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The Lessons Stem Cells Provide Vis-à-Vis Patents:

Working Towards an International/Universal Patent Regime.

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Introduction

Biotechnology research has much to promise human society. Beyond the obvious benefits of being able to clone rare animal species or potentially to revitalize *extinct* species[1], there are many practical applications that are beneficial to human society directly. Rare blood types might be created from specialized stem cells. The tragedies of Christopher Reeve and others like him who have suffered paralysis from spinal cord trauma may be reversible by using stem cells to replenish damaged and severed nerve cells in the spinal column.[2] The dire shortage of organs for those needing transplants can be reduced by creating an organ designed specifically from the patient's stem cells in a lab setting to guarantee acceptance by the patient's body.[3] Israeli scientists several years ago have already coaxed stem cells into pulsating like a heartbeat.[4] The day is very near when badly needed organs will seemingly be created from

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[1] If you have not already, rent Steven Spielberg's Jurassic Park to get the idea. But for a more mundane application go to Google.com/news and type stem cells, or go to CBSNews.com and do a website search for stem cells. CBS has at least 20 articles written on stem cells and their application, most of which are dated no earlier than 2000.

[2] Damon J. Whitaker, Note*: The Patentability of Embryonic Stem Cell Research Results*, 13 J. LAW & PUB. POL'Y 361, 365 (*citing* National Cancer Institute, Institutes and Centers Answers to the Question: "What Would You Hope to Achieve From Human Pluripotent Stem Cell Research?," at http://222.nih.gov/news/news/stemcell/achieve.htm (Apr. 26, 2000)); *see also* John Bogatko, *Stem Cell Research: A Comparative Legal Analysis*, 6 J. MED. & LAW 123, 126 (2002) (*citing* Vanessa Lu, *Spine Tissue Discovery Could Help Injury Victims; Plastic Tube Connects Tissue*, TORONTO STAR, Aug. 29, 2001, at A01; and David N. Leff, *Science Scan is a 'First', Israelis Use Human Embryonic Stem Cells to Create Heart-Like Beating Muscle Cells*, BIOWORLD TODAY, Aug. 6, 2001). On the 23rd of May CBSNews.com reported that scientists were able to partially repair damaged nerve cells in mice through stem cell injections.

[3] Whitaker, *supra* note 2 at 365 (*citing* Remarks by President George W. Bush on Stem Cell research, at http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html (Aug 9, 2001)), National Institute of Health, Stem Cells: A Primer 1, *available at* http://www.nih.gov/news/stemcell/primer.htm (May 2000)).

[4] Taiwo A. Oriola, *Article: Ethical and Legal Issues in Singapore Biomedical Research, 11 Pac. Rim L. & Pol'y 497, 519 (citing Tim Radford, Stem Cells Turned into Heart Tissue*, GUARDIAN UNLIMITED, Aug. 2, 2001, http:/www.guardian.co.uk/genes/article/0,2763,530902,00.html.).

wholecloth to replace dying or diseased ones.[5] Damaged skin from fires and accidents can be replaced with skin tissue that is grown in the lab from the patient's own stem cells; perhaps even severely scarred tissue from fires can be healed by injecting the damaged skin with potent stem cells. More recently, a young boy who had the fatal Krabbe disease (a progressive and swift genetic disorder that leads to fatal deterioration of the central nervous system)[6] was given a fighting chance of living beyond the 2 year life expectancy of those who suffer from this disease.[7] Additionally, the stem cell transplant has been so successful that now his brain is producing 100 percent donor stem cells and his brain should at least partially recover in four to six months.[8]

If the potential is so great with stem cell research, then what is all the opposition and controversy for? There are many factors. If one thinks about how biotechnological innovations have made what was once relegated to the creative world of science fiction, then concern begins to mount. Simply thinking about how the Third Reich of Nazi Germany performed horrendous scientifically based studies on humans sends a chilling reminder of the need for ethics and morality to step in at some point in scientific research. The question becomes however at what point and through which mechanisms. The United States of America and

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[5] John Bogatko, *Stem Cell Research: A Comparative Legal Analysis*, 6 J. MED & LAW 123 (citing Neil Munro, *Patents, Profits, and the Stem-Cell Debate*, 33 THE NAT'L J. 32 (2001); Ian Wilmut & Lesley A. Paterson, *Can it be Unethical to Heal the Sick?*, THE TIMES HIGHER EDUC. SUPPLEMENT, Aug 17, 2001, at 19; and James S. Grisoia, *Stem Cell grafting for Epilepsy; Clinical Promise and Ethical concerns*, 2 EPILEPSY & BEHAV. 318, 319 (2001)); and *id.*

[6] Eunice Kim, *Tiny Struggle: Mendon Neighbors Rally to Support Toddler's Fight for Life*, METRO WEST DAILY NEWS, May 16, 2004, *available at*: http://www.metrowestdailynews.com/localRegional/view.bg?articleid=68469.

