

**POLICING FUTURE NONTHERAPEUTIC
APPLICATIONS OF GENETIC
ENHANCEMENT THROUGH
INTERNATIONAL AGREEMENT**

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I. INTRODUCTION

It is fair to say that, since the International Human Genome Sequencing Consortium's announcement of the completion of the Human Genome Project on April 14, 2003, legal scholars, scientists, and the general public alike have been skeptical of

what exactly the announcement entailed.¹ Despite often being touted in unduly laudatory language,² it is yet unclear what benefits the world will reap from this massive and expensive³ scientific undertaking and who will control the legal, social, and ethical implications of such potentially powerful knowledge.

Against the backdrop of this knowledge, corporations around the world have begun to patent gene sequences with the hope of finding and developing the first blockbuster gene therapy,⁴ sometimes with little regard to the actual utility of such DNA sequences.⁵ Nearly all patent schemes have three requirements for patentability: novelty, nonobviousness, and utility.⁶ Many

1. News Release, Nat'l Human Genome Res. Inst., International Consortium Completes Human Genome Project: All Goals Achieved; New Vision for Genome Research Unveiled (Apr. 14, 2003), *available at* <http://www.genome.gov/11006929>. In reality, the 2003 announcement was the second major assertion of a "completed draft" of the human genome, the first coming in June 2000. *Id.* The June 2000 draft covered "90 percent of the gene-containing part of the sequence, 28 percent of which had reached finished form, and contained about 150,000 gaps," whereas the 2003 draft contained "99 percent of the gene-containing sequence, with the missing parts essentially contained in less than 400 defined gaps." *Id.*

2. *See, e.g., id.* Aristides Patrinos, Ph.D., director of the Department of Energy's Office of Biological and Environmental Research in the Office of Science, stated:

Sequencing the human genome was a pioneering venture with risks and uncertainties. But its success has created a revolution—transforming biological science far beyond what we could imagine. We have opened the door into a vast and complex new biological landscape. Exploring it will require even more creative thinking and new generations of technologies.

Id.

3. The estimated cost of completion for the project in 1991 was \$2.7 billion. *Id.*

4. *See, e.g.,* Himanshu Parmar, *Gene Therapy Makes a Comeback*, CLINICAL DISCOVERY, Jan. 5, 2006, <http://www.clinicaldiscovery.com/readArticle.aspx?articleId=14> (noting "improved targeting of genetic material to specific cell populations" and the potential for the oncology area "to yield several blockbuster therapeutics in [the] future."). Gene therapy is defined as a way of "treating disease by either modifying the expressions of an individual's genes or correction of abnormal genes. By administration of DNA rather than a drug, many different diseases are currently being investigated as candidates for gene therapy." American Society of Gene Therapy, *Gene Therapy Defined*, http://www.asgt.org/about_gene_therapy/defined.php (last visited Apr. 6, 2008).

5. *See, e.g.,* Diana A. Villamil, *Redefining Utility in Determining the Patentability of DNA Sequences*, 5 J. MARSHALL REV. INTELL. PROP. L. 238 (2006) (noting that initial rejections of patent applications for utility reasons did not stop patent applications).

6. *See* 35 U.S.C. §§ 101–03 (2000) (setting forth the requirements for patentability). Novelty means that no one has conceived of or reduced the invention to practice before the inventor; nonobviousness means that the invention would not have been trivial for a

scholars have questioned the wisdom of patenting such gene sequences when a direct application of the sequence has not been described.⁷ The dilemma of gene patenting will be discussed further in Part II.⁸

One especially controversial form of gene therapy is known as gene enhancement. Gene enhancement describes the field of scientific research wherein patients' genomes will be modified for "nontherapeutic" or "non-medical" reasons.⁹ Potential benefits of such technology include "everything from physical qualities such as height, weight, appearance, strength, and agility to behavioral qualities including intelligence, creativity, mood, personality, and passion."¹⁰ Although the actual implementations of such gene enhancement techniques may not be realized until the distant future, scholars are already attempting to tackle the ethical dilemma that gene enhancement presents today.¹¹

Because of the significant impact that such technology could potentially have on the world from both an economic and a human rights perspective, international bodies such as the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), and the United Nations Convention on Biological Diversity (CBD) meet frequently to develop policy and have enacted various international agreements¹² with the

person of ordinary skill in the art to develop; and utility means that the invention has some very low baseline level of usefulness. *Id.*

7. See, e.g., Cherylyn A.P. Esoy, Comment, *The PTO's 2001 Revised Utility Examination Guidelines for Gene Patent Applications: Has the PTO Exceeded the Scope of Authority Delineated by the Court's Interpretation of a "Useful" Invention?*, 33 SETON HALL L. REV. 127, 152–53 (2002) (describing the Patent and Trademark Office's new procedures for determining a patent's utility).

8. See *infra* Part II.A.

9. Daniel L. Tobey, *What's Really Wrong with Genetic Enhancement: A Second Look at Our Posthuman Future*, 6 YALE J. L. & TECH. 54, 57 (2003).

10. *Id.* at 58.

11. See, e.g., *id.* at 56. (discussing FRANCIS FUKUYAMA, *OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION* (2002) (arguing that genetic modification for nontherapeutic reasons would undermine the essence of our humanity, and thus scientific research involving genetic modification should be limited to purely therapeutic applications)).

12. See, e.g., Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex

hope of harmonizing worldwide treatment of gene modification technologies.¹³ Due in large part to the differing perspectives of developed nations as compared to developing nations, there has been a deadlock in determining how the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)¹⁴ should be amended to account for the emergence of technologies based on patented DNA sequences and gene therapy methods.¹⁵ Gene enhancement presents a novel challenge for the international intellectual property community because of the ethical considerations involved in fundamentally altering the human condition for reasons that are purely cosmetic rather than health related. Due to its potential perpetual nature,¹⁶ pursuing genetic enhancement risks "building in" any such genetic superiority to future generations: a scenario with potentially dangerous consequences.¹⁷

Part II of this paper discusses the history of gene therapy and gene enhancement, focusing on the successes and failures to

1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]. The TRIPS Agreement plays the most prominent role in international intellectual property rights disputes today due to its wide membership base and enforceability provisions. See Anna Lanoszka, *The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries*, 24 INT'L POL. SCIENCE REV. 181, 183–87 (2003) ("The TRIPS agreement is the most comprehensive legal regime ever concluded at the multilateral level in the area of intellectual property rights.").

13. See, e.g., William New, *Biotech Industry Fights Disclosure in Patents on Three IP Policy Fronts*, INTELL. PROP. WATCH, Mar. 2, 2006, <http://www.ip-watch.org/weblog/index.php?p=235&res=1024&print=0>.

14. See TRIPS Agreement, *supra* note 12, art. 66.

15. See Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433, 435–43 (2006) (explaining that while "Western" countries have been entering into bilateral agreements to enforce higher levels of international intellectual property rights (IPR) protections, developing nations have asserted that their genetic resources and associated traditional knowledge are being leveraged into profit in the form of pharmaceuticals and gene therapies without their consent).

16. See MARK S. FRANKEL & AUDREY R. CHAPMAN, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, HUMAN INHERITABLE GENETIC MODIFICATIONS: ASSESSING SCIENTIFIC, ETHICAL, RELIGIOUS AND POLICY ISSUES 2–3 (2000), <http://www.aaas.org/spp/sfrrl/projects/germline/report.pdf> (noting the benefits of gene modification over somatic cell gene therapy and explaining the potential long term use of "germ line gene modification").

17. *Id.* at 3–6.

date, public misconceptions about genetic enhancement, and the philosophical basis for opposition to this type of research. Part III reviews the current state of international agreements, proposed amendments, and the roadblocks faced in reaching an accord. Part IV proposes a solution that will help the international community distinguish between therapeutic and nontherapeutic gene modification patents, setting up a system that will discourage the latter but encourage the former, while still respecting the rights of peoples in developing countries whose genetic makeup was instrumental in the developing of such technologies. Part V concludes with a plea to the international community to move forward from gridlock to a workable plan that is not simply the result of the group of developed nations leveraging TRIPS' enforcement capabilities to strong arm their way into an overly favorable agreement on an issue that is so fundamental to the human condition.

II. WHAT THE HECK IS GENE ENHANCEMENT? AND WHAT'S ALL THE FUSS ABOUT?

This Part will discuss the development of gene therapy techniques, leading into the controversy over gene enhancement. It will focus on the differences between gene therapy and gene enhancement and attempt to shed light on public misconceptions about the current viability of genetic enhancement. This Part will also examine the underlying philosophical basis for opposition to this type of research.

