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Stem Cell Research and Patents: An Introduction to the Issues

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Summary

The announcement by President George W. Bush permitting federal funding for human embryonic stem cell research on "existing stem cell lines" has raised several patent-related issues both specific to this situation and part of the general formulation of patent policy. The grant of a patent provides the inventor exclusive rights on its practice for 20 years. This is intended to encourage the additional investment necessary to further develop an idea into a marketable technology. Concurrently, a patent places the concept on which it is based in the public domain. In return for a monopoly right to specific applications of the knowledge generated, the inventor must publish the ideas covered in the patent. Thus, the patent can, and often does, stimulate others to invent "around" existing patents to provide for parallel technical developments or to meet similar and expanded demands in the marketplace.

As with many other biotechnologies, inventions pertaining to stem cells may be subject to patent protection. To be afforded patent rights, a particular stem cell invention must be judged to consist of patentable subject matter, possess utility, and to be novel and nonobvious. In addition, an inventor must file a patent application at the U.S.Patent and Trademark Office. That application must fully disclose and distinctly claim the stem cell invention for which protection is sought. If allowed to issue, the patent grants its owner the ability to exclude others from making, using, selling, offering to sell, or importing into the U.S. the patented invention.

The Bush Administration policy decision limits federal research funding to a discrete number of human embryonic stem cell lines. At least some of these cell lines are subject to patent protection. Scientists who wish to use federal financing to explore certain research possibilities may have few alternatives but to employ a patented cell line. With federal policy having arguably limited research options, some attention might be paid to how patents on exploitable stem cell inventions are used by their proprietors. The arrangements worked out between the Public Health Service and the University of Wisconsin (through its licensing agent WiCell) may be instructive. These, and other licensing policies and practices may be especially appropriate for consideration.

Although the original embryonic stem cell patents owned by the University of Wisconsin were not developed with government support, future intellectual property may arise as a result of federally-funded R&D under the Bush plan. Ownership of patents originating from research performed by institutions outside the federal research establishment but financed by the government is prescribed by P.L. 96-517, commonly referred to as the "Bayh-Dole Act." The law provides small businesses and non-profit organizations title to inventions made under federal funding (grants or contracts) within certain limitations. If new stem cell patents are generated subject to the Bayh-Dole Act, the way the provisions of the statute are applied may be of interest given the specific parameters of the Bush plan. It remains to be seen if the research limitations associated with stem cells will influence the government to exercise the rights conferred in ways distinct from current practice.

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Stem Cell Research and Patents: An Introduction to the Issues

The announcement by President George W. Bush permitting federal funding for human embryonic stem cell research on "existing stem cell lines" has raised several patent-related issues both specific to this situation and part of broader concerns over intellectual property. This report examines the rationale behind the patent system, established in the U.S. Constitution, and its role in promoting innovation in all sectors of the economy. The application of patent law in the area of stem cell research is also discussed. However, the parameters of the Bush Administration plan may generate additional intellectual property considerations with respect to both the private sector and the federal government. To date, research in this area has proceeded without federal financing; thus any resulting patents reside in the private sector. A Memorandum of Understanding for use of certain cell lines has been signed between the Public Health Service and WiCell, the licensing agent of the University of Wisconsin that owns several relevant patents. Still, additional patents may arise from government supported research and development (R&D) in this area. Thus, this report explores the laws that influence the disposition of intellectual property generated under federally-funded R&D.[1]

The Role of Patents

Congressional interest in the availability of drugs and other therapeutics has focused attention on the role of patents in biomedical R&D and the pharmaceutical industry. Enterprises within the pharmaceutical sector frequently obtain patent protection and enforce patent rights, and reportedly place a higher comparative value on patents than do competitors in many other markets. Concurrently, the value of all intellectual property has grown as technology becomes increasingly important to the United States. It is now widely accepted that technological progress accounts for up

