoid that jurisdiction as a whole. Uncertainty also increases the cost to competitors who, not knowing whether a patent will be granted, will often avoid spending resources on R&D as a consequence. R&D requires the investment and competition that only come with certainty of IP rights.

As the world economy has become increasingly transnational, firms in various industries have faced uncertainty in patent regimes. In the

105 See Chun, supra note 1, at 133 ("[I]n 1988, pharmaceutical products were not patentable in 49 countries, animal species in 45, methods for the treatment of the human or animal body in 44, plant varieties in 44, biological processes for the production of plant varieties or animal species in 42, food products in 35, computer programs in 32, chemical products in 22, pharmaceutical processes in 10, processes for the manufacture of food in 9, and microorganisms in 9.").

106 See id. at 136.

107 See id. at 136.


109 See id. at 242–43.
telecommunications industry, where different components and databases may be spread over multiple countries with differing patent regimes, this jurisdictional uncertainty has erected many barriers to enforcement of patent rights. Concerns have also surfaced over international trade in unpatented components of patented products. This was the concern in *Deepsouth v. Laitram*, in which the U.S. Supreme Court held that unpatented components made outside the territorial boundaries of U.S. law did not violate a combination patent when assembled and sold outside the U.S. Subsequent cases have expanded the scope of infringing activities to account for a more global marketplace, but questions remain even in U.S. patent laws. Because of international uncertainty and patent disparities, international industries are “unable to know with certainty what laws will be applied to their transactions,” meaning it is difficult for businesses to know if they are infringing. Overlapping patents also put businesses at risk of multiple judgments. Because of these risks, businesses have a strong incentive to support harmonization of patent regimes internationally.

### 2. Government and state concerns.

Although inventors may be able to reap the rewards of patent protection through free riding, national economies may not. A single national economy cannot fully internalize the benefits and costs of patents. Instead, there is a significant degree of interplay among nations’ various patent systems with international spillovers of benefits. Of course, some countries are better positioned to benefit from increased investment in research than others. Governments and national patent policymakers cannot make decisions in a “bubble,” because “nearly all domestic patent policies have effects, positive and

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110 Consider, for example, NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005), in which the Canadian manufacturer of Blackberry was sued for infringement as a result of using U.S. e-mail databases that were protected by a U.S. patent issued to NTP. Although Research in Motion retained patent rights in Canada over its Blackberry product and use, this protection did not extend into the U.S., and as a result it faced liability for an essential part of its product design.


112 See id. at 532.


Gene Patent Harmonization

negative, outside a country’s borders.” By reducing the administrative burden of duplicative patent prosecution, patent law harmonization stands to benefit individual states due to the effect of IP on trade and development.

That benefits flowing from public goods are not constrained by national borders is a fundamental economic insight that explains the prevalence of free riding. Thus, the optimal level of protection in a given country depends not only on policy incentives within the country itself but also on the policies of neighboring countries, with the potential for either to benefit from or be harmed by the other(s). For example, if one nation maintains a patent system but its neighbor does not, two things will occur: first, firms will invest resources in developing patentable innovations, and consumers in the first country will bear the cost of developing the innovations in the form of above-marginal-cost prices; but second, consumers in the second country will pay only the marginal cost of reproducing the innovation and free ride off the investments of their neighbors.

This potential to externalize costs motivates nations to free ride off neighboring states’ IP protections. Within developed nations, however, the desire to attract biotech industries creates powerful incentives to provide stronger, more protective IP rights. Developed nations often seek uniform standards of patentability and harmonization of patent prosecution to ensure they are not bearing the costs of stronger IP rights. Furthermore, the interest in promoting harmonization is stronger than even the allure of free riding because the reactions of other nations can have far-reaching consequences. This does not mean that all developed nations have the same patent laws. For

