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Stemming the Stem Cell Setback

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COMMENTS

Stemming the Stem Cell Setback

I. THE GROWING BIOTECHNOLOGY INDUSTRY

"The significant problems we face cannot be solved at the same level of thinking we were at when we created them."[1]

A. Contributions to the Industry's Growth Have Included Stem Cells

The biotechnology industry[2] has seen tremendous growth in recent years that has also benefited the United States industry as a whole.[3] The industry's revenue has more than tripled in the past ten years, from $8 billion in 1992, to an estimated $27.6 billion for 2001.[4] As the monetary value of the industry grew, so did intellectual property rights in the industry.[5] What was once considered a generally academic community that had a communal approach towards research developments has now become more of a profit-driven industry focused on securing patent rights.[6] This growth can be attributed in part to legislation that has

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1. Albert Einstein (1879-1955), *available at* http://washingtonmo.net/words/00-01-25/htm.

2. The term "biotechnology industry" here denotes companies that develop cells and biological molecules for the advancement of medicine, agriculture, or the environment. *The Economic Contributions of the Biotechnology Industry to the U.S. Economy*, ERNST & YOUNG ECONOMICS CONSULTING AND QUANTITATIVE ANALYSIS, May 2000, at 3 (defining the biotech industry).

3. *Id.* at 2 (showing statistically how the biotechnology industry has also contributed to the national industry, including jobs and tax revenue).

4. Biotechnology Industry Organization, *Biotechnology Industry Statistics*, *at* http://www.bio.org/er/statistics.asp (last visited Oct. 3, 2002). The industry income for 1999 was $22.3 billion. *Id.*

5. 1993 USPTO ANN. REP. 7 (stating that biotechnology patents were growing at eleven percent compared to two percent for other patents). Approximately 12,800 biotechnology patents were filed in the fiscal year. Also, the report indicated a continuing growth in upcoming years. *Id. See also* 2000 USPTO ANN. REP. 23 (stating patent applications increased by 12.3%, with the majority coming from biotechnology, information processing, and telecommunications).

6. *See generally* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999) (examining the trends of the biotech industry). The research and development section of the biotech industry has changed

made it easier for universities to acquire patents on federally funded research, such as the Bayh-Dole Act,[7] and, in part, to the Supreme Court's decision in *Diamond v. Chakrabarty*,[8] which recognized the patentability of "nonnaturally occurring" living things.[9] Biological building blocks, such as DNA strands, were once thought to be unpatentable.[10] Now, any new discovery appears to be patentable.[11]

One particular area of divisive development in the biotechnology industry has been in research pertaining to stem cells. Human embryonic stem cells (ES cells), which were discovered in 1998, at the University of Wisconsin in Madison, Wisconsin,[12] are believed to have almost limitless potential for finding new cures for life debilitating diseases.[13] Since human embryonic stem cell research is still in its infancy, it is difficult to predict the characteristics of these cells, or what useful characteristics future cell lines may possess.[14] Even so, scientists are using ES cells in the treatment of Type I diabetes in children, Parkinson's disease, and AIDS, to name just a few of the cells' uses.[15] One of the leading organizations in the field of stem cell research, the Wisconsin Alumni Research Foundation (WARF),[16] of Madison,

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from an area where research was generally its own reward, to an area where patent rights are becoming more important than recognition. *Id.* at 110-12.

7. Pub. L. No. 96-517, 6(a), 94 Stat. 3015, 3019-28 (1980) (codified as 35 U.S.C. §§ 200-12 (1994)) (allowing universities patent rights based on federally funded research).

8. 447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980).

9. *Id.* at 309, 206 U.S.P.Q. (BNA) at 197.

10. *In re* Mancy, 499 F.2d 1289, 1291, 182 U.S.P.Q. (BNA) 303, 304 (C.C.P.A. 1974) (stating in dictum that a microorganism was presumed to be unpatentable).

11. *See, e.g.*, U.S. Patent No. 4,736,866 (issued Apr. 12, 1988) (covering a genetically modified mouse strain, the "onco-mouse," and being broad enough to cover all nonhuman animals falling within the genetically modified patented process); *see* Mike Pezzella, *Greenpeace vs. Harvard Mouse in Patent Squabble*, BIOTECH. NEWSWATCH, Nov. 19, 2001, at 1 (discussing the European Patent Office's dismissal of a complaint filed by Greenpeace to overturn the patent covering the "onco-mouse").

12. *See* U.S. Patent No. 5,843,780 (issued Dec. 1, 1998). *See also infra* note 42 (discussing the patent awarded on the human embryonic stem cell).

13. *See generally* AUDREY R. CHAPMAN ET AL., AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE & INSTITUTE FOR CIVIL SOCIETY, STEM CELL RESEARCH AND APPLICATIONS: MONITORING THE FRONTIERS OF BIOMEDICAL RESEARCH PRODUCED (1999).

14. *Id.*

15. *Id.* at 5-6.

16. WARF is a nonprofit organization that was founded in 1925 and contributes over $30 million annually for research purposes to the University of Wisconsin-Madison. The University's professors develop inventions and assign the patent rights to WARF. *See* Wisconsin Alumni Research Foundation, *available at* http://www.warf.ws/aboutus/index.jsp.

Wisconsin, was given a broad patent on these embryonic stem cells.[17] WARF also owns five of the known seventy-eight stem cell lines currently reported to the National Institute of Health (NIH).[18]

B. Governmental Funding for Stem Cell Research

Federal funding has contributed significantly to stem cell research.[19] In the research papers cited in biotechnology patents, over seventy percent of the citations are to sources that are publicly funded.[20] However, stem cell researchers may not be able to rely on federal funding in the future. On August 9, 2001, President George W. Bush announced a limit on available funds for stem cell research.[21] A stem cell line must have been initiated before 9:00 p.m. eastern daylight time, August 9, 2001, to receive federal funding.[22] This limit on federal funds will hamper the expansion of research for scientists and universities in the United States.

The scientific community has reacted with alarm and concern to the President's decision.[23] Some scientists have wondered what effect this decision will have on licensing agreements with current patent holders,[24] with one such effect being future litigation.[25] Many believe the President's decision will have a slowing effect on research and will also

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17. U.S. Patent No. 5,843,780.

18. U.S. Dep't Health and Human Servs. Nat'l Insts. Health, National Institute of Health (NIH) Update on Existing Human Embryonic Stem Cells (Aug. 27, 2001), *at* http://nih.gov/news/stemcell/082701list.htm [hereinafter NIH Update]. When the announcement was made, there were sixty-four registered stem cell lines that met the President's criteria. When the final tally of research institutes was compiled, there were seventy-eight lines that met the President's criteria. *Id.*

19. *See* John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 117 (2001).

20. *Id.* (noting "that 71.6% of citations to research papers in biotechnology patents are to publicly funded research.").

21. *See* NIH Update, *supra* note 18.

22. *Id. See also* U.S. Dep't Health and Human Servs. Nat'l Insts. Health, NIH Human Embryonic Stem Cell Registry, Information on Eligibility Criteria for Federal Funding of Research on Human Embryonic Stem Cells, *available at* http://escr.nih.gov/eligibilitycriteria.html (last visited May 12, 2003) (listing the criteria needed for a stem cell line to receive federal funding).

23. *Potential Compromise on Stem Cell Research is Controversial*, BLOOD WEEKLY, Aug. 16, 2001 [hereinafter *Potential Compromise*].

24. *Id.*

25. Tim Adams, *Stem Cell Suit Heats Up*, BIOTECH. NEWSWATCH, Oct. 1, 2001 (discussing the fact that WARF sued Geron, a biotech company, after Geron tried to establish its rights over six stem cell lines developed at the University of Wisconsin). *See also*, WARF Complaint, *infra* note 153.

increase the cost of research.[26] Some scientists, such as Roger Pedersen of the University of California at San Francisco, have even decided their current research would benefit more if they continued it outside of the United States.[27] The general consensus is that President Bush's decision will have some limiting effect on stem cell research.[28] Whether it be by the increased cost of research as more private dollars are incorporated into projects and government control over intellectual property rights lessens, or by the delays or slow downs of research as scientists have fewer stem cell lines to work with, the biotech industry will be effected.

In light of President Bush's decision, one would believe current stem cell patent holders are in a position to exert great power in enforcing their patent rights.[29] However, this Comment will show that this exertion of rights is not truly beneficial to the patent holder, or to society in general. To prevent the United States from losing its lead in the biotechnology industry to the rest of the world, and also for the world to benefit the greatest from stem cell research, the industry will need to revert back to more of a communal research mode that the industry once possessed. The U.S. Patent and Trademark Office (PTO) will need to revive the utility function needed for a patent grant, which requires that a patent must have a purposeful use to be afforded protection.[30] Also, Congress must realize the potential economic losses to the country and find ways other than direct federal funding to encourage stem cell research in the public sector. Overall, the requirements for receiving a patent will become more stringent, while the downstream rights of that patent will be strengthened.