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[1]For additional analysis of these issues, please refer to the following CRS reports: *Stem Cell Research*, by Judith A. Johnson, RL31015, 10 August 2001; *An Examination of the Issues Surrounding Biotechnology Patenting and Its Effect Upon Entrepreneurial Companies*, by John R. Thomas, RL30648, 31 August 2000; *R&D Partnerships and Intellectual Property: Implications for U.S. Policy*, by Wendy H. Schacht, 98-862, 6 December 2000; *Patent Ownership and Federal Research and Development: A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act*, by Wendy H. Schacht, RL30320, 11 December 2000; and *Federal R&D, Drug Discovery, and Pricing: Insights from the NIH-University-Industry Relationship*, by Wendy H. Schacht, RL30585, 19 June 2000.

to one-half of the nation's economic growth and is one principal driving force for increases in our standard of living.[2]

The patent system was created by Article I, Section 8, Clause 8 of the U.S. Constitution to promote new discoveries and their reduction to practice, commonly known as innovation. The grant of a patent provides the inventor with a means to capture returns to his invention through exclusive rights on its practice for 20 years from date of filing. This is intended to encourage those, often substantial, investments necessary to further develop an idea and generate a marketable technology. At the same time, the process of obtaining a patent places the concept on which it is based in the public domain. In return for a monopoly right to specific applications of the knowledge generated, the inventor must publish the ideas covered in the patent. As a disclosure system, the patent can, and often does, stimulate other firms or individuals to invent "around" existing patents to provide for parallel technical developments or meet similar and expanded demands in the marketplace.

Innovation typically is knowledge-driven — based on the application of knowledge, whether scientific, technical, experiential, or intuitive. Innovation also produces new knowledge. One characteristic of knowledge that underlies the patent system is that it is a "public good," a good not consumed when used. Patents permit novel concepts or discoveries, typically costly and resource intensive to develop, to become "property" when reduced to practice and therefore allow for control over their use. Patent ownership ". . . create[s] incentives that maximize the difference between the value of the intellectual property that is created and used and the social cost of its creation."[3]

The patent process is designed to resolve the problem of "appropriability," those ". . . factors, excluding firm and market structure, that govern an innovator's ability to capture the profits generated by an innovation."[4] Studies demonstrate that the rate of return to society as a whole generated by investments in R&D is significantly larger than the benefits that can be captured by the person or organization financing the work. It has been estimated that the social rate of return on R&D spending is over twice that of the rate of return to the inventor.[5] Without the protection provided by patents, ideas may be easily imitated, the knowledge associated with an innovation

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[2]Gregory Tassey, *The Economics of R&D Policy* (Connecticut: Quorum Books, 1997), 54. See also: Edwin Mansfield, "Intellectual Property Rights, Technological Change, and Economic Growth," in: *Intellectual Property Rights and Capital Formation in the Next Decade*, eds. Charls E. Walker and Mark A. Bloomfield (New York: University Press of America, 1988), 5.

[3]Stanley M. Besen and Leo J. Raskind, "An Introduction to the Law and Economics of Intellectual Property," *Journal of Economic Perspectives*, Winter 1991, 5.

[4]David J. Teece, "Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing, and Public Policy," in *The Competitive Challenge*, ed. David J. Teece (Cambridge: Ballinger Publishing Co., 1987), 188.

[5]For a list of relevant research in this area see: Council of Economic Advisors. *Supporting Research and Development to Promote Economic Growth: The Federal Government's Role*, (October 1995), 6-7.

dispersed and adapted to other products and processes that, in turn, stimulate growth in the economy. The difficulty in securing sufficient returns to spending on research and development has been associated with underinvestment in such activities.

If discoveries were universally available without the means for the inventor to realize a return on investments, there would result a ". . . much lower and indeed suboptimal level of innovation."[6] While research is often important to innovation, studies have shown that it often constitutes only 25% of the cost of commercializing a new technology or technique, thus requiring the expenditure of a substantial amount of additional resources to bring most products or processes to the marketplace. The grant of a patent provides the inventor with a means to capture the returns to his invention through exclusive rights on its practice. That is intended to encourage those investments necessary to further develop an idea and generate a marketable technology.