[7] *Id.*

[8] *Id.*

the European Union have come up with bipolar approaches to this question and this will be addressed below. The stem cell controversy is based on more than the wild fantasies of science fiction writers and the horrors of cruel, vile government experiments. The controversy enters into other moral and ethical concerns that are more strongly grounded in our present reality.

Stem Cells: what are they, what are their benefits, what is the controversy?

A basic understanding of stem cells and ontogeny is necessary to see the source of the ethical controversy surrounding stem cells. The human body is composed of hundreds of millions of cells[9], all derived from a single cell, that is formed when a male's gamete (sperm) fuses during fertilization with a female's gamete (egg).[10] Each gamete only contains half of the necessary commands for the assembly of a single cell; hence, the name haploid. Upon union with sperm and egg, the newly formed diploid cell, called a zygote, undergoes a series of divisions.[11] The cell that is formed upon the union is undifferentiated and has all the necessary commands for the 200 or so different types of cells in the human body.[12]

Not all cells are alike. We have around 200 different types of cells in the human body.[13] Contrary to popular myth, most human cells do not have the

[9] Whitaker, *supra* note 2 at 363 (*citing* Gerald J. Tortora & Sandra Reynolds Grabowski, Principles of Anatomy and Physiology 7 (8th ed. 1996)).
[10] *Id.* (*citing id.*).
[11] Whitaker, supra note 2, at 364 (*citing* Tortora &Grabowski, *supra* note 6, at 80-83)
[12] Meredith Mariani, *Note: Stem Cell Legislation: An International and Comparative Discussion*, J. OF LEG. 379, 381 (*citing* House of Lords, Select Committee on Stem Cell Research Report, Chapter 2, at http://www.publications.parliament.uk/1.htm (Feb. 13, 2002) (on file with author)).
[13] *Id*.

ability to divide.[14] Stem cells are the cells that replace damaged or dying specialized cells.[15] Though specialized or differentiated cells perform a specific function, they contain the exact genetic code of the original cell which was formed when the sperm fused with egg upon fertilization. However, the expression of certain functions is turned off and seemingly is never able to be turned back on (at least naturally, scientists have experimented with ways to reactivate certain functions).

During the first five days the zygote undergoes a series of critical cell divisions.[16] These cells are totipotent, meaning that they have the ability to become *any* cell and to divide and specialize to become a human being. In fact, cloning is based on taking the cells from this point in the division process. After five days the embryo forms a blastocyst, which is the structure that is made up of two types of cells: fetal and embryonic.[17] The fetal stem cells in the outer layer of the blastocyst are limited to becoming any type of fetal cell, while the embryo stem cells in the inner layer of the blastocyst have the ability to become any type of cell, except fetal cells.[18] The embryonic stem cells are pluripotent, which means that they can become any type of cell, except fetal stem cells.[19] From this point to about 14 days when the nerve streak forms the embryonic stem cells

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[14] Mariani, *supra* note 10, at 381 (*citing* House of Lords, Select Committee on Stem Cell Research report, chapter 2 § 2.2, at http://www.publications.parliament01.htm (Feb. 13, 2002) (on file with author)).
[15] *Id.*
[16] *Id.* at 382
[17] Whitaker, *supra* note 2, at 364 (*citing* National Institute of Health, *supra* note 2).
[18] *Id.*
[19] *Id*; *see also* Bogatko, *supra* note 2 at 126-27 (*citing* THE NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH, VOLUME 1, REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION, at i (1999)).