Part II of this Comment will give a brief history and explanation of stem cells and of the public's reaction to them in the United States. Part III will discuss how the patent laws have developed over time,

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26. Michele Grygotis, *Patents Could Restrict Availability of Stem Cell Lines to Researchers*, TRANSPLANT NEWS, Aug. 30, 2001 (quoting Dalton Dietrich, scientific director of the Miami Project to Cure Paralysis, in reference to the patents on the now limited stem cell lines available for public funding, "What will they charge us?").

27. *US Stem Cell Researcher Defects to Britain to Continue Work with Public Support,* TRANSPLANT NEWS, July 27, 2001 [hereinafter *Researcher Defects*].

28. Sharon Begley, *Cellular Divide,* NEWSWEEK, July 9, 2001, at 24 (drawing a consensus from scientists that the limiting of the available stem cell lines by not allowing the development of new embryonic stem cell lines will not be sufficient to continue the current progress level of research).

29. *See Potential Compromise, supra* note 23.

30. 35 U.S.C. § 101 (2000) states "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore . . . ." *Id.*

specifically over the last fifty years, and what this has meant to the biotech industry. Part IV will discuss the different legal and social norms that regulate the biotechnology industry and how these norms affect the way scientists and investors view the patent system. Finally, Part V will discuss the direction players in the biotechnology field are heading and conclude that the United States players will have to return to a more communal acceptance of patent rights to keep their status as international leaders in the biotech field, providing less protection in the early stages of research, but more protection as products evolve and become more useful to the public.

II. WHAT IS A STEM CELL?

A significant problem with stem cells and stem cell research is that there are still many uncertainties as to what the use of stem cells can actually accomplish.[31] At a National Academy of Sciences conference regarding stem cells, in Washington, D.C., Dr. Ihor Lemischka, Ph.D., Princeton University, stated, "'The state of ignorance concerning our scientific understanding of stem cells currently is rather sobering.'"[32] While the potential new discoveries for embryonic stem cell uses have intrigued some researchers and scientists, others have a more cautious tone.[33] Father Kevin FitzGerald, Ph.D., University of Loyola-Chicago, and cofounder of Do No Harm: Coalition of Americans for Research Ethics (CARE), urges that because of the uncertainties of the embryonic stem cell and its direct connection to a human being, all other avenues of research should be exhausted before embryonic stem cells are used for research.[34] Part II will explain some of the issues regarding stem cells. Section A will give a brief overview of a stem cell and its development. Section B will describe the public's reaction to the stem cell.

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31. U.S. Dep't Health and Human Servs. Nat'l Insts. Health, NIH Strategies for Implementing Human Embryonic Stem Cell Research (Feb. 28, 2002), *at* http://www.nih.gov/news/stemcell/022802implement.htm (stating that there are currently fewer than two dozen publications regarding embryonic stem cells); *See Potential Compromise*, *supra* note 23 (discussing how the limited stem cell lines available for federal research funding are not sufficiently diverse to get a true understanding of an embryonic stem cell's potential).

32. Vicki Brower, *As Stem Cell Controversy Rages, Experts Sobered by State of Art*, BIOTECH. NEWSWATCH, July 16, 2001.

33. *Id.*

34. *Id.*

A. Stem Cell Basics

A stem cell is a cell that has the ability to reproduce itself and to produce distinct differentiated tissue.[35] The ability to reproduce a single stem cell into many cells allows a single stem cell to be the basis for many separate experiments.[36] One of the earliest developments in stem cell research happened in 1954, when John Enders received a Nobel Prize for developing a polio virus inside a human embryonic kidney cell.[37] In the 1960s, as the study of stem cells progressed, scientists believed that certain mouse cells had the ability to form multiple tissue types.[38] Research was focused on forming stem cells within mice because mice had proven to be good test bodies for research that could not yet be conducted on humans.[39] In 1971 actual cells were isolated from mice, leading to new research advancements.[40] The 1990s saw significant gains in stem cell research as well. The first human embryonic stem cell was isolated at John Hopkins University in 1997,[41] and soon afterward the University of Wisconsin received a patent on primate stem cells that could last *in vitro* for over one year.[42] Using actual human stem cells (as opposed to stem cells from animals) allows scientists to conduct more realistic experiments with more definitive results.[43] However, this practice creates moral objections, especially because of the way the cells are derived.[44]

However, not all stem cells act in the same way. There are three categories of human stem cells. Human embryonic stem cells (ES cells)

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35. CHAPMAN ET AL., *supra* note 13, at 1.

36. *Id.* at 2.

37. The Nobel Prize Internet Archive, John Franklin Enders, *at* http://nobelprizes.com/nobel/medicine/1954a.html (last visited May 11, 2003).

38. CHAPMAN ET AL., *supra* note 13, at 1-2.

39. *Id.* at 3.

40. *Id.* at 1.

41. *See* U.S. Patent No. 6,331,406 (issued Dec. 18, 2001) (registering human enbryonic [sic] germ cell and methods of use).

42. U.S. Patent No. 5,843,780 (issued Dec. 1, 1998). "Given the close evolutionary distance between rhesus macaques and humans, and the fact that feeder-dependent human EC cell lines can be grown in conditions similar to those that support primate ES cell lines, the same growth conditions will allow the isolation and growth of human ES cells." *Id.* at Description of Invention 1(b).

43. *See* U.S. Dep't Health & Human Servs., Nat'l Insts. Health, Stem Cells: A Primer, *at* http://nih.gov/news/stemcell/primer.htm (last visited Sept. 2002) (discussing how experiments being carried out were once only possible in animals); *see generally* CHAPMAN ET AL., *supra* note 13 (explaining some of the basics behind stem cells).

44. *See* Brower, *supra* note 32 (the embryonic stem cell comes from a human embryo, which some believe is equivalent to a human being).

are derived from an embryo that is in a very early stage of development.[45] Human embryonic germ cells (EG cells) are derived from fetal tissue taken from an aborted fetus.[46] Human adult stem cells are cells taken from any mature human tissue, regardless of age.[47] The first two categories of stem cells have the ability to regenerate rather easily, while the third category regenerates very poorly and is not as effective as a research tool.[48] Because adult stem cells are available, and do not pose as much of an ethical debate as ES or EG cells,[49] there is an argument as to whether ES or EG cells truly need to be used in research.

B. Responses to Stem Cell Research

Stem cell research quite possibly has been contested on ethical and moral grounds more than any other area of the biotech industry. Because EG and ES cells are taken from discarded fetuses and embryos, religious organizations have weighed in against using these cells for research.[50] The general opposition to scientific research is concerned that an increase in embryonic research will lead to an increase in abortions.[51] These pressures helped formulate President Bush's decision to limit the funding of stem cell research.[52] While a majority of Americans favor funding for stem cell research,[53] strong pressure from

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45. CHAPMAN ET AL., *supra* note 13, at 2-3.

46. *Id.* at 3.

47. *Id.* at 3-4.

48. *Id.* at 4. Adult stem cells may lead to research, but the consensus is that the research is not as effective as embryonic research. *See* Justin Gillis, *Questions Raised on Stem Cells: Adult Cells Found Less Useful Than Embryonic Ones,* WASH. POST, Mar. 14, 2002, at A3 (suggesting that recent findings with regard to the potential usefulness of adult stem cells may be flawed).

49. *See* Brower, *supra* note 32 (commenting on people who regard adult stem cell research as morally acceptable compared to embryonic stem cell research).

50. *Pope John Lauds Organ Donation, Condemns Cloning to Obtain Organs,* TRANSPLANT NEWS, Sept. 24, 2000 (quoting Pope John Paul II as saying use of adult cells is acceptable for research purposes, but not EG or ES cells).

51. Dennis O'Leary, *Embryo Research Contested,* CHRISTIANITY TODAY, May 24, 1999, at 26 (discussing how American pro-life groups, often associated with antiabortion protests and crisis-pregnancy counseling, are intensifying their campaign against the use of human embryos in medical research).