The patent system thus has dual policy goals — providing incentives for inventors to invent and encouraging inventors to disclose technical information.[7] Disclosure requirements are factors in achieving a balance between current and future innovation through the patent process, as are limitations on scope, novelty mandates, and nonobviousness considerations (as discussed below).[8] They give rise to an environment of competitiveness with multiple sources of innovation, viewed by some experts as the basis for technological progress. This is important because, as Robert Merges (Boston University) and Richard Nelson (Columbia University) found in their studies, when only ". . . a few organizations controlled the development of a technology, technical advance appeared sluggish."[9]

Not everyone agrees that the patent system is a particularly effective means to stimulate innovation. It has been argued that patents do not work in reality as well as in theory because they do not confer perfect appropriability. In other words, they allow the inventor to obtain a larger portion of the returns on his investment but do not permit him to capture all the benefits. Patents can be circumvented and infringement cannot always be proven. Thus, patents are not the only way, nor necessarily the most efficient means, for the inventor to protect the benefits generated by his efforts. A study by Yale University's Richard Levin and his colleagues concluded that lead time, learning curve advantages (e.g. familiarity with the science and technology under consideration), and sales/service activities were typically more important in exploiting appropriability than were patents. That was true for both products and processes. However, patents were found to be better at protecting the former than the latter. The novel ideas associated with a product often can be determined through reverse engineering — taking the item apart to assess how it was

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[6]Kenneth W. Dam, "The Economic Underpinnings of Patent Law," *Journal of Legal Studies*, January 1994, 247.

[7]Robert P. Merges, "Commercial Success and Patent Standards: Economic Perspectives on Innovation," *California Law Review*, July 1988, 876.

[8]Dam , *The Economic Underpinnings of Patent Law*, 266-267.

[9]Robert P. Merges and Richard R. Nelson, "On the Complex Economics of Patent Scope," *Columbia Law Review*, May 1990, 908.

made. That information then could be used by competitors if not covered by a patent. Because it is more difficult to identify the procedures related to a process, other means of appropriation are seen as preferable to patents, with their attendant disclosure requirements.[10]

The utility of patents to companies varies among industrial sectors. Patents are perceived as critical in the drug and chemical industries. That may reflect the nature of R&D performed in these sectors, where the resulting patents are more detailed in their claims and therefore easier to defend.[11] In contrast, one study found that in the aircraft and semiconductor industries patents are not the most successful mechanism for capturing the benefits of investments. Instead, lead time and the strength of the learning curve were determined to be more important.[12] The degree to which industry perceives patents as effective has been characterized as ". . . positively correlated with the increase in duplication costs and time associated with patents."[13] In certain industries, patents significantly raise the costs incurred by nonpatent holders wishing to use the idea or invent around the patent — an estimated 40% in the pharmaceutical sector, 30% for major new chemical products, and 25% for typical chemical goods — and are thus viewed as important. However, in other industries, patents have much smaller impact on the costs associated with imitation (e.g. in the 7%-15% range for electronics), and may be considered less successful in protecting resource investments.[14]

Despite questions as to their efficacy, firms continue to patent their inventions. In the United States, the number of filed patent applications and issued patents continues to climb. In 1995 inventors filed 221,304 patent applications at the U.S. Patent and Trademark Office; in 2000, that number had increased to 293,244 applications. In a study of 100 companies spanning 12 industries conducted by Edwin Mansfield, about half of the eligible inventions are patented in those sectors that did not consider patents important.[15] That activity appears to be the result of additional perceived benefits including royalty payments, delays to imitators, and the ability to use patents as bargaining tools to meet alternative priorities of the firm. Others speculate that patents are used primarily to measure employee performance and to

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[10]Richard C. Levin and Alvin K. Klevorick, Richard R. Nelson, Sidney G. Winter. "Appropriating the Returns for Industrial Research and Development," *Brookings Papers on Economic Activity*, 1987, in *The Economics of Technical Change*, eds. Edwin Mansfield and Elizabeth Mansfield (Vermont, Edward Elgar Publishing Co., 1993), 254.