A. *Can You Get a Patent on That?*

The first gene patent filed in the United States was on a cDNA gene sequence and was granted in 1982.¹⁸ “However, many researchers assert that the first therapeutically important DNA patent was issued in 1985 [and concerned a DNA molecule] useful in producing proteins.”¹⁹ Each year since, courts and patent offices have refined the requirements necessary to patent

18. Villamil, *supra* note 5, at 239.

19. *Id.* (citing Recombinant DNA Molecules and Their Use in Producing Human Interferon-like Polypeptides, U.S. Patent No. 4,530,901 (filed Feb. 4, 1980) (issued July 23, 1985)).

DNA sequences in an attempt to ensure legitimate access and prevent the use of such sequences from being unduly restricted by one or more patents that lack any practical application.²⁰ These regulations have left many researchers in the unfortunate predicament of deciding between keeping their research findings to themselves or disclosing them and starting a one year timeframe in which they must derive a commercially useful application for their DNA sequence or risk never having patent protection on their findings.²¹ Not surprisingly, this has led many researchers to favor nondisclosure, an outcome contrary to the aims of any patenting system.²² Those scientists that have patented genes, especially those relating to human diseases, have faced resentment from some members of the community over the perceived lack of access to treatment that their intellectual property rights have created.²³

Arguments in favor of allowing gene patenting include the encouragement of innovation,²⁴ the elimination of duplicative

20. *Id.* at 239 n.12 (citing Revised Utility Examination Guidelines, 66 Fed. Reg. 1,092 (Jan. 5, 2001) (stating that the asserted utility of any patented DNA sequence must be “specific,” “credible,” and “substantial”)).

21. Villamil, *supra* note 5, at 255.

22. *Id.*

23. See Gavin Yamey, *Scientists Unveil First Draft of Human Genome*, 321 *BMJ* 7, 7 (2000), available at <http://www.bmj.com/cgi/content/full/321/7252/7> (explaining scientists' concern that genetic information would be under the control of one entity or corporation). Michael Crichton wrote an op-ed piece in the *New York Times*, opining “YOU, or someone you love, may die because of a gene patent that should never have been granted in the first place.” Michael Crichton, Op-Ed., *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A23, (listing breast cancer, Canavan disease, Hepatitis C, and SARS as four instances of diseases where gene patent rights have either made the tests or cures for the disease too expensive for the average person, or caused the diseases to be prohibitively expensive for scientists to pursue research). According to Crichton, the Genomic Research and Accessibility Act, introduced to Congress on Feb. 9, 2007 by Representatives Xavier Becerra (D-CA) and Dave Weldon (R-FL), which would ban the practice of patenting genes found in nature, is a step in the right direction. *Id.*

24. Oak Ridge Nat'l Laboratory, Genetics and Patenting, http://www.ornl.gov/sci/techresources/Human_Genom/elsi/patents.html (last visited Apr. 6, 2008) [hereinafter Genetics and Patenting].

research efforts,²⁵ the reduction of secrecy,²⁶ and ensured access to new inventions after a limited timeframe passes.²⁷

The arguments against gene patenting are somewhat less economic and somewhat more ethical in nature. Allowing gene patenting could potentially reward the easiest step taker in the scientific process, rather than the researcher who determines the actual function or application of the gene.²⁸ Patent stacking²⁹ could “discourage product development because of high royalty costs.”³⁰ And, theoretically, at least, gene patenting would allow “one organism to own all or part of another organism.”³¹ The ethical dilemma presented by this subject will be examined in greater detail in Part IV.

B. Gene Therapy: The Beginnings

Eventually, the idea to replace “bad genes” in humans with “good genes” was brought to fruition by Dr. W. French Anderson in September 1990.³² In that case, four-year-old Ashanthi DeSilva was treated with genetically modified copies of her own white blood cells to combat a rare, single gene, hereditary disease called Severe Combined Immunodeficiency (SCID) that

25. See Posting of Kevin Noonan to Patent Docs: Biotech & Pharma Patent Law & News Blog, http://patentdocs.typepad.com/patent_docs/2006/10/the_anticommons.html (Oct. 27, 2006, 4:54 PM) (arguing that permitting gene patenting has not restricted progress, inhibited academic freedom, or prevented scientists from working cooperatively).

26. Posting of Kevin Noonan to Patent Docs: Biotech & Pharma Patent Law & News Blog, http://patentdocs.typepad.com/patent_docs/2006/12/by_kevin_noonan.html (Dec. 7, 2006, 2:49 PM).

27. Posting of Kevin Noonan to Patent Docs: Biotech & Pharma Patent Law & News Blog, http://patentdocs.typepad.com/patent_docs/2007/01/antipatent_sull.html (Jan. 29, 2007, 10:55 PM); Joseph Fuller & Brock Reeve, *Will We Lose in the Stem Cell Race?*, WASH. POST, Feb. 3, 2007, at A15 (arguing that patents on genes have been vital to America’s preeminence in the biotechnology and pharmaceutical industries).

28. Genetics and Patenting, *supra* note 24.

29. Patent stacking refers to “allowing a single genomic sequence to be patented in several ways such as [expressed sequence tag (EST)], a gene, and a [single nucleotide polymorphism (SNP)].” *Id.*

30. *Id.*

31. *Id.*

32. See Larry Thompson, *Human Gene Therapy: Harsh Lessons, High Hopes*, FDA CONSUMER MAG., Sept.–Oct. 2000, at 19.

essentially paralyzes the patient's immune system.³³ Although the procedure was successful in helping Ashanthi return to a more normal lifestyle,³⁴ this first practical application of gene therapy was both a blessing and a curse to the field of gene therapy research. The successful treatment of SCID led to more than 400 clinical trials to test the efficacy of gene therapy on a number of diseases.³⁵ The initial foray into the field of gene therapy, however, may have been a classic case of look before you leap, meeting with little success and at least one tragic consequence.

C. The Lesson of Jesse Gelsinger

In September of 1999, a patient named Jesse Gelsinger, who had agreed to undergo an experimental gene therapy clinical trial, was being treated for a rare metabolic disease at the University of Pennsylvania's Institute of Human Gene Therapy in Philadelphia.³⁶ Unfortunately for Jesse, the researchers "were not following all of the federal rules requiring them to report unexpected adverse events associated with the gene therapy trials; worse, some scientists were asking that problems not be made public."³⁷ The now well-documented result of the trial was Jesse's untimely death. Around the same time, there were also news reports of other unreported human and animal deaths attributed to gene therapy experiments gone awry.³⁸

33. Joseph M. Rainsbury, *Biotechnology on the RAC-FDA/NIH Regulation of Human Gene Therapy*, 55 FOOD & DRUG L.J. 575, 585 (2000). SCID is often known as the "bubble boy disease." The SCID Homepage, <http://www.scid.net> (last visited Apr. 6, 2008).

34. Rainsbury, *supra* note 33, at 596 n.165.

35. Thompson, *supra* note 32, at 20.

36. *Id.* See generally Sheryl Gay Stolberg, *The Biotech Death of Jesse Gelsinger*, N.Y. TIMES MAG., Nov. 28, 1999, at 137, (recounting the Jesse Gelsinger narrative). The University of Pennsylvania was considered by most to be the world leader in gene therapy technology at the time of Gelsinger's clinical trial. *Id.* (documenting that the gene therapy program was the largest program in the country and boasted 250 employees, state of the art laboratories and a multimillion dollar budget).

37. Thompson, *supra* note 32, at 22.

38. *Id.*; see also Rick Weiss, *U.S., Researchers Reach Deal in '99 Gene Therapy Case*, WASH. POST, Feb. 10, 2005, at A3.

When the news of Jesse's death hit the general public, enthusiasm for gene therapy cooled and experiments slowed almost to a halt.³⁹ The Gelsinger case taught us how little we truly knew about the complex interaction between our genes and our environment. Gene therapies were still in their embryonic stages and, thus, were unpredictable and, for the most part, unsuccessful.⁴⁰

Gene therapy trials eventually picked back up by 2002 and have met with mild success in delivering therapeutic genes and treating an array of illnesses, including cancer.⁴¹ It is important to note, however, that all these experiments had a therapeutic or disease treating effect in the patients or animals that were a part of the trials.⁴² Though Jesse's was the first heavily

39. Thompson, *supra* note 32, at 20–22.

40. *See id.* at 23–24 (discussing conclusions produced the same month that the Gelsinger study was approved, which found that gene therapy still had “significant problems” and its clinical effectiveness had not yet been proven).