52. *See* NIH Update, *supra* note 18. There are only seventy-eight currently known lines of stem cells in the world that will meet the criteria set forth by President Bush. *Id.*

53. Meredith Wadman, *Ethicists Urge Funding for Extraction of Embryo Cells,* NATURE, May 27, 1999, at 292 (conducting a poll where 74% of Americans favored federally funded research of stem cells).

opposition to stem cell research has effectively narrowed the scope of federal funding.[54]

The scientific community has addressed President Bush's limit with concern,[55] stating that limiting the funds "will inhibit research and prevent or delay important advances toward real cures [for diseases]...."[56] Also, because of the infancy of the stem cell field, uncertainty exists as to what can be expected from the current stem cell lines.[57] Moreover, less than thirty percent of the cell lines eligible for federal funding are not developed far enough for consideration in efficient research purposes.[58] This will "effectively end the ability of the [NIH] to contribute meaningful stem cell research...." [59]

Additionally, this could strengthen the control of current patent

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54. *See* Carly Goldstein, Note, *Dipping Into Uncle Sam's Pockets: Federal Funding of Stem Cell Research: Is It Legal?*, 11 B.U. PUB. INT. L.J. 229, 237-48 (2002) (discussing the turmoil that has resulted from stem cell legislation since the 1980s). For instance, groups, such as Right to Life, have effectively limited the amount of federal funding allowed for embryonic research. *Id.* Ever since *Roe v. Wade*, 410 U.S. 113 (1973) funding of embryo research has been a controversial issue. Even after an NIH Panel voted 19-2 in favor of government funding of embryonic research in 1988, the Panel's minority view was upheld in 1989, largely because of fears that an increase in funding would lead to an increase in abortions. Nikki Melina Constantine Bell, *Regulating Transfer and Use of Fetal Tissue in Transplantation Procedures: The Ethical Dimensions*, 20 AM. J.L. & MED. 277 (1994).

55. *Potential Compromise*, *supra* note 23; *40 US Nobel Laureates Sign Joining Statement Supporting Nuclear Transplantation Technology for Research, Therapeutic Purposes; Yet They do not Support Human Cloning*, TRANSPLANT NEWS, Apr. 28, 2002 (reciting the statement the laureates wrote urging the allowance of embryonic stem cell research).

56. *Potential Compromise*, *supra* note 23 (quoting Paul Berg, Professor of Cancer Research and Biochemistry, Stanford Medical School).

57. *See* Brower, *supra* note 32 (quoting Neil Theise, Scientist, Department of Pathology, New York University). "We can get different results concerning the same stem cells depending on whether they are being tested in vivo or ex vivo, in one disease or another." *Id.*

58. Raja Mishra, *Stem Cell Research Runs Into Roadblocks*, BOSTON GLOBE, May 12, 2002, at A1 (reporting on a survey conducted by the Boston Globe that almost seventy-five percent of the reported seventy-eight stem cell lines are not accessible by U.S. researchers); *Almost 75% of Embryonic Stem Cell Lines Meeting President Bush's Criteria Are Unavailable*, TRANSPLANT NEWS, June 14, 2002 (listing the stem cells for each group or organization that meet the federal criteria and stating which lines are actually usable); *see also* Mike Pezzella, *Controversy Continues to Swirl Around Estimates of Stem Cell Lines*, BIOTECH. NEWSWATCH, Sept. 17, 2001, at 1 (pointing out that the stem cell limits are being put in place without knowing what the ramifications of those limits truly may be. When this article was written approximately forty percent of the then known sixty-four stem cell lines, or about twenty-six lines, were thought to be useful lines.).

59. Pezzella, *supra* note 58 (quoting Gerald Fischbach, MD, Executive Vice President for Health Sciences and Dean of the Faculty of Medicine, Columbia University, New York City).

holders of stem cells over current universities and research departments, which could lead to increases in research costs.[60] The limited patent monopoly a patent holder[61] receives in exchange for a societally useful invention may be artificially expanded if there is no opportunity to design around a patented stem cell line. If no new stem cell lines may be developed as previous stem cells had been with federal funding, the current cell lines can take on a monopolistic feel since they will have less competition in the research field. To put the potentially limited availability of stem cells for research in perspective, we need to consider how intellectual property rights have evolved with regards to the biotech industry. As Part III will discuss, intellectual property rights are a powerful force in the biotech industry. Specifically, patent rights that now are commonplace in a field where at one time patentability of research developments was suspect, have not necessarily allowed the biotech industry to grow as fast as it might.

III. EXPANDING THE SCOPE OF PATENT RIGHTS

Congress has the constitutional right to confer patents on inventors.[62] For a patent to be issued, the invention must be new,[63] useful,[64] and non-obvious.[65] An invention that cannot be shown to have any specific useful purpose should not receive patent protection.[66] With regard to the biotech industry, we can observe that an easing of the usefulness, or utility, requirement[67] has led to an increase in the number

60. Grygotis, *supra* note 26.

61. Currently, a patent holder has exclusive rights over her invention for twenty years from the date of filing the patent application. 35 U.S.C. § 154(a)(2) (2000).

62. U.S. CONST. art. I, § 8, cl. 8. "The Congress shall have [p]ower . . . [t]o promote the [p]rogress of . . . useful Arts, by securing for limited [t]imes . . . [i]nventors the exclusive [r]ight to their respective . . . [d]iscoveries." *Id.*

63. 35 U.S.C. § 101 (2000).

64. *Id.*

65. 35 U.S.C. § 103(a) (2000). Conditions for patentability; non-obvious subject matter: "A patent may not be obtained . . . if . . . 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 art to which said subject matter pertains."

66. Brenner v. Manson, 383 U.S. 519, 534, 148 U.S.P.Q. (BNA) 689, 695 (1966) (deciding that an invention must point to some specific utility before it may be patented).

67. *Compare id.* (disallowing patent for a process for making certain steroids because the drugs were only tested in mice and were not proven to have the actual utility for a human as claimed in the patent), *with In re* Brana, 51 F.3d 1560, 34 U.S.P.Q.2d (BNA) 1436 (Fed. Cir. 1995) (concluding that where, in a patent for an anti-tumor substance, mice were utilized as test subjects, that the mice sufficiently produced results that may be possible in a person). The argument was that an invention must show a possible use, not necessarily be perfected. *Id.*

of patents issued in the field.[68] Congress has not only developed a more liberal approach as to what is considered utile, but the courts have also developed a liberal definition of the utility requirement.[69]

A. The Court's Evolving Leniency Towards Patentable Material

Prior to the mid-1970s, courts strictly applied the utility requirement needed in granting patents. In *Brenner v. Manson*,[70] for example, respondent Manson sought a patent on a process for making certain known steroids that had a tumor-inhibiting effect on mice.[71] The Court held that there was not enough substantial public utility of the process to grant a patent.[72] While there was almost a certain viable use for the invention, that use was ruled insufficient to warrant patent rights.[73] The Court required more of a usefulness to the public, not just to scientific research.[74] In 1974, in *In re Mancy*,[75] the Court of Customs and Patent Appeals stated that a strain of microorganism was presumptively unpatentable.[76] However, three years later the court overruled *Mancy*. *In re Bergy*[77] saw the court uphold a patent for a "Process for Preparing Lincomycin."[78] The court did not even evaluate the utility of the claimed process.[79] The court instead focused on the fact that microorganisms can be classified as patentable material under § 101.[80] The case was remanded and eventually consolidated with another case, *Diamond v. Chakrabarty*.[81]

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68. *See* http://www.bio.org/er/statistics.asp (last visited Jan. 15, 2003) (showing graphically the number of biotech patents granted in each calendar year). In 1985, approximately 1,500 biotech patents were granted; in 2000, over 13,500 biotech patents were granted. *Id.*

69. *See infra* Part III.A.

70. 383 U.S. 519, 148 U.S.P.Q. (BNA) 689 (1966).

71. *Id.* at 520 n.1, 148 U.S.P.Q. (BNA) at 690 n.1 (describing the products of the steroid producing process).

72. *Id.* at 534-35, 148 U.S.P.Q. (BNA) at 704.

73. *Id.*

74. *Id.*

75. 499 F.2d 1289, 182 U.S.P.Q. (BNA) 303 (C.C.P.A. 1974).

76. *Id.* at 1291, 182 U.S.P.Q. (BNA) at 306 (dictum).

77. 563 F.2d 1031, 195 U.S.P.Q. (BNA) 344 (C.C.P.A. 1977).

78. *Id.* at 1032, 195 U.S.P.Q. (BNA) at 345.

79. *Id.*

80. *Id.* at 1038, 195 U.S.P.Q. (BNA) at 350-51.

81. Diamond v. Chakrabarty, 447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980) (consolidating *Diamond* and *In re Bergy* into one suit and then dismissing *In re Bergy* as moot).