[11]Ibid., 255 and 257. See also: Mansfield, Edwin. Intellectual Property Rights, Technological Change, and Economic Growth, in eds. Charles Walker and Mark A. Bloomfield, *Intellectual Property Rights and Capital Formation in the Next Decade*, (New York, University Press of America, 1988), 12 and 13.

[12]Levin, et. al., *Appropriating the Returns for Industrial Research and Development*, 243.

[13]Ibid., 269.

[14]Mansfield, Edwin, Mark Schwartz, and Samuel Wagner. Imitation Costs and Patents: An Empirical Study, *The Economic Journal*, December 1981, in *The Economics of Technical Change*, 270.

[15]Mansfield, *Intellectual Property Rights, Technological Change, and Economic Growth*, 14.

gain access to foreign markets.[16] The low expiration rate prior to the full term of high technology patents relative to patents on less sophisticated technologies may indicate the value that companies assign to such protection, even in industries when the life cycle of the invention is short.[17] According to Suzanne Scotchmer (University of California, Berkeley), the innovator's incentives to patent depend on: "(i) the profitability of marketing the first technology prior to the development of second generation products; (ii) the extent of disclosure that patenting entails; (iii) the ease with which the technology could be reverse-engineered if marketed but not patented; and (iv) the breadth of patent protection."[18]

Patent Law Pertaining to Stem Cell Lines

As with many other biotechnologies, inventions pertaining to stem cells may be subject to patent protection.[19] To be afforded patent rights, a particular stem cell invention must be judged to consist of patentable subject matter, possess utility, and to be novel and nonobvious. In addition, an inventor must file a patent application at the United States Patent and Trademark Office ("USPTO"). That application must fully disclose and distinctly claim the stem cell invention for which protection is sought. This report reviews each of these requirements in turn.

Many stem cell inventions may be judged patentable subject matter under U.S. law. Under the Patent Act of 1952, patents may be granted for any "process, machine, manufacture, or composition of matter."[20] Stem cell inventions would typically be classified as either a composition of matter (such as a purified suspension of stem cells); or as a process (such as a method of preparing or using stem cell products).

That stem cell inventions are derived from living beings does not necessarily bar their patentability. Although a patent will not be granted for inventions that merely duplicate materials found in nature, an inventor may obtain a patent for an artificially modified biotechnological product.[21] Inventions that require the isolation and purification of a stem cell line have been judged to involve a sufficient transformation of raw materials to be patentable. Of three patents (related to "adult" or cord blood

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[16]Levin, et. al., *Appropriating the Returns for Industrial Research and Development*, 257.

[17]Donald J. Quigg, "Safeguarding Intellectual Property — Stimulus to Economic Expansion," in Walker, *Intellectual Property Rights and Capital Formation in the Next Decade*, 40.

[18]Suzanne Scotchmer, "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," *Journal of Economic Perspectives*, Winter 1991, in Mansfield, *The Economics of Technical Change*, 209.

[19]*See generally* U.S. Library of Congress, Congressional Research Service, *An Examination of the Issues Surrounding Biotechnology and Its Effect Upon Entrepreneurial Companies*, by John R. Thomas, Report RL30648, 31 August 2000.

[20]35 U.S.C. § 101.

[21]*See* Michael A. Sanzo, "Patenting Biotherapeutics," 20 *Hofstra Law Review* (1991), 387.

stem cells) that Johns Hopkins University asserted against Cell Pro, Inc.,[22] one claimed a purified suspension of stem cells;[23] another a method of creating a purified suspension of stem cells using certain antibodies;[24] and a third patent claimed a method of using a purified suspension of stem cells in bone marrow transplants.[25] Because none of the products or processes claimed in these patents exists in nature *per se*, each was considered to be patentable subject matter.

Particular stem cell inventions may also fulfill the novelty and nonobvious requirements. The novelty requirement mandates that the invention differ from public domain knowledge.[26] To fulfill the nonobviousness requirement, the invention can not be within the capabilities of a person of ordinary skill in the art.[27] Because particular stem cell inventions may not precisely duplicate what exists in nature, or had been artificially generated by earlier biotechnicians, stem cell inventions may fulfill the novelty requirement. Similarly, the identification, isolation and purification of stem cell inventions often involves the exercise of considerable skill by highly trained scientists.[28] As a result, particular stem cell inventions may also meet the nonobviousness requirement.