may be tapped into for their pluripotency.[20] Upon the beginnings of the formation of the nervous system, the embryonic stem cells lose their potency as they continue to specialize and differentiate toward adult stem cells.[21] Adult stem cells are specialized stem cells that are located in bone marrow, muscle tissue, blood, the brain, etc.[22] Each type is specialized and replaces a limited type of cells. For instance the stem cells in the muscles are limited to just replenishing damaged or dying specialized muscle cells. Therefore, the adult stem cells are multipotent, in that they have a multitude of cells that they can specialize into, but they are limited to a much smaller range of cell types.[23]

The metaphysical debate[24]

The first controversy concerning stem cell research is the metaphysical debate over when life begins. The problem with embryonic stem cell research is that when pluripotent embryonic stem cells are removed from an embryo the embryo is entirely destroyed. The life essence that might have been, no longer can be. As was stated supra it is only before the blastocyst is formed that the individual stem cells have the potential to develop into a human being. Therefore, at that stage one could conceivably duplicate the same being. This in itself has its own moral and ethical questions that are outside of the scope of this paper.

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[20] Cyril R. Vidergar, *Comment: Biomedical Patenting: Permitted, but Permissible?*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 253, 254 (2002); and Bogatko, *supra* note 2, at 138.
[21] *See generally* Bogatko, *supra* note 2, at 126-27; Mariani, *supra* note 11, at 381-85.
[22] *See generally* Mariani, *supra* note 11, at 384.
[23] *Id.*
[24] For an argument engaging in the metaphysical debate to justify stem cell research *see* Michael Kinsley, *The False Controversy of Stem Cells: If You Think it Through, the Case for Embryonic*

However, focusing on the embryonic stem cell, we can see that once a stem cell is pulled the entire potential for an independent life is destroyed. This brings questions of religion, morals and ethics into the center of the debate.

As is evidenced by the furor and divisiveness of the abortion issue, there has been no answer to the metaphysical debate over when human life and human consciousness begins. As such, research on embryos, even if in their earliest stages, is extremely controversial. In 2001, President George Bush tried to reach a balance between two of his most powerful and active bases, the conservative Christian Coalition and his base of doctors, scientists and medical/pharmaceutical businesses.[25] First, he allowed embryo research to continue to be funded *if* they were part of a limited supply of already obtained embryos for in vitro fertilization that were not going to be used, and hence they would be destroyed anyway.[26] Second, Bush has taken an approach similar to the abortion issue. While the government allows abortions, states are left to decide whether they will subsidize abortions. In this vein Bush has allowed researchers to experiment on embryonic stem cells, but if they use embryonic stem cells that are not part of the limited government stockpile, then they will lose government funding.

Research is an Easy One, TIME MAGAZINE, 31 May 2004, *available at*: http://www.time.com/time/magazine/article/0,9171,1101040531-641157,00.html

[25] For a nice overview of these issues *see Ease Stem Cell Restrictions,* THE LEDGER, available at: http://www.theledger.com/apps/pbcs.dll/article?AID=/20040508/NEWS/405080390/1036.

[26] *See* Bogatko, *supra* note 2, at 142 (*citing The Presidency: The Meaning of Stem Cells*, TIME, Aug 20, 2001, at 14); *see also id.* at 127n.25

While this may sound like a happy compromise, it is very important to note that the government funds 28 billion dollars a year on scientific research.[27] The threat to withdraw funding based on certain activities, is actually quite prohibitive to researchers. And some states, realizing this, have started to consider legislation to fund stem cell research.[28] Additionally, great discoveries have been found through privately funded research. On the other hand, perhaps these very restrictions on embryonic stem cell prohibition will entice researches to develop other technologies that will coax differentiated and specialized cells into becoming undifferentiated pluripotent cells or provide incentive to seek other potential avenues. More recently, there have been some very positive results from adult stem cell research.[29] There are currently two additional possibilities. The first alternative is through using an *unfertilized* egg, gutting it out and replacing it with the insides of *any* cell in the human body.[30] Another option, though only with a 1/100th success rate is to isolate cells from the human body and put them in a supportive laboratory environment, and then starve the cell. Typically 1/100 cells will survive, but in a less differentiated form, enabling