115 Yelderman, supra note 73, at 203.
118 See Duffy, supra note 77, at 693–700 (discussing “jurisdictional externalities”).
119 See id. at 698.
120 This same calculus suggests that developing nations would have the opposite incentive—namely, to free ride on strong IP rights in developed nations. But due to the minimum IP protection required by TRIPS and the possible trade sanctions for violating the agreement, developing nations have relatively few options but to abide by developed nations’ IP policies.
121 See ALEXANDER STACK, INTERNATIONAL PATENT LAW: COOPERATION, HARMONIZATION, AND AN INSTITUTIONAL ANALYSIS OF WIPO AND THE WTO 30 (2011). The potential to free ride among industrialized developed nations exists in a “crude sense” because investors will always be eager to enter wealthy markets. However, between developed nations, the repercussions and reactions by other countries make this unlikely, and there are no examples among developed nations today of this sort of behavior.
example, Japan’s patent regime has been accused of promoting “imitation[,] not innovation” by ensuring that patents have extremely narrow claims, thus opening more space for non-infringing imitations. But by and large, developed nations seek more uniform patent regimes with stronger IP rights to ensure the costs of these rights are distributed evenly and to avoid potential trade consequences of lax IP laws.

Harmonization can also benefit developing nations. Innovators are concentrated in the most industrialized, patent-friendly developed nations as a result of disparities in patent regimes. Investors are less willing to enter markets where the IP laws cannot guarantee protection for their inventions. One survey found that 80% of chemical companies admitted they would not invest in India due to a general perceived lack of IP protection. Similar claims have also been made regarding China. One way nations can counteract this concentration is to strengthen their IP laws to match the most patent-friendly developed nations, such as the U.S. For example, Singapore is now a more competitive location for IP, but only since it strengthened IP rights and enforcement of infringement penalties. Similarly, Poland experienced a forty-fold increase in investment after demonstrating a willingness to strengthen IP laws in the 1990s. In hopes of increasing investment in domestic infrastructure, stimulating domestic industries, growing the domestic economy, and strengthening its biotech industry, Australia also aggressively promoted stronger IP laws. Harmonization provides one way for developing nations to become more competitive in attracting investment and innovators vis-à-vis developed nations with strong IP regimes.

3. International access concerns.

Inconsistent patentability standards and fragmented patent laws inhibit patient access as well. Flexibilities in TRIPS can give rise to restrictive practices. For example, Article 40(2) of TRIPS concerning “licensing practice conditions” allows great flexibility for member states to determine the practices that

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122 Id.
124 See id.
125 See id. at 484.
126 One empirical survey found that increased foreign direct investments are positively correlated with higher levels of intellectual property protection. See Jean Raymond Homere, Intellectual Property Rights Can Help Stimulate the Economic Development of Least Developed Countries, 27 COLUM. J.L. & ARTS 277, 287 (2004).
The biotechnology field requires global cooperation. Unlike other industries, which can deliver competitive advantages through faster or cheaper manufacturing, biotechnology companies gain competitive advantages by virtue of IP protections for their inventions. Because of its reliance on patents, the biotechnology industry has a “greater sensitivity to changes and developments in patent law” than other industries. The current system of uneven patent enforcement and legal uncertainty about the patentability of DNA sequences could dampen innovation because of uncertainty about recouping the high costs of R&D.

128 TRIPS, supra note 2, art. 40.
129 There has been no case brought before the WTO regarding Myriad, and the WTO has largely remained silent on the issue of Myriad in particular and gene patent viability more generally. See Index of Disputes, WORLD TRADE ORGANIZATION http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#selected_subject (last visited Sept. 24, 2014).
130 See Yelderman, supra note 73, at 218.
131 See GENETICS, GENOMICS AND THE PATENTING OF DNA, supra note 27, at 27 (noting that, from 1980 to 1999, China filed seventeen international “patent families”—“all the patent documents associated with a single invention”—whereas Brazil filed one, and the U.S. 5,610).
134 Id.
The exceptionally high R&D costs of biotechnology and the high risk of failure further contribute to the need for international harmonization.135 Because modern biotechnology often requires international sources of investment, it constitutes a global industry.136 Within this industry, the "ongoing differences in national standards of patentability are a constant source of complaint."137 Without some uniformity of patentability standards, biotechnology firms face legal and commercial uncertainty and risk piracy in countries with lesser patent protections. Economies without a significant biotechnology industry in place are at a disadvantage in attracting investment to develop these industries. Although biotechnology holds the promise of significant revenue for countries exporting biotech products,138 these companies are drawn to (the largely developed) countries with stronger patent protection. Greater harmonization of patent regimes could allow the economic benefits of biotechnology companies to be enjoyed more widely, including in developing nations without strong biotechnology industries.139