Finally, the utility requirement mandates that inventors patent tangible products capable of providing an immediate benefit.[29] According to the United States Supreme Court, the utility requirement enforces the principal that patents are granted for downstream, applied technology, rather than more abstract, upstream knowledge.[30] Otherwise, the Court explained, patents would impede rather than advance subsequent technological progress.[31]

Whether stem cell inventions should be considered to possess utility within the meaning of the patent law has been subject to some debate. Stem cell lines potentially possess widespread laboratory uses and have sometimes been labeled "research tools."[32] Some commentators believe that scientists who wish to use certain "research tools," including some transgenic animals and biological receptors, have sometimes found that these tools are the subject of patent protection. According to these

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[22]*See Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998).

[23]U.S. Patent No. 4,714,680.

[24]U.S. Patent No. 5,035,994.

[25]U.S. Patent No. 5,130,144.

[26]35 U.S.C. § 102.

[27]35 U.S.C. § 103.

[28]*See* Jean deVellis, "Ownership of Cell Lines," 65 *Southern California Law Review* (1991), 697.

[29]35 U.S.C. § 101. *See Brenner v. Manson*, 383 U.S. 519 (1966).

[30]*Brenner v. Manson*, 383 U.S. at 519.

[31]Ibid.

[32]*See* Janice Mueller, "No 'Dilettante Affair: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools," 76 *Washington Law Review* (2001), 1.

observers, royalty obligations and heightened transaction costs resulting from the allowance of patents on research tools threaten the development of new drugs and medical devices.[33] Other commentators believe that patents provide the incentives necessary to facilitate investment and coordination around the complex, costly, and risky activities required to generate research tools, similar to other sorts of inventions.[34]

Under guidelines issued by the USPTO, so long as a single utility is identified for an invention for which a patent is sought, the utility requirement will be considered satisfied. Patent applicants must disclose a "specific, substantial and credible" utility for their inventions, unless such a utility is already well-established.[35] To fulfill the standard set out by the USTPO guidelines, an inventor must identify a particular, "real world" use to which the subject matter claimed can be put, as compared to a general statement of the use of the invention, or a mere statement that the invention can be used to conduct further scientific investigation. In the context of stem cell inventions, inventors have sometimes asserted that particular stem cell lines have therapeutic uses, such as in bone marrow transplantation,[36] aplastic anemia treatments,[37] or efforts to inhibit the growth of prostate tumor cells.[38] If credible, such uses ordinarily suffice to meet the patent law's utility requirement.

Patent rights do not arise automatically. Even if an invention is of the appropriate subject matter, possesses utility, and is new and nonobvious, it will not be subject to patent protection unless an application is pursued at the USPTO. This application must distinctly claim and fully disclose the invention, such that a skilled person may make and use the claimed invention without undue experimentation.[39] For cell lines and other biological inventions, sometimes an inventor must provide a sample of the cell line to a recognized public depository in order to fulfill the enablement requirement.[40]

If allowed to issue, the patent grants its owner the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[41] Patent rights are not self-enforcing. A patentee bears responsibility for monitoring its competitors to determine whether they are using the

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[33]Ibid.

[34] F. Scott Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai and Eisenberg," 95 *Northwestern University Law Review* (2001), 691.

[35]United States Patent & Trademark Office, "Revised Utility Guidelines," 64 *Federal Register* (22 Dec. 1999), 71440.

[36]U.S. Patent No. 4,714,680.

[37]U.S. Patent No. 6,207,802.

[38]U.S. Patent No. 6,267,960.

[39]35 U.S.C. § 112.

[40]See: *Amgen, Inc. v. Chugai Pharmaceutical, Inc.*, 927 F.2d 1200 (Fed. Cir. 1991).