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[27] For information on a more recent bi-partisan move to increase federal funding *see Stem Cell Research: Policy and Politics*, NATIONAL PUBLIC RADIO, available at: *http://www.npr.org/features/feature.php?wfId=1891207* (last visited May 25, 2004).
[28] Stephanie Chavez, *Stem Cell Funding is Put in the Spotlight*, LOS ANGELES TIMES, *available at*: http://www.latimes.com/news/local/state/la-me-nancy9may09,1,111714.story?coll=la-news-state
[29] For an interesting article highlighting the dangers of embryo stem cell research and highlighting the benefits of adult stem cell research *see* Wesley Smith, *Adult Stem Cell Research More Effective than Embryonic Cells*, LifeNews.com, 25 May 2004, available at: http://www.lifenews.com/bio302.html; *see also Matters of Life and Death: Scientist in Stem-Cell Cover-Up, Deliberately Exaggerate Embryonic Advances, Ignore Adult*, *available at*: http://worldnetdaily.com/news/article.asp?ARTICLE_ID=38633, 25 May 2004.
[30] *See* Bogatko, *supra* note 2, at 128 (*citing* Mark Nichols, *Stem Cells, A Moral Dilemma*, MACLEAN'S, Aug. 27, 2001, at 44); *see also* Mariani, *supra* note 11, at 385 (*citing* H.R. Rep. No. 107-170, at http://www.house.gov/judiciary/legreports.htm (July 27, 2001)).

scientists to use these less potent and costly cells to bypass all the ethical and moral questions.

Stem Cells and US Patent Law.

Now that we have examined the complexity of stem cells, the political/policy debates concerning stem cells, and covered what they are, let us now consider stem cells and patent law in the US. The US patent system—in fact almost any patent system--is aimed at benefiting the public. In theory, patents work by providing the inventor an incentive to invent in the first place and then to disclose. Disclosure to the public is rewarded by giving the inventor a monopoly. Striking the right balance between incentive and public access creates a tension that must be carefully balanced. A system that does not give the inventor a long enough monopoly creates a system that lacks a strong incentive to invent, especially in regards to things that are costly to invent. A system that gives the inventor too long of a monopoly, burdens society, by preventing the free market system to step in and provide a price that is in balance with the supply and demand.

The United States has peculiar laws relative to the rest of the industrialized world in many regards. However, as the world's only remaining super power and as the country with the most prolific patent system in the world it is important in creating an international patent regime to keep in mind that perhaps the US system is so successful because it contains some essential traits.

In the US the tension between incentive for inventors and access by society is carefully balanced by the United States Patent Act of 1952 which stipulates four requirements for one to get a patent.[31] This right to exclude is for 20 years from the date of the filing of the application. There are three types of patents categories in the US: utility, design, and plant patents.[32] There are two dominant utility patents: process patents and product patents.[33] Process patents prevent others from using a particular process without compensation.[34] However, in process patents, an inventor can create another means to reach the same ends.[35] On the other hand a product utilitypatent prevents one from using or creating the patented product whether or not a different process was utilized.[36] Typically, biotechnology inventions fall within the stipulated language of utility patents: "whoever invents or discovers any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement thereof, may obtain a patent therefor."[37] There are four requirements for a utility patent:

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[31] *See generally* Qin Zhang, *Notes and Comments: Patent Law and Biotechnology: A Proposed Global Solution for the Public and the Biotechnology Industry*, 9 SW. J.L. & TRADE AM. 195 (2002-03); James J. Muchmore, *Article: Proprietary Rights and the Human Genome project: A Legal and Economic Perspective*, 8 DIGEST 45 (2000); Mattias Luukkonen, *Note: Gene Patents: How Useful are the New Utility Requirements?*, 23 T. JEFFERSON L. REV. 337 (2001); May Mowzoon, *Comment: Access Versus Incentive: Balancing Policies in Genetic Patents*, 35 ARIZ. ST. L.J. 1077 (2003); Michael John Gulliford, *Comment: Much Ado about Gene Patents: The Role of Foreseeability*, 34 SETON HALL L. REV. 711 (2004); Matthew Erramouspe, *Comment: Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. Rev 961 (1996); Courtney J. Miller, *Comment: Patent Law and Human Genomics*, 26 CAP. U.L. REV. 893 (1997); Cyril R. Videgar*, Comment: Biomedical Patenting: Permitted, but Permissible?*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 253 (2002).

[32] *See* Erramouspe, *supra* note 23, at 966 (*citing* Thomas G. Field, Jr., *Brief Survey of Intellectual Property,* 31 IDEA 85, 91-92 (1990)).

[33] *Id*. (*citing id*.).

[34] *Id.* (*citing id.*).