Diamond v. Chakrabarty[82] was a landmark decision, because its holding recognized that a "live, human-made microorganism is patentable subject matter under § 101."[83] The decision broadened the scope of patentable subject matter to everything but "[t]he laws of nature, physical phenomena, and abstract ideas . . . ."[84] The Court stated that if Congress intended anything less than this broad of a reading of the law, Congress would have stated so in a specific statute.[85]

In a more recent patentability decision based on utility, *In re Brana*,[86] the court determined that there was patentability for an anti-tumor substance that was tested in mice.[87] Even though no specific disease was noted as being possibly preventable by the invention,[88] the court held there was sufficient utility as viewed through the eyes of a person skilled in the art.[89] Thus, between the decision in *Brenner* and the decision in *Diamond*, the utility requirement for patentability went from a societal usefulness to a general usefulness in a specific area of study. In an infant area of research such as biotechnology, too much information has been patented without the "inventions" having any specific uses. This prevents a scientist from conducting any useful research without running into another scientist's patented invention. Research will suffer if the scientific building blocks are in the control of only one entity.

It must be noted that some findings will not be given patent protection, even under the current liberal approach. In *In re Wright*,[90] inventor Wright was denied a patent for a process for producing live non-pathogenic vaccines against RNA viruses.[91] The process only had a general description and only showed one working example for the alleged process.[92] However, the decision to reject the application was based on the enablement requirement,[93] not on the utility requirement.[94]

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82. *Id.*

83. *Id.* at 318, 206 U.S.P.Q. (BNA) at 200.

84. *Id.* at 309, 206 U.S.P.Q. (BNA) at 197.

85. *Id.* at 318, 206 U.S.P.Q. (BNA) at 201.

86. 51 F.3d 1560, 34 U.S.P.Q.2d (BNA) 1436 (Fed. Cir. 1995).

87. *Id.*

88. *Id.* at 1565, 34 U.S.P.Q.2d (BNA) at 1440 (holding that a model of a tumor in a mouse was a sufficient basis for determining utility).

89. *Id.* at 1569, 34 U.S.P.Q.2d (BNA) at 1444.

90. 999 F.2d 1557, 27 U.S.P.Q.2d (BNA) 1510 (Fed. Cir. 1993).

91. *Id.* at 1558-59, 27 U.S.P.Q.2d (BNA) at 1510-11.

92. *Id.* at 1559, 27 U.S.P.Q.2d (BNA) at 1511.

93. 35 U.S.C. § 112 (2000).

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

The enablement requirement says that a patent's specifications must be clear enough for a person having ordinary skill in the art to be able to repeat the invention on her own.[95] While the invention only discussed general RNA viruses and no specific diseases,[96] the court did not even raise concerns over usefulness. Utility appears to be presently taken for granted in patent applications, and only given cursory attention.

B. Legislative Initiatives Have Made Patenting Information More Easily Acceptable

During the Twentieth Century, Congress enacted legislation that substantially expanded the scope of material that can be considered patentable. The Plant Patent Act of 1930[97] allowed the patenting of certain asexually reproduced plants.[98] In 1970, Congress passed the Plant Variety Protection Act,[99] which protected breeders of certain sexually reproduced plants.[100] Congress recognized that patent rights should keep up with the changes and innovations of biological technology.[101] Along with allowing more material to be patented, Congress also passed legislation that made it easier for the academic world and the private sector to work together in research and development. The Stevenson-Wydler Technology Innovation Act of 1980[102] required transfer of findings and records from federal

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terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Id.

94. *Wright*, 999 F.2d at 1561, 27 U.S.P.Q.2d (BNA) at 1512-13.

95. 35 U.S.C. § 112.

96. *See* Application Serial No. 06/914,620 (filed Oct. 2, 1986), a continuation of Serial No. 06/469,985 (filed Feb. 25, 1983), now abandoned.

97. Ch. 312, § 1, 46 Stat. 376 (codified as 35 U.S.C. § 161 (2000)).

98. *Id.* ("Whoever has invented or discovered and asexually reproduced any distinct and new variety of plant . . . may . . . obtain a patent . . . .").

99. Pub. L. No. 91-577, ch. 4, § 42, 84 Stat. 1547 (1970) (codified as 7 U.S.C. § 2402 (2000)).

100. I7 U.S.C. § 2402(a). "The breeder of any novel variety of sexually reproduced plant . . . shall be entitled to plant variety protection . . . ." *Id.*

101. *See* Rai, *supra* note 6, at 95-97 (discussing some of the factors leading Congress to enact changing statutes). Among the factors was the encouragement of firms to invest in biotech research and to keep United States science from being "piggy-backed" by foreign companies. *Id.* at 96.

102. Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. §§ 3701-3714 (2000)) (requiring federal laboratories to make technology transfer to private industry an easier undertaking).

laboratories to private industries.[103] The Bayh-Dole Act of 1980[104] gave universities patent rights to federally sponsored research.[105]

Between expanding access to federal research and federal funding, and increasing the ability to patent findings, Congress has given the scientific community an increasingly wide scope of protection for research and development. Now, patents cover nearly all biotechnology research.[106] Congress has adhered to the broad ideal of the Constitution, "[t]o promote the . . . useful arts,"[107] with a seemingly endless zeal. The President's order to limit stem cell research contrasts with these expanding rules.[108] What was quickly becoming an open field with unlimited potential to travel down new, unexplored avenues for research, especially in the past twenty-plus years, now has travel constraints limiting specific building blocks of the research. Regardless of the reasoning behind these limits, they are in place,[109] and the industry must react accordingly. The next section will discuss developments in the industry, and possible solutions to the problems it faces.

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103. 15 U.S.C. § 3710(a) (2000). This section states:

> (1) It is the continuing responsibility of the Federal Government to ensure the full use of the results of the Nation's Federal investment in research and development. To this end the Federal Government shall strive where appropriate to transfer federally owned or originated technology to State and local governments and to the private sector.
>
> (2) Technology transfer, consistent with mission responsibilities, is a responsibility of each laboratory science and engineering professional.
>
> (3) Each laboratory director shall ensure that efforts to transfer technology are considered positively in laboratory job descriptions, employee promotion policies, and evaluation of the job performance of scientists and engineers in the laboratory.

Id.

104. Pub. L. No. 96-517, 6(a), 94 Stat. 3015, 3019-28 (1980) (codified at 35 U.S.C. §§ 200-12 (1994)).

105. *Id.*

106. *See* Demaine & Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303 (2002).

107. U.S. CONST. art. I, § 8, cl. 8.

108. *See generally* Brower, *supra* note 32 (discussing how stem cell research is only in its early stages and that research on all types of stem cells should be continued). At a National Academy of Science conference in Washington D.C. to discuss the ethical issues related to stem cells, Bert Vogelstein, cancer researcher at John Hopkins and Chair of the conference said, "it is imprudent to prohibit any avenue of stem cell research at this time." *Id.* While President Bush's decision does not completely *prohibit* stem cell research, it does definitely place prohibitions on stem cell research. *See* NIH Update, *supra* note 18.

109. This Comment does not intend to focus on the ethics behind stem cell research limits. While ethical and moral concerns have affected the President's decisions, the Comment focuses on the consequences and repercussions of these decisions on the law and the biotech industry, given these enactments.

IV. THE COMPETING FACTIONS IN THE BIOTECH WORLD

Before suggesting solutions to the problem of balancing the continued growth of the biotechnology industry against insuring a proper scope of the property rights of biotech discoveries, it is noted that the industry is not completely homogenous. While everyone involved, from university scientists to corporation shareholders, benefits from technology's advancements,[110] the motives propelling those advancements may not be the same. The academic world may base its norms of behavior on a communal idea of discovering more information to further its research goals.[111] On the other hand, the private industry, which funds the inventive process, relies on more profit-orientated norms.[112] Also, the federal government plays a part in finding a suitable middle ground between industry and academia.[113] The next sections compare and contrast these norms, and consider how these competing "law-and-norm theor[ies]"[114] might work together to help rectify the predicament caused by the recent stem cell limit. Section A will discuss the general communal sharing of research within academia, Section B will explain private industry's interest in biotech findings, and Section C will show how government has helped bring the two divergent sides together.

A. Academic Norms: What's Mine is Yours

Molecular biology began as a highly theoretical science.[115] Prior to the legislation and court decisions in the early 1980s, discussed above in Part III, molecular biology was governed by the traditional norms of a cohesive scientific community that shared the same goals.[116] These

110. It should be noted that an increase in technology has benefited, as well.

111. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 181-82 (1987) (discussing how patents rights negatively effect scientific norms in basic biological research); Rai, *supra* note 6 *passim* (discussing how the norms of the scientific community with regard to research are focused on advancing research).