V. RESOLVING THE DIFFERING INTERNATIONAL APPROACHES TO GENE PATENTS

International organizations and agreements contribute to a degree of international uniformity in patent regimes. This harmonization needs to expand to patentable subject matter in the field of biotechnology and, in particular, to gene patents. Due to the globalized nature of biotechnology, harmonization would be difficult without international organizations.140 There are a number of possible solutions available within existing international agreements, but these solutions are not without their faults. This Comment will analyze two potential remedies available within the TRIPS agreement and then propose a new solution that may facilitate greater harmonization in the international approach to gene patents.

135 R&D costs for the biotechnology industry averaged from U.S. $1.4 billion to $1.9 billion in 2011. See Economic Analysis of the Impact of Isolated Human Gene Patents, supra note 26, at 16.
136 See Pila, supra note 132, at 370.
137 Id.
138 See id.
139 See Davis & Wales, supra note 133, at 439.
140 See id. at 438.
A. Potential Solutions Currently Available through International Organizations

International organizations have played an integral role in the development of patent standards and enforcement because of the increasingly global nature of intellectual property. However, patent law is still territorial, and there is "no such thing as a 'global patent.'"\textsuperscript{141} Multinational businesses often seek IP protection in a variety of jurisdictions. These globalized industries, particularly in developed nations, have pushed for increased harmonization of patent protection internationally.\textsuperscript{142} Certain international organizations, such as the WTO and WIPO, are in a unique position to influence patent regimes internationally and coordinate a more coherent global approach to patents.

International organizations, in particular the WTO, could potentially resolve or reconcile differing views of gene patents through a number of mechanisms. One possibility is for the WTO or WIPO to either amend the TRIPS agreement or draft a new substantive patent treaty. However, this approach is extremely unlikely given that past efforts have failed. If there is no feasible means of enforcing a single standard for gene patents, then perhaps the next best solution is ensuring that patent holders’ rights are protected and that patients have access without paying costs grossly in excess of marginal cost. Again, in recognition of the unlikelihood that any global agreement would succeed, an alternative may be able to ensure a more even approach to the diagnostic tests and products that gene patents protect. This approach might entail member states taking advantage of the inherent flexibilities in the TRIPS and WIPO agreements to resolve any international gene patent conflicts within their own territories. This approach may not be effective: after all, countries have been able to exploit flexibilities in the TRIPS agreement for years, which include using compulsory licenses and excluding certain subject matter from patentability. Few countries, however, have taken advantage of these flexibilities.\textsuperscript{143}

\begin{footnotes}
\item[141] Wasserman Rajec, \textit{supra note 70}, at 154 (quoting \textsc{Martin J. Adelman et al.}, \textsc{Global Issues in Patent Law} 3 (2011)).
\item[142] See id. at 156.
\item[143] After the signing of TRIPS, governments were unsure about the use of compulsory licensing. The 2001 Doha Declaration clarified that developing nations were to use compulsory licenses to provide access to technology for public health. However, research suggests the Doha Declaration did little to encourage more compulsory license use. Only 24 compulsory licenses for pharmaceuticals issued between January 1995 and June 2011; since 2006, compulsory licensing activity has largely diminished. See Reed Beall & Randall Kuhn, \textit{Trends in Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Database Analysis}, PLoS Med. 9(1) (2012), available at http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154.
\end{footnotes}
1. Use international organizations for substantive patent uniformity.