[35] *Id.* (*citing id.*).

[36] *Id*. (*citing id*.).

[37] 35 U.S.C. § 101

utility/usefulness, novelty, non-obviousness, and disclosure.[38]

Under US law, "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" are patentable.[39] Besides usefulness, novelty is a prerequisite for a utility patent. Before one can obtain a patent, the idea must be new. In addition, "a patent may not be obtained…, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the [relevant] art."[40] Finally, one must make a sufficient disclosure so that "one skilled in the art" can practice the invention [41]

Article I, Section 8, Clause 8 of the US Constitution states that the government is "to promote the Progress of Science and Useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Congress has from time to time enacted patent regulation to carry out this constitutional mandate. The current US patent regime was created in 1952, well before biotechnology was even on the minds of most congressmen. Although the US patent system does not deal with the morality of patents, to be patent eligible the application must fall within patentable subject matter.[42]

The founding fathers wanted a system that would reward creativity and

[38] *Id.*
[39] *Id.*
[40] 35 U.S.C. § 103
[41] 35 U.S.C. § 112
[42] 35 U.S.C. §§ 100-01

invention. They realized that things would change over time; that situations would change over time. Just as they allowed for the Constitution to be flexible to adapt and change to unforeseen happenings and situations, so too did they give Congress the power to create a patent system that was flexible enough to adapt to unforeseen technologies.

Stem cells are one of many new advances in technology that our flexible patent system has adapted to.[43] The courts for a time struggled with the new biotechnologies, seemingly wavering on incorporating the moral utility doctrine into our system.[44] Fortunately, the courts moved away from that. In the human/animal *Chimera* case; the courts decided to stay away from the moral utility doctrine and instead rejected his patent on account of the post civil war amendments.[45]

Stem cells are as controversial in their own right as abortion for many of the same reasons. Currently, the US and other industrialized nations are trying to negotiate a world patent regime that incorporates the current universal

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[43] *see generally* Erramouspe, *supra* note 33, at 966-70; Gulliford, *supra* note 33, at 722; Summers, *supra* note 33, at 484-85 &505-09; Farrell, *supra* note 33, at 520-530; Lacy, *supra* note 33, at 788-91; Videgar, supra note 33, at 256-65; Linda J. Deaine and Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 312-320; Zhang, *supra* note 33, at 198-202; Luukkonen, *supra* note 33, at 345-48; Muchmore, *supra* note 33, at 50-53.

[44] *See* Benjamin D. Enerson, *Note: Protecting Society From Patently Offensive Inventions: the Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 690-94) (Mr. Enerson skillfully shows a general trend away from Justice Story's assertion that for something to be useful it must not be immoral and a significant move towards a patent system that does not consider morality at all. Additionally, Mr. Enerson notes that the Revised Interim Utility Guidelines Training Materials of the United States Patent and Trademark Office necessitates specificity, substantiality, and credibility in utility. He notes that there is not mention concerning moral utility).

[45] *See* Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH L.J. 443, 452, 1999). In the Chimera case, though leaning towards stating that the issuance of a patent would violate public morals, the USPTO rejected the patent application concluding that Congress when it created the 1952 Patent Act it did "not intend to allow patents on humans or on

application patent procedures to a substantive universal patent regime. However there are key stumbling blocks that need to be addressed. Stem cells in particular and biotechnology in general have thrown many challenges to our patent system, to Europe's patent system as well as to the patent systems of the industrialized countries of the world.

European patent law and stem cells.

The European Union's patent system has some starkly different rules and regulations regarding patents. Central to these differences is the The European Patent Convention's (hereinafter "EPC") statutory moral utility doctrine. On account of the differing structures and level of use of the moral utility doctrine, the US and EU responded differently to biotechnological innovations in general and stem cell research in particular.[46] In fact, the US system adapted more readily and actually promoted biotechnological innovation, whereas the EU system seemed for a time to stifle it. Even today, many in Europe wonder if they struck the right balance via the Council Directive 98/44 on the Legal Protection of

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creatures that are essentially human." (Press Release, U.S. Patent and Trademark Office (April 1, 1998), *available at* http://www.upto.go/web/offices/com/s06.htm).