112. F. Scott Kieff, Forum, *Facilitating Scientific Research: Intellectual Property Rights and The Norms of Science – A Response to Rai and Eisenberg*, 95 NW. U.L. REV. 691 (stating that patents are necessary and that they increase general community good).

113. *See* Golden, *supra* note 19, at 131-36 (discussing the "triple helix" of government, university, and industry, and how they work together).

114. *See* Rai, *supra* note 6, at 81-82 (explaining how "law-and-norm theories" are used to explain how the policies of research institutes affect individual scientists).

115. *Id.* at 88 (explaining that Warren Weaver, the founder of the field, was a mathematical physicist).

116. *Id. But see* Kieff, *supra* note 112, at 697-98 (stating that the scientific norms were a product of legislation as opposed to what the true sentiments of the scientific community

norms "promoted a public domain of freely available scientific information" and independent and uninhibited research.[117] The norms have a communal flavor,[118] and secrecy and "claiming property rights in inventions is often seen as immoral."[119] The general idea is that there is a large pot of intellectual development that everyone can add to or take from, as they feel necessary.[120] The drive for continuing research came from the accolades and recognition a researcher would receive from the scientific community and from her peers.[121]

However, during the 1970s the academic world began to lose its communal bond. In 1973, "Stanley Cohen and Herbert Boyer of Stanford University invented gene splicing."[122] The scientists patented the invention only after forceful lobbying by the University's patent counsel.[123] While Cohen and Boyer did not want to put any fences around what they had revealed,[124] the University's regents and directors had different ideas. The communal principles would change as private industry became more involved in the biotech industry.

B. Private Industry Norms: What's In It For Me?

The late 1970s and the early 1980s saw an increase in the private industry's interest in the biological research community. Observing the potential profit a company could make from the new biological discoveries in the mid- to late- 1970s, many biotechnology firms began

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were at the time).

117. *See* Rai, *supra* note 6, at 88-90 (arguing that the scientific world is driven by new breakthroughs rather than becoming rich).

118. *Id.* at 90 (stating that a "scientist's claim to 'his' intellectual 'property' is limited to that of recognition and esteem.").

119. *Id.* (stating that a scientist is under a moral obligation to publish research).

120. An example of this type of sharing program is the Uniform Biological Materials Transfer Agreement (UBMTA). *Id.* Over one hundred universities pool information for use in noncommercial activities. *Id. See also* Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement, *available at* http://grants1.nih.gov/grants/guide/notice-files/not95-116a.html (last visited Jan. 15, 2002) (listing the UBMTA complete guidelines).

121. *See* Eisenberg, *supra* note 111, at 181-84 (discussing that prior to commercialization, a researcher's interest was an increase of other scientists using her findings, as opposed to a monetary gain).

122. *See* Rai, *supra* note 6, at 93 (referencing Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids in Vitro*, 70 PROC. NAT'L ACAD. SCI. 3240 (1973)).

123. *Id.*

124. *Id.* at 94 (noting that Georges Köhler and Cesar Milstein, Nobel Prize winners for work with monoclonal antibody technology, suggested that it would be "ethically inappropriate to patent their technique").

to emerge on the market.[125] Congress' passing of the Bayh-Dole Act in 1980[126] fostered the growth of these generally "young, small, and privately held [firms]."[127] These companies were more concerned with the monetary gains from an invention than with expanding the frontiers of science.[128] Although profit-driven, these firms generally did not and do not make it rich quickly.[129] It takes several years to develop a product and several hundred million dollars as well.[130] In fact, many of these firms live on the edge of insolvency.[131] These firms do not have the luxury to be rewarded with recognition and fame from others in the industry for their findings. Rather, a profit must be made to survive. Earlier patent rights in inventions mean an earlier opportunity to show a profit in an area of research that may help the short-term goal of a company fending off insolvency.

C. Government's Initiative: Developing A Suitable Relationship Between the Researcher and Private Industry

Government sits as a middleman between industry and the universities.[132] The government-run National Institute of Health (NIH) spends over twenty-three million dollars per year to advance the sciences.[133] The NIH is primarily concerned with advancing the interests

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125. *See* Golden, *supra* note 19, at 120 (discussing how the United States was losing its technological edge in the world market, which changed the perception of intellectual property rights and opened the doors to biotech companies).

126. 35 U.S.C. §§ 200-12 (2000).

127. *See* Golden, *supra* note 19, at 117-18 n.70-72 (discussing that approximately seventy percent of biotechnology firms were less than fifteen years old in 1994). Also, there were about 1,000 biotech companies with less than 100 employees and roughly fifty-five to sixty-five percent of biotech firms were privately owned. *Id.*

128. *Id.* at 121-23 (evaluating the legislative trends post-1980 that allowed small companies to work along with universities in a way that was profitable for the small companies).

129. *Id.* at 116-19; Lydia Nenow, *To Patent or Not to Patent: The European Union's New Biotech Directive*, 23 HOUS. J. INT'L L. 569, 570-71 (2001); *see generally* Kieff, *supra* note 112, at 698-99 (setting forth the economic reasons why a company must persistently enforce its patent rights).

130. Golden, *supra* note 19, at 118 (stating that a typical new drug will take between "five to ten years and at least a few hundred million dollars" to become marketable); Nenow, *supra* note 129, at 581-82 (stating it takes between four and seven years and $250 million to bring a pharmaceutical product to the market).

131. *See* Golden, *supra* note 19, at 118; Nenow, *supra* note 129, at 581-82.

132. *See* Golden, *supra* note 19, at 104-05.

133. *See* Press Release, National Institutes of Health, Press Release for the FY 2003 President's Budget (Feb. 4, 2002), *available at* http://www.nih.gov/news/budgetfy2003/2003NIHpresbudget.htm (showing the 2002 budget at over twenty-three million dollars, and the proposed 2003 budget at over twenty-seven million

of the nation, by putting information into the public domain or by giving it to people who will use it for the national benefit.[134] The NIH must balance the interests of society as a whole with the companies who may make a beneficial contribution to the government, while still profiting from the NIH-developed research.

The NIH does not necessarily have completely pure and true philanthropical motives, however. When tiny gene fragments, known as expressed sequence tags (ESTs),[135] were isolated in 1992, almost the entire scientific community condemned the idea of giving ESTs intellectual protection.[136] The NIH had intended to seek patents on certain ESTs, but withdrew the patent applications after pressure against filing the patents.[137] In fact, the uproar against the registration of the ESTs may have led to a possible curb on the relaxed utility standard for patents.[138] John J. Doll, a PTO official, stated that "patent applicants must demonstrate a more 'substantial, real-world utility; not some throwaway utility.'"[139] This is a good suggestion for all research tools that do not have "substantial real-world utility."

However, the NIH has done a generally good job of balancing the interests of the researcher with the goals of the private industry. While there has been a significant amount of information that has entered into the public domain from federally funded activities,[140] the U.S. biotech industry has still been able to maintain its world prominence in the market.[141] Even though funding for the NIH is increasing, a federal funds restriction for stem cell research[142] has pushed the key funding issue as to how to continue balancing everyone's needs to ensure a continuing "win-win" situation: that is, a continuing situation where research will still move forward and a profit still can be made.

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dollars).

134. *See* Golden, *supra* note 19, at 132-34.

135. Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 742-50 (2000) (discussing the basic science behind ESTs).

136. *Id.* at 738-39.

137. *Id.* at 738.

138. *Id.* at 738 n.1 (noting that EST applications "'will have a difficult time' meeting the utility requirement"). *Id.* (quoting John J. Doll, *The Patenting of DNA*, 280 SCIENCE 689, 689 (1998)).

139. *Id.* at 738.

140. *See* Golden, *supra* note 19, at 117-20 (noting that in addition to the direct contributions of the NIH, one-tenth to one-fifth of all biotech patents are university patents).

141. *Id.* at 107 n.27 (stating that the United States has priority for over 50% of the most highly cited biotech inventions).

142. *See* NIH Update, *supra* note 18.

D. Let's Work Together

As the 1980s began, the scientific community eased their norms opposing invention for capitalistic gains somewhat to include capital investment from the private sector.[143] In the mid-1990s, most biotech firms and universities had partnership agreements.[144] In exchange for giving private companies patent rights, the universities received more funding. The academic world has not, however, relinquished all of its rights over the innovations it invents. In 1995, over "one hundred universities formulated the Uniform Biological Materials Transfer Agreement (UMBTA),"[145] allowing universities to use biological materials for non-commercial activities and research purposes without having to negotiate license agreements.[146] Because patent rights may be secured to protect the inventive process behind the invention, the idea to share information freely and the ability to turn a profit do not necessarily go together.