Within the WTO, amendments or new treaties are unlikely to pass. Previous attempts to amend the TRIPS agreement have failed, including attempts to address the issue of gene patents. WTO members discussed the issue in 2010 after Bolivia introduced an amendment proposing a ban on patents of life forms.144 The Council discussed concerns about whether life forms should be eligible for patenting, but the amendment died on the floor.145 The debate over the scope of patent exceptions was also prevalent in the talks that resulted in the Doha Declaration.146 Some states argued that Article 27.3(b) should be amended “in light of the CBD (Convention on Biological Diversity)” and that “the present review should clarify that the following are not patentable: all living organisms (including whole or parts or plants and animals and importantly, including gene sequences), biological and other natural processes for producing plants, animals and their parts.”147 However, members never agreed upon this amendment.148

Discussions have continued for years since TRIPS was first enacted, but WTO members continue to disagree about how best to address the recognized problem of biopiracy149—let alone the somewhat newer concern over human gene patents. Previous years of debate and the lack of any formal response from the WTO suggest that the WTO is unlikely to reach any sort of consensus in the near future. Additionally, the TRIPS agreement suffers from a “law-making deficit because of the rarity and non-precedential character of WTO panel decisions,”150 further suggesting how unlikely is it that the WTO will exert its

146 See World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001).
148 See id.
149 For example, a number of WTO members, including Brazil, India, and several developing nations, argued that TRIPS is not supportive of the Convention on Biological Diversity. In 2011, a draft including an amendment to TRIPS was created to enhance the supportiveness between the two instruments. Members have yet to agree on these changes. See World Trade Organization, Draft decision to enhance mutual supportiveness between the TRIPS Agreement and the Convention on Biological Diversity, TN/C/W/59 (April 19, 2011), available at http://docsonline.wto.org/imrd/directdoc.asp?DDDocuments/ t/m/c/W59.doc.
150 Strandburg, supra note 8, at 906.
law-making powers in such a controversial fashion so as to exclude from patentability subject matter that some members currently allow.

2. Rely on the flexibilities inherent in TRIPS to ensure access to diagnostic tests covered by gene patents.

Because it seems increasingly unlikely that either nations themselves or the WTO or WIPO will achieve uniform gene patent policies in the near future, a second possibility could still ensure that the products and diagnostic tests protected by gene patents are available in a more uniform fashion to patients around the world. Within the framework of the TRIPS agreement and various WIPO treaties, countries have flexibility both to determine the scope of patentable subject matter and to use the option of compulsory licensing to ensure the availability of technology in the public interest. It should be noted that these very flexibilities can work against harmonization of patent regimes by ensuring that countries still retain the ability to tailor their patent regimes to idiosyncratic cultural and political needs. However, when the concern is the availability of technology, these flexibilities can allow a country to refuse to patent certain restrictive technologies or issue compulsory licenses to ensure that the technology is available at a relatively cheap price to its people.

During the negotiations of the TRIPS agreement, developed and developing nations often had opposing interests. Developed nations advocated harmonization and strong protection, whereas developing nations advocated flexibility to lower protection.\(^{151}\) While developed nations’ strong views and potentially coercive tactics\(^{152}\) led to TRIPS’s relatively high minimum level of protection, the agreement does retain flexibilities to accommodate developing nations’ desires. Due to these flexibilities, countries can exclude certain subject matter from patentability and they can issue compulsory licenses.\(^{153}\)

Patents must be available to all technologies without discrimination under the TRIPS agreement.\(^{154}\) Nonetheless, nations are afforded some flexibility to differentiate between industries, and TRIPS even includes explicit exceptions to the uniform grant of patent rights.\(^{155}\) The WTO has accepted some deviations for specific industries, most notably the pharmaceutical industry: it explicitly

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\(^{151}\) See Wasserman Rajec, supra note 70, at 166.

\(^{152}\) “[T]he United States has been criticized for using coercive negotiating techniques to gain the consensus of developing countries. In particular, the Office of the United States Trade Representative threatened countries with trade retaliations under Special 301 Report if they chose to object to the negotiating positions of the United States on intellectual property rights in the TRIPS agreement.” Id. at 166–67.

\(^{153}\) See id. at 164.

\(^{154}\) See TRIPS, supra note 2, art. 27.1.