41. *See* Jennifer Fisher Wilson, *Murine Gene Therapy Corrects Symptoms of Sickle Cell Disease*, THE SCIENTIST, Mar. 18, 2002, at 36, 36 (describing treatment of sickle cell disease in mice); Sylvia Pagán, *DNA Nanoballs Boost Gene Therapy*, NEW SCIENTIST, May 12, 2002, <http://www.newscientist.com/article.ns?id=dn2257&print=true> (describing a new means for delivering DNA into cell nuclei); Danny Penman, *Subtle Gene Therapy Tackles Blood Disorder*, NEW SCIENTIST, Oct. 11, 2002, <http://www.newscientist.com/article.ns?id=dn2915&print=true> (describing a technique with potential to treat various genetic diseases, including the blood disorder thalassaemia, cystic fibrosis, and some cancers); Anil Ananthaswamy, *Undercover Genes Slip into Brain*, NEW SCIENTIST, Mar. 22, 2003, at 16 (describing the treatment of epilepsy and Parkinson's by delivering liposome covered genes into the brain); News Release, Cincinnati Children's Hosp. Med. Ctr., *Gene Therapy Appears to Cure Myeloid Blood Diseases in Groundbreaking International Study* (Mar. 31, 2006), <http://www.cincinnatichildrens.org/about/news/release/2006/3-gene-therapy.htm> (describing the first study showing that gene therapy can cure myeloid system diseases); Brian D. Brown et al., *Endogenous MicroRNA Regulation Suppresses Transgene Expression in Hematopoietic Lineages and Enables Stable Gene Transfer*, 12 NATURE MED. 585, 585, 589–90 (2006) (describing a breakthrough for gene therapy in which researchers developed a way to prevent the immune system from rejecting a newly delivered gene using by inherent properties of microRNA).

42. *See* Wilson, *supra* note 41, at 36 (discussing treatment of sickle cell disease); Pagán, *supra* note 41 (discussing treatment of cystic fibrosis); Penman, *supra* note 41 (discussing treatment of thalassaemia); Ananthaswamy, *supra* note 41, at 16 (discussing treatment of Parkinson's disease); *Gene Therapy Appears to Cure Myeloid Diseases*, *supra* note 41 (discussing treatment of myeloid system diseases); Brown et al., *supra* note 41, at 585, 590 (discussing a method of preventing the immune system's rejection of a newly delivered gene).

publicized death relating to gene therapy treatments, it will not likely be the last setback on the road to scientific advancement.⁴³

D. Gene Therapy vs. Gene Enhancement

Scientists and ethicists have struggled for years to pin down the exact difference between gene therapy and gene enhancement.⁴⁴ Certainly, one obvious distinction is that gene therapy must have therapeutic or disease treating ends, whereas gene enhancement may have nontherapeutic aims.⁴⁵ However, under certain circumstances, the waters become muddied as to whether or not a given technique should be considered to be therapy or enhancement based on the individual, the type of disease, and also the society in which the treatment is being carried out.⁴⁶ Another difficulty in ascertaining which technologies should be considered enhancement and which should be considered therapeutic is that enhancement technologies are likely to first be employed as

43. See, e.g., Brandon Keim, *Gene Therapy Trial Death Caused by Massive Infection*, WIRED, Aug. 21, 2007, <http://blog.wired.com/wiredscience/2007/08/more-informatio.html> (discussing the death of another gene therapy patient). Newer, safer technologies, such as the use of polymers, are now being developed to try and prevent some of the dangers faced by patients involved in previous gene therapy clinical trials. Katherine Bourzac, *Gene Therapy Without Viruses: A New, Highly Effective Polymer May Make Gene Therapy Safer*, TECH. REV., Sept. 12, 2007, <http://www.technologyreview.com/Biotech/19367/>.

44. See, e.g., LORI B. ANDREWS ET AL., GENETICS: ETHICS, LAW AND POLICY 560 (2d ed. 2006) (discussing the difficulty in distinguishing gene therapy from gene enhancement). For instance, would a vaccine conferring an immunity power beyond that which is naturally produced constitute therapy or enhancement? It would not treat any present affliction, and it enhances normal levels of functionality, yet it undoubtedly has potentially therapeutic ends. *Id.*

45. *Id.* at 483; Tobey, *supra* note 9, at 57.

46. See David Gems, *The Face of the Future*, 397 NATURE 222, 222 (1999) (reviewing ERIK PARENS, ENHANCING HUMAN TRAITS: ETHICAL AND SOCIAL IMPLICATIONS (1998)) (pointing out, for example, different views on whether homosexuality, deafness, or giving birth to twins are considered illnesses or disabilities). If therapy is thought of as a treatment to bring people back to a normal or healthy level, and enhancement is thought of as making a person more than “normal” or “adequate,” then the entire distinction will rest on our perhaps questionable or biased assumptions about what the definition of “normal” is. ANDREWS ET AL., *supra* note 44, at 560; see Gems, *supra* at 222 (giving examples of how illness may be a cultural construction).

“off-label”⁴⁷ uses of legitimate therapeutic products, and, thus, social policy will discourage the elimination of these products altogether because of their vast potential to do good when used in the appropriate manner.⁴⁸

Some thought provoking instances in which the use of gene therapy may be questioned as “enhancement” rather than “therapy” include intelligence, sexual orientation, mental illness, addictive behavior, and tendency towards violent behavior.⁴⁹ Is there even a way to quantify “lower than average” intelligence? Isn’t there a valid and important place in our society for people of all intelligence levels? Could lack of intelligence or sexual orientation ever be thought of as a disease or affliction that needs “curing?” The answers to these and other difficult philosophical questions are certain to differ from country to country and from person to person.⁵⁰

To be on the safe side of this debate,⁵¹ international bodies should adopt policies that favor and encourage, first and foremost, the development of clearly disease treating technologies, while reviewing more closely those technologies with a combination of therapeutic and “cosmetic” benefits before

47. “Off-label” refers to using a product in ways not intended or promoted by manufacturers. Maxwell J. Mehlman, *How Will We Regulate Genetic Enhancement?*, 34 WAKE FOREST L. REV. 671, 678 (1999). The uses are often not tested for in clinical trial and, thus, are dangerous to the end users. *Id.* at 678 & n.28.

48. *Id.* at 678–79 (describing Human Growth Hormone (HGH) as an example of a drug developed initially to help children deficient in growth hormone but eventually used in healthy individuals in an attempt to attain greater than average height and muscle mass).

49. See Dan Bustillos, Assistant Professor, Department of Health Care Ethics, Saint Louis University, Lecture on Genetics & the Law (Nov. 13, 2006) (listing intelligence, sexual orientation, mental illness, addictive behavior, and violence as current research topics in behavioral genetics) (on file with Author).

50. See *infra* Part E.

51. Scientists and philosophers have expressed concern that rampant gene enhancement would simply reinforce already existent disparate positions in social and economic status between peoples, essentially creating a “genetic upper class” who would continue to pass on their superior genetic materials to future generations. Mehlman, *supra* note 47, at 687–88. The approval of such techniques could also stigmatize certain groups as abnormal or serve to validate racial or ethnic stereotypes. Sujatha Jesudason, *The Future of Violence Against Women: Human Rights & the New Genetics*, CTR. FOR GENETICS AND SOC’Y, Feb. 21, 2006, http://geneticsandsociety.org/downloads/Jesudason_USWomen_022106.pdf.

approving the use of incentivizing policies such as patent protection and clearance for clinical trials. These policies will be discussed further in Part IV.

E. W.W.P.D. (What Would Prometheus Do?)

In his book, *Redesigning Humans: Our Inevitable Genetic Future*, Gregory Stock hearkens back to the Greek legend of Prometheus in an attempt to rationalize man's temptation to utilize new technologies:

Some imagine we will see the perils, come to our senses, and turn away from such possibilities. But when we imagine Prometheus stealing fire from the gods, we are not incredulous or shocked by his act. It is too characteristically human. To forgo the powerful technologies that genomics and molecular biology are bringing would be as out of character for humanity as it would be to use them without concern for the dangers they pose. We will do neither. The question is no longer whether we will manipulate embryos, but when, where, and how.⁵²

Stock paints a vision of the future where technological advances in the fields of genomics and molecular biology will fundamentally change who we are as human beings, and he claims that these changes may well be unavoidable.⁵³ While the realities of genetic engineering may not approach Stock's vision within our lifetimes, the seeds of progress are no doubt being planted now, and many believe that the risks of such research are too vast and too unpredictable to justify unbridled scientific forays into the field.

One such concern is determining how to ensure equal access to any successful genetic enhancement technologies.⁵⁴ Because

52. GREGORY STOCK, *REDESIGNING HUMANS: OUR INEVITABLE GENETIC FUTURE* 2 (2002).

53. *Id.* at 5 ("Well before this new millennium's close, we will almost certainly change ourselves enough to become much more than simply human The coming possibilities will be the inadvertent spinoff of mainstream research that virtually everyone supports.").