[46] See gener*ally* Teresa M. Summers, *Note: The Scope of Utility in the Twenty-First Century; New Guidance for Gene-Related Patents*, 91 GEO. L.J. 475 (2003); Enerson, *supra* note 47; *Jasemine Chambers, Patent Eligibility of Biotechnological Inventions in the United States, Europe and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH INT'L L. REV. 223 (2002); Taiwo A. Oriola, *Article: Ethical and Legal Issues in Singapore biomedical Research*, 11 PAC. RIM L. & POL'Y 497 (2002); Timothy Caulfield, *A Colloquy on the Romanow Report: Sustainability and the Balancing of the Health Care and Innovation Agendas: The Commercialization of Genetic Research*, 66 SASK. REV. 629 (2003); Lorelei Perez Westin, *Notes and Comments: Genetic Patents: Gatekeeper to the Promised Cures*, 25 T. JEFFERSON L. REV. 271 (2002); David Korn and Stephen J. Heinig, *Public Versus Private Ownership of Scientific Discovery: Legal and Economic Analysis of the Implications of Human Gene Patents*, 77.12 ACADEMIC MEDICINE 1301 (2002); and Kate Murashige, *Patents and Research—An Uneasy Alliance*, 77.12 ACADEMIC

biotechnological Inventions (hereinafter "Directive 98/44/EC"), which was an attempt to reign in the EPC's strong codified moral utility doctrine.

The EPC provides inventors the opportunity to apply simultaneously for patents in numerous EU countries. The EPC centralizes the application process. However, patent infringement and enforcement challenges must be brought within the nation in which the violation occurs.[47]

Article 52 of the EPC establishes four prerequisites for a patent to be issued: 1) it must be an invention, 2) it must be novel, 3) it must have inventive activity, and 4) it must have industrial application.[48] There was controversy in the EU over whether biotechnological innovations were patentable. Article 6 of the EPC states that inventions must not violate ordre public or morality.[49] If they do, then citizens are given standing to show that it violates ordre public or morality and can block the issuance of the patent.

In many EU member states, unlike the US there are laws prohibiting certain biotech inventions from being patented.[50] The US system is different from the EU system in that the US system has classes of patents.[51] While the EU does not have classes of patents, it does preclude "the patenting of certain biotechnological inventions" [52] Under EPC 52 (4) gene therapy patents are

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MEDICINE 1329 (1329); and David Keays, *Article: Patenting DNA & Amino Acid Sequences—An Australian Perspective*, 7 HEALTH L.J. 69 (1999).

[47] Enerson, *supra* note 44, 694 (citing Gerald Paterson, THE EUROPEAN PATENT SYSTEM: THE LAW AND PRACTICE OF THE EUROPEAN PATENT CONVENTION SECTIONS 1-12, at 3 (2d ed. 2001)).

[48] Keays, *supra* note 46, at 84; *see generally* Chambers, *supra* note 46.

[49] Chambers, *supra* note 46, at 232.

[50] *Id.*

[51] *Id.*

[52] *Id.*

prohibited "because they are not susceptible to industrial application."[53]

Unlike the US system, the Article 53(a) of the EPC prohibits patents for inventions that are contrary to the morals of society. This concept is called ordre public gives "automatic standing to concerned citizens, empowering them to challenge individual patents on the ground that issuance would be morally offensive and allowing the use of the judicial process to shape the law regulating bio tech patents.[54] This type of standing, ordre public, is not available in the US. As the EU continued to fall ever further behind the US in biotechnological innovations, Directive 98/44/EC was created "to protect inventor's rights in certain biotechnological produces."[55]

The current international patent regime

While there are several important regional patent treaties, I wish to address two treaties that are historical and function beyond mere regional treaties. The first is the Paris Convention, which was signed in that late 1800s. This treaty is designed to give national treatment to foreign inventors who are residents of a member state. In other words, an inventor in the UK, according to this treaty, would get the same treatment in France as a French resident. This was a monumental step towards creating an international patent regime.

The second main international treaty (created in the mid 1990s) is the Trade-Related Intellectual Property Rights Agreement (hereinafter "TRIPS").

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[53] *Id.*
[54] *Id*. at 233.
[55] *Id.* at 237.

TRIPS provides that patents shall be available for any inventions, whether products or processes, in all fields of technology provided they are new, involve an inventive step (non-obvious) and are capable of industrial application (useful). It is important to note at the onset that TRIPS in this regard is similar to the requirements of the EPC. Therefore, it seems that the International community is currently following the EPC in this regard.