Shortly after President Bush's announcement of new research guidelines, these competing ideas—communal sharing of inventions and discoveries and capitalistic gains—have butted heads. WARF[147] negotiated a commercial license with Geron Corporation of Menlo Park, California, over WARF's five lines of stem cells.[148] Geron funded a large portion of the research on these cells.[149] Possibly because of the recently imposed limit on stem cell availability, Geron claimed exclusive rights to all five lines.[150] WARF, realizing that research for new cell lines now has been slowed, wished to negotiate with other companies,[151] including the NIH.[152] One day after President Bush issued his order, WARF filed a complaint against Geron.[153] An industry that was beginning to work together may now have to reevaluate its position on intellectual property rights, since new stem cell lines, possibly holding

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143. See Rai, *supra* note 6, at 109-11.

144. Golden, *supra* note 19, at 118-20 (stating that 70.5% of the biotech firms had some partnership agreement with a university).

145. *See* Rai, *supra* note 6, at 113.

146. *Id.*

147. *See supra* note 16 and accompanying text (discussing WARF).

148. *See* NIH Update, *supra* note 18.

149. *See* Adams, *supra* note 25.

150. *Id.* (the claim to exclusive rights came very quickly after President Bush's announcement).

151. *Id.*

152. *See* NIH Update, *supra* note 18.

153. Wisconsin Alumni Research Fund v. Geron Corp., No 01-C-0459, *compl. filed* (W.D. Wis. Aug. 13, 2001) [hereinafter WARF complaint].

new intellectual patent rights, may not be developed as easily with a stem cell limit. A limited amount of raw materials to work with may make both industry and academia more hesitant when negotiating future agreements. In light of the limited amount of stem cells, how do we balance the pure scientific advancement with the profits of the economy? What is the solution?

V. WHERE DO WE GO NOW?

Inevitably, battles will continue over intellectual property rights; therefore, compromises must be made to keep the United States biotech industry moving forward. Already, the United States is losing prominent scientists who wish to continue research in a less restrictive environment.[154] Three possible solutions seem viable. The United States patent system may fall more in line with the European system, which allows exemptions from patent infringement for experimental use or research of a patented invention.[155] There may be more cross-licensing of patents, with more of the profits determined from downstream revenues. Finally, the industry may look to Congress to give it more direction so as to alleviate the problems arising in the field today, by passing legislation that may encourage the President to rethink his decision, or possibly give other incentives besides early patent rights to companies involved in biotech research.[156]

A. The European Alternative: Experimental Use

While the United States has had an experimental use exception for a person to use a patented invention,[157] it has been narrowly tailored towards nonprofit, noncommercial uses.[158] If a research program could

154. *See Researcher Defects*, *supra* note 27 (stating that Roger Pedersen will leave the University of California at San Francisco to take a position at the University of Cambridge, United Kingdom, so that he may conduct embryonic stem cell research).

155. The Commission of the European Communities proposed a Council Regulation on the Community Patent. In Art. 9(a) of the Regulation, there would be an exception for noncommercial uses.

156. *See* Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 56-58 (2001) (discussing how "royalty-stacking" is a problem in biotech research).

157. 35 U.S.C. § 271(e)(1) (2000).

158. *See generally* Mueller, *supra* note 156 (discussing how the experimental use doctrine has been narrowly construed and virtually nonexistent). Basically anything resulting in a sale at anytime will not be allowable as an experimental use under the exception. Even in an area of study like biotechnology where many findings currently are more theoretical than practical, there is still not sufficient distance from a possible future profit to currently warrant an experimental use exception. *Id.*

lead to profits somewhere down the road, it does not fall under the experimental use exception.[159] So, for example, the patent issued to WARF covering stem cells,[160] which has no immediate societal benefit, but has research applications, would not warrant the experimental exception, because the "invention" is being used by researchers who may one day develop a commercial product out of the patented research. The established exception has a very narrow scope.

This narrow United States standard for an experimental use exception comes from *Sawin v. Guild,*[161] where Justice Story stated that patent infringement deals with "the making [of the patented invention] with an intent to use for profit, and not for the mere purpose of philosophical experiment . . . ."[162] Researchers can use the exception only if they intended the experiments they were conducting to be just for display, such as a demonstration during a lecture of class. Once the patented invention is used as a step for another invention that may eventually lead to profit at some unknown time, the experimental use exception may not be used.[163] Considering the uncertainty of what research in the biotechnology field may lead to and the likelihood that it will lead to a dead end, this narrow interpretation of the exception covers areas that are not profitable paths. Unlike the United States, Europe has wider exceptions for experimental use,[164] which allow scientists to focus more on the advancement of technology, rather than worry about paying royalties on patents.

The European Commission has proposed an amendment in the European Commission's proposed Council Regulation on the Community Patent that would allow an experimental exception for research.[165] "For example, Germany's patent law provides that '[t]he effects of the patent shall not extend to acts performed for experimental

159. *See id.* at 5, 7-18, 24.

160. U.S. Patent No. 5,843,780 (issued Dec. 1, 1998).

161. 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

162. *Id.* at 555.

163. *See* Mueller, *supra* note 156, at 27-29 (commenting on Federal Circuit Judge Rader's concurrence in *Embrex, Inc. v. Serv. Ice Engineering Corp.,* 216 F.3d 1343 (Fed. Cir. 2000), and noting that the decision all but eliminates the experimental use exception in U.S. patent law).

164. *Id.* at 15; *see generally* Nenow, *supra* note 129, at 593-600 (stating that the use of human embryos for industrial and commercial purposes is generally not allowed. While the issue is about the morality of patenting such discoveries, the discoveries may still be used for experimentation).

165. *See* Mueller, *supra* note 156, at 38-39.

purposes relating to the subject-matter of the patented invention.'"[166] Similarly, the European Commission has a proposed exception for "acts done for experimental purposes relating to the subject-matter of the patented invention."[167] Also, the European proposal has an exception for research using "research tools."[168] Research tools are scientific findings that do not have any true utility as of now, but will lead to experiments in the future.[169] Many biotech patents can be considered research tools.[170] Besides the patent on stem cells, another example is DNA segments, which have no present utility, but are believed to be useful when searching for full-length genes.[171] The experimental exception and "research tools" exceptions allow scientists to focus on developing products rather than negotiate for the use of another's tools.

Currently, universities must spend a portion of their time and resources focusing on licensing agreements and fighting patent suits.[172] Even though suits, such as WARF's suit with Geron, may eventually settle,[173] the time spent in the courtroom would be better spent in the laboratory. Though broader exceptions may benefit research and possibly society as a whole,[174] this may still not appease the private sector, which will not be putting any less money into the process.

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166. *See id.* at 38 (quoting § 11, No. 2 of the German Patent Act of 1981).

167. *Id.* at 38 (quoting Art. 9(b) of Commission of the European Communities, *Proposal for a Council Regulation on the Community Patent*).

168. *See* U.S. Dep't Health and Human Servs. Nat'l Insts. Health, Report of the National Institute of Health, Working Group on Research Tools (June 4, 1998), *at* http://www.nih.gov/news/researchtools/index.htm (defining what a research tool is). *See also* Rai, *supra* note 6, at 111 n.190 (defining research tools as early discoveries of items that will be used in research for therapeutic compounds).

169. *See* Mueller, *supra* note 156, at 10-11 (adopting the definition of a research tool from the NIH).

170. *See id.* at 12-14 (listing some possible patents that could constitute an experimental use exception). For example, the cre-loxP mouse, U.S. Patent No. 4,959,317 (issued Sept. 25, 1990) ("Site-Specific Recombination of DNA in Eukaryotic Cells"), is used to develop a new product, but is not actually part of the new product. *Id.* Some institutions have paid more than $100,000 to use the mouse. Eliot Marshal, *The Mouse that Prompted a Roar*, 277 SCIENCE 24 (1997).

171. *See* Mueller, *supra* note 156, at 13-14.

172. *See generally* WARF Complaint, *supra* note 153.