[41]35 U.S.C. § 271.

patented invention or not. Patent proprietors who wish to compel others to observe their intellectual property rights sometimes must commence litigation in the federal courts. In addition to arguing that they do not practice the patented invention, accused infringers may defend on the ground that the patent was improvidently granted by the USPTO and is therefore invalid. Issued patents are presumed to be valid, however, and the burden lies upon the accused infringer to demonstrate that the patented invention lacks utility, would have been obvious, or another ground for defeating the patent.[42] The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[43]

A patentee may license others to practice the patented invention. A patent license essentially consists of a promise by the patentee not to sue the licensee for infringement.[44] In addition to the payment of royalties, licensees often make additional promises in exchange for the license. One such promise is sometimes referred to as a "reach-through" agreement. Under a reach-through agreement, the licensee promises to provide the patentee with rights in future discoveries made by the licensee. These rights range from the payment of royalties, the grant of a license back to the original patentee, or even the requirement that licensees obtain approval of the patentee before passing on or commercializing new discoveries.[45]

Some commentators believe that reach-through agreements do not serve valid social policies, particularly when the licensed patent concerns a "research tool."[46] According to these accounts, reach-through agreements lessen the incentive to complete downstream research, and may discourage the very innovation that intellectual property is intended to promote.[47] In addition, reach-through agreements may allow patentees to leverage their proprietary positions in upstream research tools into a broad veto right over downstream research and product development.[48] Other observers suggest that reach-through agreements present an effective price discrimination and metering tool, allowing the patentee to charge a low base price, while charging higher prices only to licensees whose research is successful.[49]

A number of issued U.S. patents concern stem cell inventions. Through August 28, 2001, a total of 168 U.S. patents with the term "stem cell" in the title had been

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[42]35 U.S.C. § 282.

[43]35 U.S.C. § 154(a)(2).

[44]See: *Fromson v. Western Litho Plate and Supply Co.*, 853 F.2d 1568, 1572 (Fed. Cir. 1988).

[45]Michael A. Heller. and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," 280 *Science* (1998), 698.

[46]Clarissa Long, "Proprietary Rights and Why Initial Allocations Matter," 49 *Emory Law Journal* (2000), 823.

[47]Mark R. Patterson, "When Is Property Intellectual? The Leveraging Problem," 73 *Southern California Law Review* (2000), 1133.

[48]Heller & Eisenberg.

[49]Patterson.

granted, the majority of which appear to associated with "adult" or cord blood stem cell inventions rather than the embryonic stem cells covered by the Bush Administration plan. Because the USPTO maintains many pending patent applications in secret until they are issued as granted patents,[50] the number of filed patent applications concerning stem cell inventions is uncertain. The correspondence between these patents and patent applications, on one hand, and stem cell lines for which federal research grants for embryonic stem cell research may be obtained, on the other, has not been determined.

Several patents pertaining to an embryonic stem cell invention, on research performed by Dr. James A. Thomson, have been the subject of discussion in both the lay and scientific press.[51] These patents, held by a foundation associated with the University of Wisconsin, claim both a method of isolating stem cells and the resulting stem cell line. Some observers reportedly believe that the Wisconsin patents have an extremely broad scope, in that they cover basic tools and techniques of embryonic stem cell research.

Under this view, even those who obtain patents on subsequent improvements may be subject to the dominating Wisconsin patent. In assessing this argument, it is important to understand that an inventor who obtains a patent remains subject to other laws and property rights, including the patents of others. To use a simple example, suppose that Inventor A invents and obtains a patent on a chair. Inventor B later invents and obtains a patent on a rocking chair. Because a rocking chair incorporates an ordinary chair into its design, Inventor B would be unable to manufacture rocking chairs without infringing Inventor A's patent. In these circumstances, the chair patent is often termed a "basic" or "dominant" patent, while the rocking chair patent is termed an "improvement" or "subordinate" patent. Similarly, according to some observers, the Wisconsin patent covers such fundamental stem cell tools and methods that it would dominate subsequent improvement patents.[52]

When considering the scope of protection offered by a "basic" or "dominant" patent, it is important to note that the proprietary rights associated with a particular patent are, generally speaking, only as broad as the technical information disclosed within that patent instrument. Even though a particular patent may be worded broadly, the patent is effective to the extent that its claims are supported by a technical disclosure that enables others to practice the patented invention. Applying this principle to the present circumstances, some observers have noted that the Wisconsin patents appear to have broadly worded claims to fundamental inventions, such as the process of isolating stem cells and the resulting stem cell lines. However, if other scientists invented new methods of isolating stem cell lines that are sufficiently

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[50]35 U.S.C. § 122.