54. Jon W. Gordon, *Genetic Enhancement in Humans*, 283 *SCIENCE* 2023, 2023 (1999).

the alteration of germ cell lines has the potential to affect future generations, commentators have opined that such enhancements would affect human evolution and amount to scientists “play[ing] God.”⁵⁵ Empirical studies have also shown that offering patent protection on such technologies does not stimulate research and development efforts around the world, but rather serves to make such technologies prohibitively cost expensive in the very countries that need the treatment the most—those that lack the substantial scientific capacity to develop such technologies on their own.⁵⁶

Another concern about opening up the Pandora’s Box of gene enhancement is that it *intrinsically* goes against whatever it is that makes us fundamentally human and therefore should not be attempted on those grounds alone.⁵⁷ Francis Fukuyama, in his book *Our Posthuman Future*, labels this elusive concept of humanness “Factor X.”⁵⁸ “Factor X is something shared by all humans and lacked by all nonhumans . . . [however,] genetic engineering threatens to undermine Factor X, which will in turn undermine our moral system of natural rights.”⁵⁹ Fukuyama’s underlying theme is that genetic enhancement will destroy what it is to be human, and, therefore, we should pursue only genetic modification with purely therapeutic ends.⁶⁰ If it becomes a simple process to order intelligence, beauty, or athletic prowess for ourselves or our offspring, we will no longer appreciate these qualities in their naturally occurring states, and we will destroy

55. *Id.*

56. Dennis S. Karjala, *Biotech Patents and Indigenous Peoples*, 7 MINN. J. L. SCI. & TECH. 483, 519–21, 525 (2006) (“Many commentators have argued that developing countries have little to gain from recognizing foreign patents, as required by TRIPS, except to avoid trade retaliation We may conclude that access to patented inventions, especially pharmaceuticals, is not as great as it might be were these inventions unpatented everywhere in the world.”).

57. Tobey, *supra* note 9, at 59 & n.5.

58. FUKUYAMA, *supra* note 11, at 149. “Factor X is the human essence, the most basic meaning of what it is to be human. If all human beings are in fact equal in dignity, then X must be some characteristic universally possessed by them.” *Id.* at 150.

59. Tobey, *supra* note 9, at 68; FUKUYAMA, *supra* note 11, at 149–52.

60. Tobey, *supra* note 9, at 68; FUKUYAMA, *supra* note 11.

the very humanistic joy that comes with determination, struggle, and accomplishment in our lives.⁶¹

Finally, even if we require that genetic enhancement procedures be carried out with informed consent, that there be a large possibility of success, that the treatments be affordable, that there be limited side effects, and that they are carried out in a regulated fashion, irresponsible use of the technology can never be stopped, not even by legislation.⁶² For this reason, it is better that society be prepared to cope with and contain the inevitable effects of genetic enhancement when they do come, rather than stand idly by, confident that their proclamations can stop the onrushing current of scientific progress.

So, what would Prometheus do if he were handed down from the gods the knowledge to unlock the secrets of genetic enhancement? He might share the secrets with all of mankind for the greater good, and, just as today we have firefighters as well as arsonists, our future “post-genetic enhancement future” will have both amazing scientific breakthroughs and those who would use the technology for harm. We just have to hope that, through preventative actions and international cooperation, we can catch as many of the arsonists as possible before they set fires.

III. ON REACHING INTERNATIONAL ACCORD

A. Overview

Concerns over intellectual property rights (IPRs) span international boundaries and affect different nations in a myriad of ways. Thus, it is no surprise that several major international agreements have attempted to set the rules for the manner in which IPRs should be treated globally, and it is even less surprising that, based on their current levels of industrialization and their various capacities to conform with multilateral standards, nations disagree which policies are best to pursue.⁶³

61. See Tobey, *supra* note 9, at 121.

62. Gordon, *supra* note 54, at 2024.

63. See, e.g., TRIPS Agreement, *supra* note 12.

Dr. Kamil Idris, Director General of WIPO since 1997, said in 2003 that “[i]n a world marked by huge material disparities, intellectual property is a means by which individuals, companies of all sizes, universities and other research institutions, and economies at the local, national, and regional levels can empower themselves to compete more effectively in the international marketplace.”⁶⁴ It is with this powerful significance in mind that we examine the current state of affairs in international protection of IPRs and how they came to be what they are today.

B. How WIPO Started it All

The first major agreement to deal with the issue of protecting an inventor’s intellectual property in another country was the Paris Convention for the Protection of Industrial Property, signed in 1883.⁶⁵ The Convention set out to protect patents, trademarks, and industrial designs internationally for the first time.⁶⁶ It was followed several years later by the Berne Convention, which set up an international organization that would, in 1967, become the WIPO that is in existence today.⁶⁷ WIPO now has 184 member states,⁶⁸ administers 24 treaties,⁶⁹ and aims to “promote the protection of intellectual property throughout the world.”⁷⁰

64. Kamil Idris, *Introduction*, 26 *FORDHAM INT’L L.J.* 209, 210 (2003).

65. World Intellectual Property Organization, WIPO Treaties—General Information, <http://www.wipo.int/treaties/en/general/> (last visited Apr. 6, 2008) [hereinafter WIPO Treaties].

66. *Id.*

67. *Id.*

68. World Intellectual Property Organization, About WIPO: Member States, <http://www.wipo.int/members/en/> (last visited Apr. 6, 2008) (listing WIPO’s current member states).

69. WIPO Treaties, *supra* note 65.

70. Convention Establishing the World Intellectual Property Organization pmbl., Jul. 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3. WIPO’s main goals are to: harmonize national intellectual property legislation and procedures, provide services for international applications for industrial property rights, exchange intellectual property information, provide legal and technical assistance to developing and other countries, facilitate the resolution of private intellectual property disputes, and marshal information technology

1. *WIPO Treaties*

Although WIPO has limited implementing powers due to its status as a United Nations (UN) agency, it has recently become a center of attention for developed and developing countries alike.⁷¹ The three major patent related treaties that have been put into place by WIPO are the Patent Cooperation Treaty (PCT), the Patent Law Treaty (PLT), and the Substantive Patent Law Treaty (SPLT).

a. Patent Cooperation Treaty

The PCT went into force in 1970 and now has 138 contracting members.⁷² The PCT allows inventors “to seek patent protection for an invention simultaneously in each of a large number of countries by filing an ‘international’ patent application.”⁷³

A single filing results in a single search and written opinion from the International Searching Authority (ISA), after which the applicant may either decide to go forward with pursuing IPR protection at the various national levels or abandon his application entirely if patentability seems unlikely.⁷⁴ Advantages of the PCT include the increased amount of time (18 months) the applicant has to reflect on the desirability of seeking protection in foreign countries compared to a procedure outside the PCT, the elimination of duplicative search and examination procedures that would otherwise be carried out by multiple nations’ patent offices, and the faster dissemination of patent related information to third parties.⁷⁵ The success of the PCT can be shown by the fact that the number of PCT

as a tool for storing, accessing, and using valuable intellectual property information.

WIPO Treaties, *supra* note 65.

71. Amit Sen Gupta, *Development Agenda in the World Intellectual Property Organization*, PEOPLE’S HEALTH MOVEMENT, Apr. 28, 2006, <http://www.phmovement.org/en/node/181>.

72. See World Intellectual Property Organization, *About the Patent Cooperation Treaty*, <http://www.wipo.int/pct/en/treaty/about.htm> (last visited Apr. 6, 2008).

73. *Id.*

74. *Id.*

75. *Id.*

international applications grew at an average annual rate of 16.8% from 1990 to 2005 and reached 135,000 in 2005.⁷⁶ PCT national phase entries account for 47% of all nonresident patent filings.⁷⁷ Despite the increase in filings worldwide, the five major world patent offices still account for about three-fourths of all filings, suggesting that smaller industrialized countries still have a way to go before catching up to the major players.⁷⁸

b. Patent Law Treaty

The PLT negotiations were concluded on June 1, 2000, and the PLT entered into force on April 28, 2005.⁷⁹ The PLT attempted to harmonize the formal procedural aspects associated with patent applications by setting out guidelines for the strictest requirements that member states could adopt in their local patent offices and allowing for more lenient inventor requirements if the individual member state saw fit.⁸⁰ The PLT now stands as a solid example of the international community coming together to reduce the costs of obtaining patent protection worldwide and achieving mutual recognition of the results of substantive examination, but it excludes issues of

76. Press Release, World Intellectual Prop. Org., WIPO Report Shows Internationalization of Patent Trends (Oct. 16, 2006), http://wipo.int/edocs/prdocs/en/2006/wipo_pr_2006_463_rev.html.

77. *Id.*

78. *Id.* The five major offices include those of the United States, Japan, Republic of Korea, China, and the European Union's European Patent Office (EPO). *Id.* "In 2004, of the total of 5.4 million patents in force worldwide, 81% were granted in six countries: USA, Japan, the United Kingdom, Germany, Republic of Korea and France." *Id.*

79. World Intellectual Property Organization, Summary of the Patent Law Treaty (2000), http://www.wipo.int/treaties/en/ip/plt/summary_plt.html (last visited Apr. 6, 2008).