173. Tom Abate, *Stem-Cell Suit Accord Could Help Research/Geron Gives Up Some Rights in Deal with University*, S.F. CHRON., Jan. 10, 2002, at B1 (stating the terms to the settlement between Geron and WARF). Geron retains an exclusive license to use three of the six WARF stem cell lines for heart disease, diabetes, and nervous disorders, while giving up exclusive rights to the remaining stem cell lines. *Id.*

174. *Contra* Kieff, *supra* note 112, at 703-05 (arguing that patent protection is needed to keep investment into the biotech industry). Consequently, more investment means more products that will have a beneficial use for society. *Id.*

Private companies must still put forth a significant sum of money that has not returned a profit as of yet. If a company cannot patent a discovery early in the inventive process, the company will perceivably have to wait a longer time to receive a return investment. The private sector may look for some other areas outside of biotechnology to invest if profits cannot be derived from early research patents. However, as the next section will suggest, a worthwhile profit may be made, even if a company does not receive early royalties on a discovery.

B. Waiting for the Payoff

One of the problems with allowing a broad patentability scope for biotech discoveries is "royalty stacking,"[175] which occurs when many patents are issued on experiments before the patents have any valid marketability.[176] If a discovery is patented, scientists and researchers must pay royalties to use that discovery, even though it may turn out to have limited or no value to the final invention marketed to the public. Thus, the costs of a research program are increased. Also, royalty stacking happens when patents are issued on what are truly incomplete patents.[177] For example, an express sequence tag (EST) of DNA may be patented even though a clear-cut use is not known for the EST.[178] Royalty stacking has increased dramatically since 1989.[179]

This is an especially costly common trend in an area, such as biotechnology, where early stages of research do not necessarily lead to any commercial results. For instance, a patented genetically engineered mouse may be implanted with certain patented DNA strains. The experiment may or may not lead to an improved process. It may not develop or improve any technology. However, the researcher would have to pay royalties for two or more separate patents, the mouse and every patented DNA strain. This "royalty stacking" raises the cost of research without actually producing an immediate societal benefit, or without producing societal benefits ever. Consequently, less money is available for new research because much money is spent on patent licensing for patents that do not necessarily have any real benefit.

Pseudo-cross-licensing could remedy this situation. Patent holders could allow others to use their patents or research without having to pay

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175. *See* Mueller, *supra* note 156, at 56-58.
176. *Id.* at 57-58.
177. *Id.* at 57.
178. Holman & Munzer, *supra* note 135, at 757-59.
179. Mueller, *supra* note 156, at 57.

royalties, or with minimal royalties. Because each specific scientist would diligently record the research,[180] it should not be overly difficult to show what each patent holder (or, in the absence of a patent, the discoverer of an "invention") contributed to a useful discovery. This could be accomplished very similarly to the UMBTA,[181] discussed above in Section D of Part IV, where different universities pool their research without getting or enforcing patent rights on "research tools."[182] Society would benefit as research could be expedited. Regents and university board members would have to contemplate less where research dollars would end up and come from. More funds from private donations, like WARF, could bolster new research, such as new lines of stem cells that cannot be created by using federal funds.

As for private industry, a company could derive its profits from a reasonable royalty determination to assess each inventor's contribution to the final invention after the product reaches the market. An arbitration system could be implemented where a company's "research tool" would get a share of royalties in proportion to the amount the "tool" contributed to the overall product. This system would not have to wait for a product to come to market. Rather, once a line of research shows that it will lead to a viable commercial use, royalties could be affixed. Knowing that a company would have a definite interest in the future profitable interests of a discovery could ease the decisions of investors of whether they should put forth funding for a specific project. BresaGen, an Australian-based company, has taken such an approach.[183] Universities will have free access to the company's stem cell lines.[184] In exchange, BresaGen will be able to derive profits from future inventions that a university may make.[185] It is yet to be determined how well the arrangement will work.[186]

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180. The United States patent system is a first-to-invent system, rather than a first-to-file system. 35 U.S.C. §§ 104-12 (2000). Consequently, the "date of conception" of an invention may take on added importance to show that a person conceived an idea for an invention before another person. The best and easiest way to show such a date is by thoroughly documented research materials.

181. *See* Rai, *supra* note 6, at 129-30 (discussing patent pools, where patent holders add their patents to a collective pool, thus reducing the costs associated with licensing).

182. *Id.* at 113 n.201 (stating that as of January, 22, 1998, 126 institutions had signed the UMBTA. Currently there are over 300 signatories.).

183. *See* Tim Friend, *Free Stem-Cell Lines Will Be Offered to Researchers,* USA TODAY, Aug. 22, 2001, at D10.

184. *Id.*

185. *Id.*

186. *See* Justin Gillis & Rick Weiss, *Stem Cell Research Not Yet Booming; Some Scientists Blame Political Controversy*, WASH. POST, Aug. 6, 2002, at A1 (updating current

A problem with waiting for downstream profits, however, is that many biotech firms do not have the economic luxury to wait for profits.[187] It would be ideal for a scientist or researcher to use a patented invention more because it is less cost restrictive, which would lead to more eventual royalties for the owner of the patent rights. However, a small biotech firm may not have the ability to wait for *all* of their profits to come from future discoveries. Besides the question of when to patent, there needs to be another viable solution for balancing intellectual property rights from outside the two competing sides of the industry. A balance between free dispersion of information and strict enforcement of patent rights may be assisted from outside of industry and academia.

C. Government Can Help the Situation

Just as Congress eased the interaction between private and public sectors through the Stevenson-Wydler Technology Innovation Act of 1980[188] and the Bayh-Dole Act of 1980,[189] it could also help the public sector in its ability to profit from biotech innovations. Congress should not limit the scope of patentability, but rather ensure that companies that undertake new research are rewarded, especially in an area such as stem cell research that can lead to great societal benefits. Congress could give an incentive, such as tax breaks, to private industries that work with universities and federal research complexes, so that these private companies become less reluctant to enforce patent rights in early research, specifically with stem cells. Also, Congressional incentives, such as reduced costs of using federal resource facilities and equipment, will give private companies inducement to perform or fund research into new lines of stem cells. It is not certain, however, if tax or other incentives would be perceived as circumventing the ban on federal funding of stem cell lines. A tax break may be construed as actually giving federal funds to companies that are developing stem cell lines, which are not supposed to receive federal funds.

Also, state governments will need to take up some of the funding burden. California recently enacted legislation that would allow state funding of stem cell research, stem cell research that would not be

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progress on delivering stem cells to researchers. Progress has been slow, but BresGen is beginning to ship cells to others this fall).

187. *See* Golden, *supra* note 19, at 116-19 (discussing the tedious balance many biotech companies must negotiate); Nenow, *supra* note 127 at 581-82.

188. 15 U.S.C. §§ 3701-14 (2000).

189. 35 U.S.C. §§ 200-12 (2000).

covered under the current federal guidelines.[190] The law took effect on January 1, 2003.[191] The California legislation could provide other states with a model for how to formulate future legislation. However, the law will probably not have any sway toward allowing stem cell research in any future decisions of the President.[192]

Even with the limit on federal funding, public universities may still research on stem cell lines that do not meet the President's criteria, provided the research is kept completely separate from federally funded research and, also, thorough bookkeeping is kept.[193] A brief ruling by the NIH on March 29, 2002 allows for research on stem cell lines that cannot receive federal funding if (1) funding is carefully allocated, and (2) the university has a method for separating costs.[194] This alleviates some financial pressures for universities that may receive private grants, such as the University of California, San Francisco, which has recently received a five million-dollar grant for stem cell research.[195] Still, it is not necessarily certain whether the ability to distinguish federal and non-federal funding will alleviate research problems or cause headaches for university researchers and administrators.[196]

Besides deciding where funding comes from and where funding is applied for a firm developing new embryonic stem cell lines, the actual patent rules could be reformulated. For instance, the courts and the United States Patent and Trademark Office (PTO) could revisit the

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190. S.B. 1272, 2001-02 Leg., Reg. Sess. (Cal. 2002). The bill will allow for research on stem cells, but does not put aside any new funding for stem cell research.

191. *Id.*

192. Jim Warren, *Taking Aim at Washington, California Adopts Law Permitting Embryonic Stem Cell Research*, TRANSPLANT NEWS, Sept. 27, 2002 (quoting Ari Fleischer, White House press secretary, "The president has always said states have authority within their states[,]" but later adding, "[the President] does differ from what the governor of California has done.").

193. National Institute of Health, Office of Extramural Research, Implementation of Issues for Human Embryonic Stem Cell Research Frequently Asked Questions, *at* http://grants1.nih.gov/grants/stem_cell_faqs.htm (last visited Oct. 6, 2002) (answering questions of using ineligible stem cell lines in a university funded laboratory).

194. *Id.*

195. *Intel Chairman Gives UCSF $ 5 Million Matching Grant for Stem Cell Studies*, TRANSPLANT NEWS, Sept. 13, 2002 (stating that Andy Grove, chairman of the Intel Corporation, will be donating $5,000,000 for a new research fund for stem cells).