\(^{155}\) See id.
requires the recognition of pharmaceutical patents even in developing nations where the patents have not yet been granted. By exploiting this flexibility, countries could refuse entirely to patent genes or to allow a subset of gene patents.

Some countries have taken advantage of the flexibility to exclude certain subject matter from patentability. India in particular has been leading this charge, passing laws that exclude certain chemicals from patentability and allowing compulsory licensing of pharmaceutical products. However, countries are under mounting pressure to increase patent protection. Nations can face negative consequences if they take advantage of the flexibilities in TRIPS too aggressively. For instance, nations known to be hostile to patent protection are likely to have trouble attracting biotechnology firms and may hurt their chances of obtaining a fair licensing agreement for access to these technologies. Moreover, if a nation exploits the flexibilities too aggressively, it may violate TRIPS and face potential retribution in unrelated trade matters. The threat of sanctions contributes to a culture of overcompliance that discourages countries from experimenting with flexibilities protected under TRIPS.

A more feasible alternative would be for countries to take advantage of TRIPS Article 31(f)’s provision for compulsory licensing when necessary for public health. In the past, compulsory licenses have issued for pharmaceuticals, albeit infrequently, but there is no reason they could not for genetic diagnostic tests as well. Article 31 permits compulsory licensing “where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by government . . . a) authorization of such use shall be considered on its individual merits.”

Despite their availability under TRIPS, compulsory licenses are infrequently used. After the initial implementation of TRIPS, the international community was uncertain of when and where compulsory licenses may be

156 See id. art. 70.8–9 (requiring countries, even those that have not yet made pharmaceuticals eligible for patent protection, to make certain provisions for filing of pharmaceutical patents).
157 See Wasserman Rajec, supra note 70, at 180.
159 See Wasserman Rajec, supra note 70, at 170.
161 See TRIPS, supra note 2, art. 31(f).
162 See Wasserman Rajec, supra note 70, at 180.
163 TRIPS, supra note 2, art. 31.
issued. However, even after the WTO clarified the use of compulsory licenses in the interest of public health, their number remains low. In practice, WTO panels have interpreted the exceptions narrowly in formal dispute resolutions. This places the burden on developing countries to defend their invocation of an exception.

Some nations have taken advantage of the compulsory license option under TRIPS. For example, India issued a compulsory license in March 2012 for the cancer drug Nexavar (manufactured by Bayer). In the spring of 2013, India took steps towards issuing compulsory licenses for three more cancer drugs, but other nations have received negative reactions after issuing compulsory licenses. In 2008, for example, after issuing compulsory licenses for four cancer drugs, Thailand was criticized for interpreting TRIPS more broadly than intended. Given the “stiff opposition by patent holders to the granting of compulsory licenses,” many states would prefer to avoid a confrontation with patent holders (who are often backed by their governments). Additionally, due to the small number of biotechnology firms that control the majority of patents, states are often reluctant to enter into disputes that may limit their future access to patented innovations.

B. A Pragmatic Approach to Gene Patent Harmonization

While substantive harmonization of patent regimes may be difficult and years away, independent licensing agreements offer a realistic possibility for tempering the restrictive practices of patent holders and helping to facilitate

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164 “Following the adoption of TRIPS in 1995, the novelty of the agreement and its hard-to-understand text left developing countries uncertain of their right to promote access to essential medicines.” Peter Maybarduk & Sarah Rimmington, Compulsory Licenses: A Tool to Improve Global Access to the HPV Vaccine, 35 AM. J. L. & MED. 323, 328 (2009).

165 See Beall & Kuhn, supra note 143, at 7.


167 See Wasserman Rajec, supra note 70, at 180.


169 See Wasserman Rajec, supra note 70, at 180.

170 See Tejavani, supra note 10, at 673.

171 Carlos M. Correa, Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 227, 248 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

172 See id. at 230.
greater uniformity in patent regimes. More extensive and coordinated use of voluntary licensing would provide a degree of certainty for patent holders that their rights would be protected, while also ensuring that patients in both developed and developing nations have access to biotechnology at a lower cost.