80. *Id.* The treaty requires member states to: accord filing dates to inventors immediately once they have received an application; indicate inventor contact information and a description of the application; conform to standardized application formats; not revoke substantive patent rights due to unintentional procedural or time limit related noncompliance; and begin to implement electronic patent application filings. *Id.*

substantive patent law harmonization altogether,⁸¹ leaving open the door for yet another international cooperative effort.

c. Substantive Patent Law Treaty (SPTL)

“The SPLT is a proposed international patent law treaty aimed at harmonizing substantive points of patent law.”⁸² In contrast with the PLT, which deals only with procedural formalities involved with filing patent applications internationally, the SPLT attempts to harmonize the substantive requirements for obtaining a patent among different patent offices.⁸³ The SPLT deals with “requirements such as novelty, inventive step and nonobviousness, industrial applicability and utility, as well as sufficient disclosure, unity of invention, or claim drafting and interpretation.”⁸⁴

The SPLT is generally favored among nations that already have developed economies because it promotes higher levels of intellectual property protection and would allow for faster global protection of patents.⁸⁵ On the other hand, developing nations fear that the SPLT will limit their access to certain prescription drugs and other beneficial technologies that are produced under patents that their governments previously would have had discretion in deciding whether or not to respect them.⁸⁶

2. Current WIPO Concerns

Nobel laureate Joseph Stiglitz warns that, “[i]ntellectual property is important, but the appropriate intellectual property regime for a developing country is different from that for an

81. Shozo Uemura, Presentation: Developments in Substantive Patent Harmonization and PCT Reform (2001), in 7 CTR. FOR ADVANCED STUDY & RES. ON INTELL. PROP. SYMP. PUBLICATION SERIES 136, 136 (2002).

82. Gupta, *supra* note 71.

83. *See id.* (discussing the functions of the PLT and SPLT).

84. *Id.*

85. *Id.*

86. *WIPO at Crossroads over Substantive Patents Law Row*, FIN. EXPRESS, June 30, 2006, <http://www.financialexpress.com/news/WIPO-at-crossroads-over-substantive-patents-law-row/162512/>.

advanced industrial country.”⁸⁷ Scholars in some developing countries share concerns that WIPO is already moving too far in favor of developed nations and that the current round of discussions concerning a development oriented intellectual property regime are of great importance.⁸⁸

In 2004, fourteen developing countries, calling themselves the “Group of Friends of Development” presented a proposal to WIPO which advocated ways in which WIPO could protect the sovereign interests of developing nations and “promote indigenous science and technology based development.”⁸⁹ These efforts have been ongoing in WIPO.⁹⁰

Others fear that, while the world focuses on the WTO’s TRIPS Agreement, developed nations are using WIPO as a forum to ratchet up IPR protection beyond even those limits set out in the TRIPS Agreement, with little public or political resistance.⁹¹ This Comment will now look into the TRIPS Agreement and see how its provisions are playing out against the treaties that WIPO is attempting to enforce.

87. Joseph Stiglitz, *Intellectual-Property Rights and Wrongs*, YEMEN TIMES, Aug. 18, 2005, <http://www.yementimes.com/article.shtml?i=869&p=culture&a=2>.

88. *Id.*

89. Gupta, *supra* note 71. The group’s recommendations included “the adoption of a high-level declaration on intellectual property and development; amending the WIPO Convention; the inclusion of provisions on technology transfer, competition, etc., in treaties under negotiation; establishing technical assistance programmes based on particular principles and objectives; and establishing a working group on the development agenda.” *Id.*

90. William New, *WIPO Committee To Increase Focus on Genetic Resources*, INTELL. PROP. WATCH, Dec. 16, 2006, <http://www.ip-watch.org/weblog/index.php?p=491&res=1024&print=0>. Specifically, the Intergovernmental Committee on Intellectual Property and Genetic Resources (IGC) met from July 3–12, 2007 to further discuss the proper attribution of genetic resources. Tove Iren S. Gerhardsen, *WIPO Meets on Traditional Knowledge, Genetic Resources*, INTELL. PROP. WATCH, July 3, 2007, <http://www.ip-watch.org/weblog/index.php?p=675>.

91. Gupta, *supra* note 71.

C. What is the WTO?

The WTO's largest impact in the field of international IPR protection came in the form of the TRIPS Agreement, which was ratified in 1994.⁹² TRIPS requires member states to provide strong protection for intellectual property rights. For example, under TRIPS, patents must be granted in all "fields of technology," although exceptions for certain public interests are allowed.⁹³ In each contracting state, laws may not offer any benefits to local citizens that are not available to citizens of other TRIPS signatories with regard to the protection of intellectual property.⁹⁴ TRIPS also has a most-favored-nation clause.⁹⁵

Additionally, TRIPS is unique among IPR treaties "because membership in the WTO is a 'package deal,' meaning that WTO members" cannot abide by some WTO treaties and disavow others that they deem inappropriate to their current situation.⁹⁶ This puts some nations in the precarious position of accepting the terms of TRIPS or missing out on other potentially favorable trade agreements to be garnered from membership in the WTO.⁹⁷

92. TRIPS Agreement, *supra* note 12; see World Trade Organization, Overview: The TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Apr. 6, 2008) (explaining that the TRIPS Agreement, forged by the WTO, is the most comprehensive intellectual property agreement and enhances protections provided by prior agreements).

93. TRIPS Agreement, *supra* note 12, art. 27. Public interest exceptions include "to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, . . . diagnostic, therapeutic and surgical methods for the treatment of humans or animals [and] plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than nonbiological and microbiological processes." *Id.* art. 27(2)–(3).

94. *Id.* art. 3(1).

95. *Id.* art. 4. This clause allows member states to discriminate in their treatment of other nations if their actions are based on other international agreements not particularly confined to intellectual property or if their actions are based on international agreements predating the TRIPS Agreement. *Id.*

96. Paul E. Salmon, *A Short Guide to International IPR Treaties*, U.S. STATE DEPT. INT'L INFO. PROGRAMS, Jan. 2006, <http://usinfo.state.gov/products/pubs/intelprp/guide.htm>.

97. Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 21–22 (2004).

TRIPS has recently come under the same international scrutiny that WIPO treaties have. Developing nations fear that developed nations are overexerting their IPRs in the developing nations and, in the process, are depriving their people of necessary technologies and medicines while at the same time stifling technological advances by scientists in their own countries due to the fear of treading on some large corporation's already established IPRs.⁹⁸

Another issue with TRIPS is that, because it is over a decade old, it does not deal with topics "such as the Internet and digital copyright issues, advanced biotechnology, and international harmonization, the process of creating uniform global standards of laws or practice."⁹⁹

Recent events at WIPO have complemented the TRIPS Agreement¹⁰⁰ in developing policy in the area of biotechnology, and new issues are now arising, specifically in the fields of biodiversity and genetic enhancement.

D. International Treaties and Genetic Enhancement

Biological diversity, or "biodiversity," refers to the wide variety of life forms on our planet and the genetic differences within those species that determine our uniqueness.¹⁰¹ Biodiversity is important because the information contained in

98. Stiglitz, *supra* note 87; see also Andrew Leonard, *Department of Health, Human Services, and Partisan Ideology*, SALON, Sept. 28, 2006, <http://www.salon.com/tech/htww/2006/09/28/steiger/index.html> (discussing the ineffectiveness of the "flexibilities" built into the TRIPS Agreement). See generally Paul J. Heald, *Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game*, 88 MINN. L. REV. 249, 250–52 (2003) (suggesting that a rational, self interested approach taken by a developing country, rather than simply implementing the highest protection standards possible, would already seek to minimize the costs of complying with TRIPS while maximizing the potential for necessary technological development).

99. Salmon, *supra* note 96.

100. See Helfer, *supra* note 97, at 25 ("TRIPS itself implicitly acknowledges the continuing importance of WIPO as a forum for negotiating treaties, particularly those embodying 'higher levels of protection of intellectual property rights.'" (quoting TRIPS Agreement, *supra* note 12, art. 71(2))).

101. SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, SUSTAINING LIFE ON EARTH: HOW THE CONVENTION ON BIOLOGICAL DIVERSITY PROMOTES NATURE AND HUMAN WELL-BEING 2 (2000), <http://www.biodiv.org/doc/publications/cbd-sustain-en.pdf>.

each of our genetic makeups can be instrumental to the development of new, economically beneficial technologies and products.¹⁰²

With this in mind, in 1992, the United Nations chartered the Convention on Biological Diversity (CBD) as the first global agreement on the conservation and sustainable use of biological diversity.¹⁰³ The Convention's three main goals are the conservation of biodiversity, the sustainable use of the components of biodiversity, and the sharing of the benefits arising from the commercial and other utilizations of genetic resources in a fair and equitable way.¹⁰⁴

Access to, and the equitable use of, genetic material is a major part of the WIPO and CBD missions.¹⁰⁵ In the WTO, developing nations have proposed an amendment to TRIPS wherein patentees would be required to disclose the nation of origin of any biological materials used in their patent applications and to show informed consent of all participants.¹⁰⁶ Much of the technical work in developing this agreement may be carried out in WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources (IGC) committee.¹⁰⁷ If passed, this amendment would also require that the patentee and the owners of the material agree to "appropriate sharing

102. *See id.* at 3 (listing agriculture, cosmetics, pharmaceuticals, pulp and paper, horticulture, construction, and waste treatment as examples of industries supported by biodiverse resources).