196. *See* Sheryl Gay Stolberg, *Ruling by U.S. Widens Study of Stem Cells*, N.Y. TIMES, Aug. 7, 2002, at A1. "The best and the brightest young people who are attracted to the science are generally put off by the enormous amount of administrative headaches on the one hand, combined with the controversy on the other." *Id.* (quoting Harvard stem cell scientist Douglass Merton).

utility doctrine.[197] In the past twenty years, the required utility for a patent has received little more than a cursory okay from the PTO. Those applying for patents do not need to show a truly concrete use for their invention to overcome the low standard for utility.[198] Having patent applicants offer a definite use for an invention before they rush to the PTO will alleviate some of the financial pressure of early licensing arrangements, which would free funds for new research. Newly suggested PTO guidelines on utility may indicate some changes in the near future.

The PTO released new utility guidelines on January 5, 2001.[199] Examiners are instructed to reject applications for inventions that do not contain a "specific, substantial, and credible" utility.[200] The new guidelines, which declare genetic sequences alone unpatentable,[201] could be broadened to include "research tools," such as stem cells, which only can be used for performing other research. Though stem cells assist in research directed towards curing diseases, no specific cure comes from the cells. This does not necessarily relate to the statutory need for utility in an invention. "Utility" should have a realistic meaning as opposed to a theoretical, idealistic generalization that anything used must have utility.[202] More importantly, the requirement of having a viable usefulness for an invention should not be a disincentive to investors, since the patents that eventually issue will become more valuable.[203]

For example, suppose a university is researching cancer treatments. The university's scientist believes patent A and patent B, both of which could be considered "research tools," may both be starting blocks for a cancer treatment. However, due to budget constraints, the university can only pay the royalties on one patent. The scientist chooses patent A, which means no profits at all for the holder of patent B. Now, suppose that patent A and patent B are not afforded direct patent rights. The scientist can experiment with either A or B. The scientist may find that invention B offers a viable cancer treatment. Because B is used when it may not have previously been used, the discoverer of B

197. 35 U.S.C. § 101 (2000).

198. *See* Holman & Munzer, *supra* note 135, at 756-57.

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

200. *Id.* at 1098.

201. *Id.* at 1093 (stating that utility must be claimed for a gene sequence for it to be considered patentable).

202. *See* Holman & Munzer, *supra* note 135, at 759-60.

203. *See* Golden, *supra* note 19, at 178-80 (commenting on the impact of the current patent system on the biotech industry).

may now collect profits. Though no patent rights are enforced, the information derived from invention B will still show the contributions of the inventor of B. Eventually, the inventor of B will receive a monetary payback when a viable treatment is found.

The problem with this approach is that it does not create any new "raw materials" to work with. However, the approach does open up more capital that can be used for the creation of new "raw materials," such as new stem cell lines.[204] If less money is spent on prosecuting and litigating patents, more money should be available for research. More raw materials to work with means more of an incentive for scientists and companies not to look outside the United States for research and investment opportunities. Countries, such as Great Britain,[205] Singapore,[206] and Canada,[207] have already enacted guidelines that will allow continuing embryonic stem cell research.[208] The United States needs to be aware that its current stem cell regulations may limit its power and strength on the world biotech market.[209]

VI. CONCLUSION

While society has been improved by current stem cell research that has helped in the fight against diseases, such as cancer or Parkinson's disease, limits on stem cell research are slowing the progress of research.

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204. *See* Nicholas Wade, *Study Expands Range of Stem Cell Abilities*, N.Y. TIMES, Mar. 7, 2002, at A22 (reporting on new uses for adult stem cells). However, Dr. Helen Blau, a stem cell expert at Stanford University, points out that just because adult stem cells have produced results, this is no reason to stop embryonic stem cell research. *Id.*

205. Nigel Hawkes, *Stem Cell Research on Embryos is Approved by Lords*, LONDON TIMES, Feb. 28, 2002, at 6 (setting up guidelines that would allow research on embryonic stem cells).

206. *See* Taiwo A. Oriola, *Ethical and Legal Issues in Singapore Biomedical Research*, 11 PAC. RIM L. & POL'Y J. 497, 497-98 (2002); *Singapore Stem Cell Research Gets Tentative Nod, Cloning Prohibited*, AGENCE FRANCE PRESSE, Nov. 17, 2001, at Int'l News 1 (allowing stem cell research to proceed, but not allowing research aimed at cloning).

207. *See Canada's Stem-Cell Experts Can Use Embryos*, CAP. TIMES (Madison, Wis.), Mar. 5, 2002, at 4A (stating that Canadian scientists may use left-over embryos from fertility clinics. Embryos from abortions may also be used).

208. It should be noted that some countries, such as Australia, are still debating whether to allow stem cell research. *See* Gemma Daley, *Australia May Ban Embryonic Stem Cell Research, Paper Says*, BLOOMBERG NEWS CANBERRA, Feb. 25, 2002 (stating that Prime Minister John Howard's cabinet voted to ban embryonic research, against the recommendations of a parliamentary committee in September 2001).

209. *See* Oriola, *supra* note 206, at 518-20 (discussing recent guidelines which would allow Singapore to conduct research with stem cells). The guidelines are much more permissible than U.S. guidelines, as stem cell research will be allowed under supervision, with the only definite ban being on cloning. *Id.*

Following President Bush's decision to limit federal funding for stem cell development, companies and universities alike are concerned about property rights and where the money will come from to enforce or create these rights. Exceptions for experimental use of inventions and stricter utility requirements for patenting would alleviate some of these costs and concerns.

However, new stem cell lines are needed to continue the advances with regard to finding cures for diseases. Foreign countries, which have ethical issues with regards to stem cells, but not as intensely debated as the United States, such as the United Kingdom,[210] may see an increase in investment and scientists for their research. The negative effect of the funding differential on United States research must be abated. For the interactive model between industry and academia to work, Congress must make concrete concessions towards the biotech industry that will ensure companies will have future incentives to continue research with stem cells.

Likewise, tougher utility patent standards should be enacted for discoveries for which a clear societal benefit is known. While companies and investors may balk at the idea that they will receive less protection for their ideas, this does not necessarily have to be the case. As stated earlier, an organized recording system for research would allow a researcher to claim some eventual rights or royalties in a future invention once that future invention is shown to have a useful purpose. Though companies may not believe it makes economical sense to wait for profits, they may not have to worry about results when biotech jobs move overseas to places such as Singapore.

President Bush's decision does not prohibit new stem cell research, but does not afford new research federal funds for new research, either. Companies involved in biotech research will not sit idle and watch profits go elsewhere; they will follow profits overseas. Research, as a whole, will not be impeded. The stem cell guidelines will just slow the United States' contribution to the overall research picture. Whether by providing tax incentives or other like programs that will give companies reasons for staying in the United States, Congress must realize the potential that will be lost when companies leave the country. Congress should not let its hands be bound by a single executive decision, nor

210. *See* Hawkes, *supra* note 205; Robert Verkaik, *British Couple Given Go-Ahead for an IVF Baby Whose Cells Could Save the Life of Critically Ill Son*, LONDON INDEP., Feb. 23, 2002, at 5 (discussing the allowability of a transplant that is questioned by antiabortion advocates).

should it believe that following President Bush's lead in curtailing stem cell research benefits society.[211]

Furthermore, it should be noted that there are limited resources, no matter where they come from. Because many of the private biotech firms live on the edge of insolvency, they may not have the capability to increase funds.[212] Also, money that comes from outside of the government-industry-university triangle may be affected as well. For instance, after hearing of President Bush's decision to limit stem cell research, Jim Clark, founder of Netscape, limited his gift toward a biomedical research center at Stanford University.[213] Clark, who was to donate $150 million to the University, is withholding $60 million of his donation in protest of President Bush's decision.[214]

While there may be clear ethical reasons to limit funding for stem cell research, it does not appear that these reasons are beneficial to the United States' prosperity. Besides losing possible research avenues, the country will also lose scientists and business to overseas endeavors. Though the President has stood by his decision, Congress, the Court, and the states themselves must take initiatives to lessen the negative effect of the President's decision on stem cell research in the United States.

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211. *See* H.R. 736, 2001-02 Leg., Wis. Stat. 146.347 (2002) (proposing a bill that would make it a crime to conduct any type of stem cell research).

212. *See* Nenow, *supra* note 129, at 581-82.

213. Kelly St. John, *Donor Cuts Off $60 million to Stanford: Entrepreneur Upset by Limits on Stem-Cell Study,* S.F. CHRON. Aug. 31, 2001, at A1.

214. *Id.*