In most instances, patent holders have the incentive to enter into negotiations to reach voluntary agreements for licensing IP rights. Studies show that patentees are often provided sufficient compensation to recover R&D costs through the royalties received from voluntary licenses.\(^{173}\) In comparison to compulsory licensing, independent voluntary licensing allows for terms to be negotiated that were agreed by both parties, rather than having terms imposed through the granting of a compulsory license.\(^{174}\) Independent voluntary licenses are preferable to both monopolistic restrictions that limit use of a patent and the alternative of compulsory licensing. In light of these advantages, this Comment advocates the use of independent voluntary licensing agreements under the supervision and coordination of WIPO and the WTO, which are best situated to reduce the transaction costs associated with coordinating licensing of multiple organizations with many nations.\(^{175}\)

1. Promote the use of independent licensing agreements.

Individual biotech firms are better positioned than governments to grant licenses that address concerns about access costs yet still allow the firms to recoup the costs of R&D. The formation of contract-based institutions such as patent pools, IP clearinghouses, and open source licensing does not require waiting for domestic or international law reform.\(^{176}\) With private licensing options, institutions can lower private transaction costs and increase responsiveness to “varied and dynamic local conditions,” as compared to the “relatively slow-moving, broad-brush instruments available to state actors.”\(^{177}\)

As a general matter, intellectual property must reconcile two conflicting aims: first, to provide innovators with incentives by restricting the use of their

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173 See id. at 249.


175 Cf. Broadcast Music, Inc. v. CBS, Inc., 441 U.S. 1, 20 (1979) (holding, in the context of copyrighted sound recordings, that blanket voluntary licensing coordinated by a centralized body is a desired means of reducing the “prohibitive” transaction costs associated with seeking “licenses with individual [companies].”).

176 See Hope, supra note 11, at 172.

177 Id.
innovation and guaranteeing gains; and second, to protect "society's interest in allowing maximum use of innovative products by keeping their price low." An innovation policy that encourages both the creation and the diffusion of new technology strikes the right balance between the "right to exclude and the right to use innovations." Independent licensing can play this role by enhancing broad access to knowledge and fostering the capability to use the knowledge in pursuit of a multiplicity of economically and socially beneficial activities.

Licensing agreements consist of the authorization to use a patent "rented out by the owner of an intellectual right," which in the context of gene patents is most often the patent-holding biotechnology firm. Patent owners are "effectively free to dictate the terms of use of an established test" and thus may choose to license it broadly and ask for a reasonable royalty. This would be the ideal situation. However, patent holders may also choose to restrict the license to only a select number of laboratories or even a single laboratory and demand high royalties that increase the cost of genetic tests for patients.

Restrictive licensing is the largest potential pitfall of relying on individual biotech firms to issue independent licensing agreements. Cases of restrictive licensing or refusals to license have generated controversy and disapproval because of the potential adverse effects on public health. Human gene patents for diagnostic tests are a particularly acute problem in this area. Myriad came under public scrutiny over its refusal to issue licenses in multiple countries, thus creating a monopoly with high costs for their genetic tests for BRCA1/2 screening. Such restrictions can increase inequalities in access to health care and genetic testing across jurisdictions, which conflicts with the principle of access to medical care in the Universal Declaration of Human Rights.

2. International organizations intervene to coordinate licensing agreements.

International organizations can overcome the potential problems inherent in relying on voluntary licensing agreements by enforcing and settling disputes.

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178 Carlos M. Correa, Pro-Competitive Measures under the TRIPS Agreement to Promote Technology Diffusion in Developing Countries, 4 J. WORLD. INTELL. PROP. 481, 481 (2001).
179 Id. at 482.
180 Id. at 482.
182 See id.
183 See Williams-Jones, supra note 4, at 125.
First, international organizations such as WIPO and the WTO can overcome the transaction costs inherent in organizing voluntary licensing agreements. Second, they have the weight to pressure countries to allow licensing agreements in developing nations where firms may otherwise be less willing to license. Further, international organizations can enforce and settle disputes when a firm engages in restrictive licensing with the hopes of creating high costs of genetic tests.