103. *Id.* at 8.

104. *Id.*

105. *Id.* at 14 ("Foreign bioprospectors have searched for natural substances to develop new commercial products, such [as] drugs. Often, the products would be sold and protected by patents or other intellectual property rights, without fair benefits to the source countries."); New, *supra* note 90.

106. New, *supra* note 90; *see also* Tove Iren S. Gerhardsen, *Developing Countries Propose TRIPS Amendment on Disclosure*, INTELL. PROP. WATCH, June 1, 2006, <http://www.ip-watch.org/weblog/index.php?p=323&res=1024&print=0> [hereinafter Gerhardsen 1] (stating that patentee would be required to "show that the owners of the material agreed to let them use it"); Tove Iren S. Gerhardsen, *TRIPS Meeting: Boost to IP Issues as Part of Resumed Trade Talks, US Submits Enforcement Proposal*, INTELL. PROP. WATCH, Feb. 14, 2007, <http://www.ip-watch.org/weblog/index.php?p=531&res1024&print=0> (noting a repeated attempt by a group of developing countries to amend the TRIPS Agreement).

107. New, *supra* note 90.

between the two parties of potential commercial or other benefits arising from the process.”¹⁰⁸

These issues are of great concern to developing nations because of the years of so-called “biopiracy” committed by developed nations against indigenous peoples.¹⁰⁹ Biopiracy refers to “taking genetic resources and associated traditional knowledge from biodiverse developing countries without permission, then patenting related inventions but failing to share any of the resulting commercial profits.”¹¹⁰

Patents are not generally available for genetic sequences themselves, because they are naturally occurring in nature, but patents *have* been granted for isolated gene products or genetic engineering processes, such as gene therapy or gene enhancement.¹¹¹ It is for these processes that the international community must reach an accord on how much protection is due and how that protection may be exploited by IPR holders.

The TRIPS Agreement mandates that member states provide “minimum” standards of intellectual property protection,¹¹² which includes patent rights, “without any mention of whether such rights need be contingent on compliance” with the CBD’s “goals of ‘conservation and

108. Gerhardsen 1, *supra* note 106.

109. See Ho, *supra* note 15, at 437 (“Developing countries believe that this is a real issue, as reflected by years of advocacy among multiple international forums, including the WTO, the CBD and the [WIPO].”).

110. *Id.* at 436.

111. *Id.* at 448; TRIPS Agreement, *supra* note 12, art. 27; see also Greenberg v. Miami Children’s Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1067–68, 1072 (S.D. Fla. 2003) (holding that biotechnology companies that appropriate genetic material from patients or research subjects without their consent or knowledge, and then patent and profit from their use, could be liable under a theory of unjust enrichment); Shanshan Zhang, *Proposing Resolutions to the Insufficient Gene Patent System*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1139, 1143–44 (2004) (proposing heightened eligibility guidelines, inter partes reexamination, patent pooling, compulsory licensing schemes, and research exemptions as modifications to the current U.S. scheme of DNA sequence patenting).

112. Ho, *supra* note 15, at 452–53; Karjala, *supra* note 56, at 505 (“TRIPS requires patents only for inventions that are ‘new,’ and member states may decide for themselves whether or not a naturally occurring substance, like a gene or gene product, is ‘new’ in the sense required by their patent statutes.”).

sustainable use of biological diversity.”¹¹³ The result of the situation is that the CBD offers only weak protections for the biological diversity of developing countries’ resources when placed up against strong national patent laws and international treaties, and there will almost always be disagreement and stalemate between developing and developed nations on which course of action is the best to pursue on the issue of patenting genetic information.¹¹⁴

One group in particular, comprised of roughly twenty industrialized countries plus the European Union and the European Patent Office and calling themselves “Group B+” or the “Alexandria Group,” has gone outside the forum of WIPO to attempt to achieve an agreement on global patent law harmonization with regards to issues such as first to file, grace period, and secret prior art treatment.¹¹⁵ Once aligned, this group of powerful nations could attempt to wield its influence by shaping other issues of substantive international intellectual property law (including in the area of biotechnology) more favorably for developed nations.

This Comment argues that gene enhancement is a fundamentally different means of patenting human genetic material and should categorically be disallowed and unendorsed by international agreements. As a nascent technology, gene enhancement is not a part of any existing international IPR treaty, nor is it at the forefront of ongoing discussions. However, allowing developed nations to patent genetic enhancement techniques today is likely to violate principles of biodiversity

113. Ho, *supra* note 15, at 452–53 (quoting Convention on Biological Diversity art. 8(j), June 5, 1992, 31 I.L.M. 818 (1992)).

114. Ho, *supra* note 15, at 455 (“In some instances, substantive discussion is curtailed on the grounds that another forum would be a more appropriate venue to address the issue.”).

115. *Patent Harmonization: Oversight Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 109th Cong. 8–9 (2006) (statement of Q. Todd Dickinson, Vice President and Chief Intellectual Property Counsel, General Electric Company); see also William New, *Group B+ Draft Patent Harmonisation Treaty Emerges*, INTELL. PROP. WATCH, Nov. 7, 2006, <http://www.ip-watch.org/weblog/index.php?p=448&res=1024&%20print=0> (discussing a new version of a Group B+ draft agreement).

preservation, encourage biopiracy, and lead the global community down a morally deleterious road in the future.

IV. PROPOSING A SOLUTION

A. Overview

As discussed in Part II.D, gene enhancement is broadly defined as altering a person's genetic makeup for nontherapeutic reasons in an attempt to make that person more than "normal" or more than "adequate."¹¹⁶ Gene therapy, on the other hand, is a term used to describe the burgeoning field of science wherein the manipulation of genetic data is utilized as a tool to help cure or prevent disease in patients.¹¹⁷ Distinguishing between therapeutic and nontherapeutic uses will be the key to determining what technologies should be classified as gene therapies and which should be classified as gene enhancement. This Comment will now discuss why nontherapeutic genetic enhancement technologies should philosophically be treated differently from therapeutic technologies, how such classifications should be made, and the proper manner in which to respect and reimburse the people and nations whose genetic information would allow the research into these technologies to become a reality.

1. *Therapeutic vs. Nontherapeutic*

To distinguish between therapeutic and nontherapeutic genetic technologies, we must determine whether the technology in question has a substantially disease curing end. This could prove to be more difficult than it appears upon first glance. For instance, Human Growth Hormone (HGH) can now be reproduced using biotechnology techniques and given to children with short stature (caused by classical growth hormone deficiency) to help them achieve a normal height.¹¹⁸ As we have

116. See *supra* Part II.D.

117. Reese McKnight, *RNA Interference: A Critical Analysis of the Regulatory and Ethical Issues Encountered in the Development of a Novel Therapy*, 15 ALB. L.J. SCI. & TECH. 73, 75 (2004).

118. Mehlman, *supra* note 47, at 672.

seen, however, athletes of normal stature are now using HGH as a means to gain even more bone and muscle growth and give them an advantage against others in their field, sometimes with harmful consequences.¹¹⁹ Few would argue that HGH is being used as gene therapy in the former instance and gene enhancement in the latter instance.

Other potential genetically based treatments, such as those to control hair color, eye color, intelligence levels, sexual orientation, or the hypothetical ability to breathe underwater, have ends that are more clearly non disease related. For instance, having blue eyes or being of average intelligence should never rationally be considered a disease or a condition that would need medical treatment. Encouraging the development of these technologies would simply allow some cultures to develop perpetual heritable advantages in their societies to which other societies would not have financial or technological access.¹²⁰ Over time, it would potentially put those cultures at a species level disadvantage in terms of sustainable development.¹²¹ This would not be an advantage due to political, economic, scientific, or even geographic strength. It would instead be an advantage built into what it fundamentally means to be “human.” Once these advantages are put into place, it will be nearly impossible for those without access to the technologies to stem the tide of disparity.¹²²

119. *Id.* at 672–73.

Athletes looking to build mass may also abuse Human Growth Hormone (hGH). Excessive hGH levels increase muscle mass by stimulating protein synthesis, strengthen bones by stimulating bone growth and reduce body fat by stimulating the breakdown of fat cells Side effects include overgrowth of hands, feet, and face (known as acromegaly), enlarged internal organs, especially heart, kidneys, tongue and liver and heart problems.

How Stuff Works Express, *The Wrong Way to Win*, <http://express.howstuffworks.com/express-doping1.htm> (last visited Apr. 6, 2008).

120. Mehlman, *supra* note 47, at 687.

121. *See id.* (stating that if gene enhancement is made available to the public, only the wealthy would have access to it, and they would gain advantages additional to those they already possess).