In addition, article 27 of TRIPS has a statutory moral utility doctrine, again similar to the EPC over against the US patent code. Though US case law shows a general trend towards minimizing the US common law moral utility doctrine, cases minimizing the moral utility doctrine (such as *Chakrabarty*) were decided *before* the passage of the TRIPS. Therefore, it remains to be seen if current US patent case law concerning minimizing the moral utility doctrine would remain valid in the face of the US' ratification of TRIPS and its statutory moral utility doctrine.

Additionally, TRIPS, again like the EPC, allows patents for *inventions*. Therefore, it seems that what patent protection TRIPS does provide, resembles the EPC over against the US patent law system. Finally, TRIPS like the EPC provides patents for "technological innovations." In other words, US business methods under the EPC and under TRIPS do not seem patentable, unless they are patents for technological innovations.

Finally, TRIPS utilizes like the EPC a patent system that has a first to file system, while the US has a first to invent system. Therefor e, as it currently stands, TRIPS provides a minimal substantive international patenting regime that

is more closely aligned with the EU system, rather than the US system.

Moving towards a universal international patenting regime.[56]

The EU, Japan, and the US are spearheading negotiations to create a world patent regime called the Substantive Patent Law Treaty that utilizes the Patent Cooperation Treaty and the Patent Law Treaty. This trinity likely will one day form a substantive world patent regime.

The first of the tripartite patent regime, the Patent Cooperation Treaty ("PCT") was created in 1970, amended in 1979, and modified in both 1984 and 2001.[57] The treaty is open to any state part of the Paris Convention.[58] It currently is in force and has been since 1970. Article one, section one of the PCT states that the treaty provides for "cooperation in the filing, searching and examination, of applications for the protection of inventions, and for rendering special technical services." Article 1, section 2 states that "No provision of this treaty shall be interpreted as diminishing the rights under the Paris Convention for the Protection of Industrial Property of any national or resident of any country party to that Convention." In essence, the Paris Convention gave national treatment to foreigners so long as they were residents of a state party to the

[56] See *id.*; Shira Pridan-Frank, Article: Human-Genomics: A Challenge to the Rules of the Game of International Law, 40 Colum. J. Transnat'l L. 619 (2002); Diana D. McCall, Note: Stating the obvious: Patents and Biological Material, 2003 U. Ill. J.L. Tech. & Pol'y 239 (2003); James Bradshaw, Comment: Gene Patent Policy: Does issuing Gene Patents Accord with the Purposes of the U.S. Patent System?, 37 Willamette L. Rev 637 (2001); Trilateral Working Group: Substantive Harmonization of Patent Law (SPLT): The European Perspective, European Patent Office, Sept. 2003 (available from author); Patent Reform (need to get form Yu's site); WIPO website splt

[57] International Protection of Industrial Property: Patent Cooperation Treaty ("PCT") (1970), *available at*: http://wipo.int/pct/en/treaty/about.htm).

Paris Convention. Therefore, the PCT clearly states that it does *not* add any rights apart from those already given. In essence the PCT grants patent applicants a streamlined process in which they can do an international patent search for a fee. The patent search does not guarantee the granting of patents with member states. However, it does provide an additional 18 month grace period to the PCT patent applicant to decide whether to apply for patents around the world.

Before moving to the second treaty in the tripartite agreement, lets first consider how biotechnology in general and stem cells in particular would have been dealt with at this treaty apart from the later two components. There are two important time zones pre-TRIPS and post-TRIPS. Before the passage of TRIPS, the Paris Convention was the key intellectual property regime and as stated supra it invoked national treatment for applicants of member states. This being said, stem cell research would have been accepted or denied per state according to whether the individual state granted patents on stem cell research. Nations at the forefront of biotechnological innovations, however, could pressure member states through bilateral agreements or through other more aggressive means. Pressure coming from the United States, however, is very influential and likely to have lead to a positive result for the United States in regards to individual bilateral agreements with nations not as willing to accept the progressive biotechnological patenting agenda of the United States.