At the most general level, institutions “create the capability for states to cooperate in mutually beneficial ways by reducing the costs of making and enforcing agreements.” Intergovernmental organizations, such as the WTO, are able to provide public goods to members by promoting rules to regulate fairness in competition—an advantage for intergovernmental organizations compared to individual states or firms. These organizations are in a unique position to resolve the conflict over human gene patents by stepping in and coordinating licensing in order to promote fairness in competition and ensure access to diagnostic tests that are necessary for human health.

International organizations have already “stressed the importance of avoiding . . . conflicts and of promoting consistency among an increasingly complex and overlapping set of treaty commitments and soft laws.” Furthermore, they are already familiar with coordinating policy. The World Health Organization (WHO), the WTO, and WIPO have previously coordinated policy reports in order to “contribute to enhancing the empirical and factual information basis for policy makers and supporting them in addressing public health in relation to intellectual property.” During the recent Trilateral Cooperation on Public Health, IP, and Trade Symposium in 2013, these organizations discussed the importance of developing “work sharing,” particularly in the field of biotechnology where “often small and medium size biotechnology companies . . . do basic or specialized research . . . and license out the R&D results.” Both the WTO and WIPO, then, are familiar with coordinating intellectual property offices and have openly encouraged global cooperation.

185 Jordan & Field, supra note 79, at 236.
186 See id.
187 Helfer, supra note 102, at 72.
The WTO and WIPO have also worked together in other situations to ensure cooperation. The Convention on Biological Diversity and the related Nagoya Protocol on Access to Genetic Resources are examples of collaboration by international organizations to ensure access to patented technology.\textsuperscript{191} As part of the Convention, member countries have signed on to participate in information sharing of patented technologies relating to biological diversity. The Protocol also created the Access and Benefit-sharing Clearinghouse as part of the agreement to provide a means of access and benefit sharing.\textsuperscript{192} The WTO has continued to hold meetings to ensure that the Clearinghouse is making progress and that nations are participating. Because information-sharing agreements have been used in the past, they could provide a feasible framework for the development of a similar arrangement concerning gene patents and other public health technologies.

Alternatively, WIPO and the WTO could look to certain informal collaborations as examples of how to promote the disclosure of particular gene patent sequences. The DNA Databank of Japan and the European Nucleotide Archives have experienced limited success in sharing nucleotide-based patent sequences.\textsuperscript{193} However, the WTO and WIPO might carry much more weight and can coordinate and build upon these already existing databases.

International organizations, including the WTO and WIPO, are also in the best position to prevent the kind of restrictive licensing that characterized the dispute over Myriad’s BRCA sequences. When coordination occurs, economic activity is not solely based on “perceptions of price advantages within individual transactions,” but is instead influenced by consciousness of the value of membership in the organization.\textsuperscript{194} Membership in the WTO or WIPO is valuable for states. As such, these organizations can influence the cooperation of firms that are often backed by their governments. Due to their unique power to


\textsuperscript{194} Hope, supra note 11, at 108.
encourage cooperation and their ability to monitor restrictive licensing practices, the WTO and WIPO can and should coordinate voluntary, independent licensing agreements to ensure more even patent access and protection.

VI. CONCLUSION

International organizations, while increasingly seeking to harmonize the worldwide patent regime, have been unable to resolve the currently fragmented regime in the field of gene patents. The suggestions of a TRIPS amendment or increasing use of compulsory licenses are unlikely to prove long-term solutions. While a new treaty dictating uniform terms of patentability would be ideal, this is unlikely to occur.

Currently, the most pragmatic solution involves promoting the wider use of voluntary independent licensing agreements between biotechnology patent holders and laboratories in other countries. This option would promote the best interests of patent holders by ensuring they can recoup the high costs of biotechnology R&D. In addition, this solution offers the best opportunity for both developed and developing nations to ensure access to valuable genetic tests. Due to the reasonable fear of restrictive licensing, the WTO and WIPO have a responsibility to intervene in this effort. By coordinating licensing agreements and monitoring for overly restrictive practices, the fragmented patent regimes may be better used to promote international public health.