122. *Id.*

In the worst case scenario, unequal access to genetic enhancement will divide society into the enhanced and the un-enhanced. Germ cell enhancement will perpetuate enhancements from generation to generation,

While it may make perfect sense from an economic standpoint,¹²³ from an ethical standpoint, nontherapeutic applications of gene enhancement are morally repugnant.¹²⁴ Genetic enhancement may take away from what it fundamentally means to struggle and to be human.¹²⁵

In addition to its questionable morality, genetic enhancement will surely have some unsuccessful outcomes and unintended side effects in its infant stages that the world would be better off avoiding than suffering.¹²⁶ Without the “therapeutic light” at the end of the tunnel, gene enhancement should not be encouraged or rewarded with exclusive IPR protection on the international stage.

creating a hereditary aristocracy or ‘genobility.’ Added to their wealth, a prerequisite to being able to afford genetic enhancement, will be the advantages conferred by the enhancements themselves. The result will be a group of privileged individuals and families whose position in society will be virtually unassailable.

Id.

123. A society of genetically enhanced people will likely be smarter, happier, more productive, and more successful than a similar society that is not genetically enhanced. See, e.g., Julian Savulescu, *Genetic Interventions and the Ethics of Enhancement of Human Beings*, in *THE OXFORD HANDBOOK OF BIOETHICS* 516–17 (B. Steinbock ed., 2007). When one group of people could hold many inherent advantages over another group of people, it would be in their best economic interests to take advantage of them. See Tobey, *supra* note 9, at 100 (“Humans may act, to a reasonable approximation, as rational utility maximizers.”).

124. Tobey, *supra* note 9, at 83.

The first [concern] is that genetic enhancement may stratify the distribution of genetic talents and advantages more widely than the current natural lottery does. This type of stratification could increase inequality and hierarchy in society The second more fanciful concern is that creating mixed-species beings, also known as chimeras or transgenic animals, would truly obliterate the species boundary.

Id.

125. *Id.* at 104. To be human is to possess virtue and strive for accomplishment in an honorable way. *Id.* at 118–19.

With enhancement we achieve an end not through struggle but with the ease of one selecting an item from a menu—it is the difference between cooking a meal and ordering in. The purchased meal might taste better objectively, but it is not *ours*, and in not working for it, we lose the sense of ownership and accomplishment.

Id. at 121.

126. See Mehlman, *supra* note 47, at 681 (noting three categories of possible risks: “threats to social equality, ‘cheating,’ and the loss of personal autonomy”).

2. TRIPS Council on Genetically-Based Technologies (CGT)

So, how then does the international community go about deciding what is gene therapy and what is gene enhancement? And, once it has been decided, what are the best means to regulate who, when, and how these technologies are used?

The World Health Organization (WHO), an agency of the United Nations concerned with improving international public health, conducted a major study in 1999 about “genetics, cloning and biotechnology” which recommended an immediate “global ban on inheritable genetic modification.”¹²⁷ However, these guidelines were never published in final form, and, as with all UN recommendations, would not have possessed the force of law.¹²⁸ Nations have since taken varying stances on the subject of gene therapies, ranging from an all out prohibition on inheritable genetic modification¹²⁹ to allowing germ line (inheritable) modification research if it is backed by private funding.¹³⁰

The WTO’s TRIPS Agreement is the most effective international forum to build a unified international approach to IPR treatment.¹³¹ Rather than being used—as it had been in the past—as leverage by developed nations to coerce developing nations to agree to higher IPR enforcement standards than they truly need,¹³² TRIPS now has a chance to encourage all nations to traverse down an ethical path by amending itself to exclude from patent protection those therapies that are deemed to be genetic enhancement procedures. Private funding will always

127. N. Schichor et al., *Should We Allow Genetic Engineering? A Public Policy Analysis of Germline Enhancement*, DEVELOPMENTAL BIOLOGY ONLINE, <http://www.devbio.com/article.php?cy=21&id=172> (last visited Apr. 6, 2008); World Health Organization, About WHO, <http://www.who.int/about/en/> (last visited Apr. 6, 2008).

128. Schichor et al., *supra* note 127.

129. CTR. FOR GENETICS AND SOC’Y, NATIONAL POLICES ON HUMAN GENETIC MODIFICATION: A PRELIMINARY SURVEY (2003), <http://geneticsandsociety.org/article.php?id=304>.

130. Sarah M. Markwood, Comment, *Creating a Perfect Human Is Not So Perfect: The Case for Restricting Genetic Enhancement Research*, 110 PENN ST. L. REV. 473, 479–80 (2005).

131. See Helfer, *supra* note 97, at 6, 8 (emphasizing that the TRIPs agreement brought IPR issues to the forefront on an international level).

132. *Id.* at 24.

exist to push science forward at the fringes, but, by setting an example at the international level, TRIPS may put pressure on other nations to pass similar legislation or self-regulatory measures.¹³³

a. Anatomy of the CGT

One way to implement these policies would be to institute a Council on Genetically-Based Technologies (CGT) in the WTO. The CGT would serve as a subsidiary body under the TRIPS Council, which is itself under the General Council of the WTO.¹³⁴ This new CGT would convene whenever a member state raised a complaint or when a majority of members on the CGT had concerns that another member state was attempting to grant or enforce IPR protection on a technology that could be deemed to be a genetic enhancement procedure.¹³⁵ The Council's determination would then dictate whether the nation in question could continue to enforce IPRs on the patent internationally and still remain a member in good standing of the WTO.

The makeup of the CGT would consist of seven delegates representing a broad range of countries around the world,¹³⁶ similar to the WTO Dispute Settlement Body's (DSU)

133. See Susan M. Fitzpatrick & John T. Bruer, *Science Funding and Private Philanthropy*, 277 *SCI.* 621, 621 (1997) (noting the next few decades may provide an "unprecedented opportunity to increase the amount of private funding available to support scientific research"); Markwood, *supra* note 130, at 474 (discussing the various regulations regarding human embryo research that have been implemented by different countries). Canada recommends that "no research involving the alteration of DNA for enhancement purposes will be permitted or funded." Markwood, *supra* note 130, at 474 (quoting 2 *ROYAL COMM. ON NEW REPROD. TECHS., PROCEED WITH CARE: FINAL REPORT OF THE ROYAL COMMISSION ON REPRODUCTIVE TECHNOLOGIES* 945 (1993)).

134. Lina M. Montén, *The Inconsistency Between Section 301 and TRIPS: Counterproductive with Respect to the Future of International Protection of Intellectual Property Rights?*, 9 *MARQ. INTELL. PROP. L. REV.* 387, 395 (2005).

135. There could also be a review petitioning procedure by which a state not included on the CGT that wished to have a technology reviewed for a determination on its status as a gene enhancement procedure could initiate a convening of the CGT.

136. There could potentially be one member each from North America, South America, the European Union, Africa, Central Asia (including India and Russia), East Asia (including China), and Australia and Oceania.

permanent, seven member Appellate Body.¹³⁷ A preliminary plan for the CGT would include inviting members to four year terms. The members of the CGT would have to be individuals with recognized standing in the field of law and biotechnology and not affiliated with any government.¹³⁸ A system such as this would not allow the CGT to be dominated by developed nations alone. A four-to-three majority vote would be required to decide whether or not a technology should be banned from international IPR protection on the grounds that it embodies a genetic enhancement procedure. Abstentions would not count towards the four vote majority needed to condemn a potential gene enhancement technology. A natural meeting place for the CGT would be the WTO's current headquarters in Geneva, Switzerland.¹³⁹

Penalties for noncompliance with the decisions of the CGT would include traditional measures such as trade sanctions against the noncomplying nation.¹⁴⁰ It will be of great importance for all WTO members to join in the boycott of the gene enhancement technologies so that the global community can send the strongest message possible.¹⁴¹

137. World Trade Organization, Dispute Settlement: Appellate Body, http://www.wto.org/english/tratop_e/dispu_e/appellate_body_e.htm (last visited Apr. 6, 2008).

138. The current Ministerial Council could be in charge of the search for the initial CGT members. It will be important to find persons with highly specialized knowledge in the fields of genetic enhancement and gene therapy because, as these technologies have yet to become widely successful, there are very few scientists around the world who would be able to fully appreciate and understand the complexity of the issues involved.

139. World Trade Organization, What Is the WTO?, http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited Apr. 6, 2008).

140. Ho, *supra* note 15, at 480–81 (noting that TRIPS requirements have “extreme weight” because noncompliance can result in trade sanctions).

141. Elizabeth Trujillo, *Mission Possible: Reciprocal Deference Between Domestic Regulatory Structures and the WTO*, 40 CORNELL INT'L L.J. 201, 238 (2007) (“The WTO’s ability to influence the behavior of its member states rests primarily in its ability to authorize members to retaliate against other members not in compliance with GATT agreements Ultimately, however, the WTO relies on its member states to enforce its decisions.”).

b. Role of the CGT

In making their determination as to whether the technology in question will be considered gene enhancement or gene therapy, the CGT will need to have a framework in place to guide their decision making process. First, genetic technologies that have a primary purpose of treating what are commonly regarded as disease conditions¹⁴² will be considered therapeutic, even if there are other “off-label”¹⁴³ uses for the technology.¹⁴⁴ The benefits of any legitimate therapeutic use will outweigh a potential nontherapeutic side effect.