It seems that Article 27 of TRIPS has provided a trump card for many

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[58] *Id.*

smaller nations with qualms about biotechnological patents: the statutory moral utility doctrine. Furthermore, it seems that growing regional treaties such as the European Union and the European Patent Convention have provided the many smaller nations of Europe the bargaining power to match or even exceed that of the United States. What this means, ultimately, is that regional agreements, such as EPC, have provided greater, more cohesive opposition to the US biotechnological agenda. However, this seems to have simplified things a little bit too much, as is evidenced by EU Directive 98/44/EC, which attempted to provide patenting protection for some biological inventions. In essence however, it seems that pre-TRIPS the US would have had an easier time pushing its biotechnological patent agenda, rather than in the post-TRIPS world.

Now that we have examined the first tripartite, lets take a look at the second, the Patent Law Treaty. PLT currently is not in effect, primarily because 40, mostly unindustrialized, nations have refused to sign it. They are arguing for implementation of the Convention on Biological Diversity.[59] If enacted the treaty would harmonize patent office formalities for the administration of patent applications. This treaty makes clear in article three that it is *not*a *substantive* patent law treaty, but rather that the provisions in the PLT apply to applcations that are permitted in the Paris Convention and the PCT. In other words, this treaty creates a uniform set of rules for patent applications to all countries that sign up. Generally speaking, this treaty neither helps nor hinders the US biotechnological patent agenda.

[59] Grain, *supra* note 56.

However, the third tripartite in the developing world patent regime is the Substantive Patent Law Treaty (SPLT). If negotiations go poorly for the US, then the US risks being excluded or having a world patent treaty that is extremely difficult for it to accept. The main areas of concern for the United States continue to be a statutory moral utility doctrine that preempts granting patents to *any* invention that adversely affects the ordre public or morals of a society. The United States stands to lose too much if it allows negotiations to create a world patent regime that will not grant patents to the US' prolific biotechnological industries.

The United States needs to show the EU that the statutory moral utility doctrine is very problematic. As is shown by the diversity of responses of EU member states to biotechnology patents, EU member states that have similar histories can not even agree on what violates the ordre public.[60] This is a very big problem. If a group of nations with shared histories cannot agree on what is moral and what is not, then how can nations across the world? The key problem, really, is that nations around the world do not fully realize that the United States has mechanisms *outside* the patenting regime that can keep science in a comfort zone of morality. President Bush's response to embryonic stem cell research is one such example. Another example involves the *Chimera* case, where the court held that a patent could not be issued because it violated the post civil war amendments.

[60] Germany and Ireland and Italy do not allow many biotechnology patents, whereas the UK is rather progressive in this arena. What is critical to note is that Germany has still failed to ratify

However, the United States may need to bend on other areas to allow for a world patent regime that is acceptable for all nations. For instance the United States is practically the only nation in the world that has a first to invent system. While the rest of the world is concerned about the welfare of their societies in *general*, the United States seems concerned about the welfare of *individuals* in their society. The United States does this by providing a first to invent system, as opposed to the procedurally much simpler first to file system. The rest of the world can address the US concern of individual fairness by modifying the first to file system by adding a comfortable grace period for inventors to claim priority ahead of those who are first to file.

The United States needs to allow other nations to have the freedom to prevent the utilization of biotechnology patents that they feel violate the morals of their society. Therefore, countries like Ireland, Italy and Germany according to such a proposition will recognize stem cell patents and other controversial biotechnology patents, but they will have the right to *exclude* the utilization of that patent within its borders. In other words, they will have the right to prevent techniques that utilize these patents by deeming their use illegal within its borders. This allows these more conservative countries to uphold the morals of their society, while at the same time protecting the intellectual property of other foreign countries.

As we examined the EPC and US patent regime we saw that the US system was more flexible than the EPC. The US needs to argue for a patenting

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the EU Directive on Biotechnology, despite pressure from member states, the United States, and

regime that is flexible, in much the same manner as the founding fathers establish the foundations for a flexible patenting regime. The US system appears to have more readily responded to the challenges of biotechnology patents. The EU system had too many hiccups and this is probably due more to the statutory moral utility doctrine, than anything else.

As stem cells have shown us vis-à-vis patents, any successful patenting system must be flexible and adaptable to changing and unforeseen technologies. Without a flexible patent system that is free from the shackles of a statutory moral utility doctrine, science and technology may be unnecessarily stunted. That being said the response of the US system to the metaphysical debate and the ethical considerations of stem cell research has shown that there are many avenues outside of a patenting regime that can be used to keep science and research within a healthy and acceptable parameter.

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biotechnology industries within its borders.