Second, technologies that are not targeted at any medical condition and have no potential therapeutic benefit, such as changing hair color or eye color, will be considered gene enhancement technologies and will not be afforded international IPR protection. The third, and trickiest, class of genetic modification technologies to deal with will be those that have only an attenuated link to therapeutic ends. For instance, procedures that would add intelligence in mathematics, “cure” sexual orientation, or curb addictive behavior, may not have direct therapeutic impacts, but they may each possess a more indirect therapeutic impact that could justify the technology’s proliferation.

In the case of intelligence in mathematics, most would agree that bringing someone from a level of mental retardation to that of the average person would be therapeutic. But would increasing someone’s mathematical ability from a fourth grade level to a twelfth grade level be therapeutic? One could argue that with less than average intelligence, persons are confined to lower paying jobs and, by extension, a lower standard of

142. The CGT will turn to worldwide professional medical organizations for official definitions and classifications of diseases. See, e.g., Manuel B. Graeber et al., *A Free Community Approach to Classifying Disease*, 1 PUB. LIB. SCI. MED. 113, 113 (2004) (“The main characteristics of the ICDNS are free collaboration via the Internet, online access to all collaborative tools via the World Wide Web, global participation, and democratic decision making.”).

143. Mehlman, *supra* note 47, at 678.

144. See, e.g., *id.* at 678–79 (discussing the off label use of HGH to enhance athletic performance).

living.¹⁴⁵ Perhaps the opportunity of having a slightly greater intelligence level would open new doors to jobs providing healthcare coverage, awareness of disease, and better living conditions that would in turn increase life expectancy. Is that not a therapeutic effect? This question is more difficult to answer.

In the case of sexual orientation, there is an ongoing debate over whether, or to what extent, the condition is even genetically linked.¹⁴⁶ In instances such as these, the CGT should attempt to remain as politically neutral as possible.¹⁴⁷ Until there is a preponderance of scientific proof that a condition has a direct genetic cause, the CGT should not even begin to attempt to interpret whether the condition is truly a disease or whether eradicating it would produce a therapeutic benefit.

Finally, while addictive behavior has been shown to likely have a genetically inheritable component,¹⁴⁸ many would wonder whether or not the voluntary behavioral aspect of the condition dominates the genetic aspect. In such a case, the CGT may have a difficult time making a direct link from the genetic condition to the resulting behavior of the patient. The effectiveness of the genetic treatment in affecting the ultimately desired outcome in the patient will be the key to determining whether or not a given treatment is truly a genetic therapy treating a disease or just an enhancement to someone's temperament that allows them to act differently if they so choose.

145. See, e.g., World Health Organization, Health Impact Assessment (HIA): The Determinants of Health, <http://www.who.int/hia/evidence/doh/en/index.html> (last visited Apr. 6, 2008) (“[H]igher income and social status are linked to better health. The greater the gap between the richest and poorest people, the greater the differences in health.”).

146. See, e.g., Francy Floral, Book Note, 1 J. HEALTH & BIOMEDICAL L. 193, 202–04 (2004) (reviewing PHILIP R. REILLY, ABRAHAM LINCOLN'S DNA AND OTHER ADVENTURES IN GENETICS (2000) (discussing the debate over the reliability of early research that claimed to have isolated the “gay gene”)).

147. With conditions such as homosexuality, some scholars fear that, should a gene triggering homosexuality be identified, then “parents might choose to abort fetuses with that gene to avoid having a child genetically predisposed to homosexuality.” *Id.* at 204.

148. See Stephen J. Morse, *Addiction, Genetics, and Criminal Responsibility*, 69 L. & CONTEMP. PROBS. 165, 169 (2006) (discussing the many researchers who, based on “highly technical anatomical, physiological, and genetic research” are under the belief that “addictions appear to have a biological basis”).

c. *Decision Making Process*

In making a decision on the status of a gene modifying technology (therapy vs. enhancement), the CGT should use a proximate cause-like analysis, similar to that which the courts employ in tort contexts.¹⁴⁹ There often will not be a clear link from a technology to its therapeutic ends. However, if the CGT can ascertain such a link, without making so many logical leaps that the gene modification no longer seems related to the outcome in the recipient, then the CGT should determine, in good faith, that the treatment is indeed therapeutic in nature. Again, the impeccable technical knowledge and judgment of the members of the CGT will be critical in making the correct decisions on the more difficult cases.

d. *The Treatment of Indigenous Peoples and Traditional Knowledge*

The CGT should encourage compliance with the developing nations' current TRIPS amendment proposal calling for informed consent and proper attribution when the biological resources and/or traditional knowledge of indigenous peoples are used in the development of any newly granted patent.¹⁵⁰

149. Proximate cause refers to a cause that "is legally sufficient to result in liability." BLACK'S LAW DICTIONARY 234 (8th ed. 2004). Justice Andrews famously attempted to describe proximate cause with the following analogy:

The spring, starting on its journey, is joined by tributary after tributary. The river, reaching the ocean, comes from a hundred sources. No man may say whence any drop of water is derived. Yet for a time distinction may be possible. Into the clear creek, brown swamp water flows from the left. Later, from the right comes water stained by its clay bed. The three may remain for a space, sharply divided. But at last inevitably no trace of separation remains. They are so commingled that all distinction is lost.

Palsgraf v. Long Island R.R. Co., 162 N.E. 99, 103 (N.Y. 1928) (Andrews, J., dissenting).

150. Gerhardsen 1, *supra* note 106; Communication from Brazil, India, Pakistan, Peru, Thailand and Tanzania, *Doha Work Programme—The Outstanding Implementation Issue on the Relationship Between The TRIPS Agreement and the Convention on Biological Diversity*, WT/GC/W/564 (May 31, 2006); *Discussions on CBD-TRIPS Gain Momentum With New Proposals*, INT'L CTR. FOR TRADE & SUSTAINABLE DEV., June 16, 2006, <http://www.ictsd.org/biores/06-06-16/story3.htm> ("To ensure compliance the proposed amendment would require Member governments to empower domestic authorities to deny and revoke patents 'when the applicant has, knowingly or

In addition, the CGT should propose methods in which indigenous peoples are reimbursed with the profits from successful gene therapy technologies in proportion with how much of their genetic material was used in the development of the patented technology. It is unjust to allow an outside nation to be the sole benefactor of a patent that was developed literally through the life blood of those to whom it is now being sold.¹⁵¹

While there will likely continue to be deadlock on these issues in the near future,¹⁵² developing countries must continue to strive for the protection of their rights, and the CGT could be used as another forum where equitable and ethical principles are applied to the burgeoning field of patentable genetic enhancement technologies.

V. CONCLUSION

While discussion of this issue may seem somewhat premature given that there are relatively few, if any, documented uses of successful gene enhancement technologies with purely nontherapeutic ends, science is already pushing the research in that direction, and it is best not to be caught unprepared when the time comes.

There is something unique about the patenting of gene enhancement technologies that is fundamentally different from patenting the latest in cell phone technology or even the latest pharmaceutical “wonder pill.” Genetic technologies strike to the very core of what makes us human, altering our bodies’ preprogrammed instructional sets, sometimes in a way that will allow us to pass those changes on to our offspring. The less

with reasonable grounds to know, failed to comply with the disclosure requirements, or provided false information.”).

151. See Ho, *supra* note 15, at 459 (explaining that, currently, compensation measures are sometimes inadequate or granted only after the patentee has received negative publicity and that compensation for such resources violates the cultural beliefs of some communities); see also Convention on Biological Diversity, *supra* note 113, art. 8(j) (calling for the respect, preservation, and maintenance of the knowledge, innovations, and practices of indigenous and local communities and encouraging the “equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices”).

152. Ho, *supra* note 15, at 504.

therapeutic effect that these technologies have, the less we can justify the “playing of God” that gene enhancement entails.

The WTO, and the TRIPS Council in particular, is the most effective international forum to deal with this issue due to the organization’s widespread membership and effective enforcement measures.¹⁵³ The creation of a CGT will begin to bring together leading minds on the subject from across the world and put in place procedures to discuss, investigate, and ultimately come to conclusions on the risks inherent in these newly discovered technologies.

Though we may not be able to stop Prometheus¹⁵⁴ from bestowing these new technologies to mankind, and privately funded research will often take immoral and even illegal steps forward, it is the duty and the responsibility of the international community to take sufficient measures to ensure that such benefits are proliferated in the most just and ethical fashion possible. The creation of the CGT can be the first step on that journey.

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153. *Id.* at 480–81.

154. *See supra* Part II.E.

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