[51]*E.g.*, Sheryl Gay Stolberg, "Patent Laws May Determine Shape of Stem Cell Research," *New York Times* (17 Aug. 2001).

[52]*See* Susan Greenlee, "Dolly's Legacy to Human Cloning: International Legal Responses and Potential Human Rights Violations" 18 Wisconsin International Law Journal Spring (2000), 537.

different from those methods described in the Wisconsin foundation patents, they would be entitled to use and themselves patent their distinct inventions.

On September 5, 2001, the Public Health Service, U.S. Department of Health and Human Services, signed a Memorandum of Understanding (MOU) with WiCell Research Institute, Inc., the licensing agent of the University of Wisconsin regarding the use of certain technologies and materials covered by the Wisconsin patents.[53] The MOU generally parallels the standard uniform biological material transfer agreement used by NIH since 1995. It permits Public Health Service employees, particularly NIH scientists, to utilize the University of Wisconsin embryonic stem cell materials covered by the University's patents for research purposes that meet the relevant criteria for such work. Any new intellectual property arising from this intramural research is to be the property of the Public Health Service/NIH. While there is no expressed statement regarding retention of patent rights, the contract does not negate federal patent law that provides the inventor, in this case the NIH, the rights to any intellectual property generated. The Memorandum does not deny the NIH publication rights so therefore by implication the PHS is free to publish the results of research using Wisconsin materials covered by the University's patent.

The Memorandum of Understanding makes it clear that the use of University of Wisconsin materials are for research purposes only; any future commercial activity is not covered by this document. However, it acknowledges that the results of federally-funded research may lead to products for the marketplace. A separate contract, with WiCell, must be entered into regarding use of any Wisconsin materials for commercial purposes. The parties anticipate that any future agreement for commercial activities will be similar to existing commercial licenses with WiCell. (It should be noted that commercial licenses often use reach-through provisions, although this has not been verified in the case of of WiCell.)

While the memorandum covers research performed by NIH scientists, it also indicates that WiCell agrees to make parallel agreements containing the same provisions with other research institutions receiving federal funding. While these have not been executed, to date, it may be presumed that the university or other non-profit research organization would keep any new intellectual property rights as the Public Health Service does under the current MOU. However, any activities to commercialize these patents are expected to require a separate commercialization agreement with WiCell.

Patents and Federally-Funded R&D

Although the original stem cell patent owned by the University of Wisconsin was not developed with government support, as discussed above, future intellectual

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[53]The Memorandum of Understanding is available at the NIH Office of Technology Transfer Web site at [http://www.nih.gov].

property may arise as a result of federally-funded R&D under the Bush plan.[54] Ownership of patents originating from research performed by institutions outside the federal research establishment but financed by the government is prescribed by P.L. 96-517, Amendments to the Patent and Trademark Act. This law, commonly referred to as the "Bayh-Dole Act" after its two main sponsors, former Senators Birch Bayh and Robert Dole, provides small businesses and non-profit organizations title to inventions made under federal funding (grants or contracts) within certain limitations.[55]

The Bayh-Dole Act evolved out of congressional interest in developing a uniform federal patent policy to promote the utilization of inventions made with the support of the federal research establishment.[56] Such action was deemed necessary because, at the time the legislation was under consideration, only 5% of federally-owned patents were being used. While there were possibly several reasons for such a low level of utilization (including no market applications), this was thought by many to be one consequence of the practice by most agencies of taking title to all inventions made with government funding while only permitting the nonexclusive licensing of contractor inventions.[57] Without title to inventions, or at least exclusive licenses, companies may be less likely to engage in and fund the additional R&D necessary to bring an idea to the marketplace. The legislation, by providing universities, nonprofit institutions, and small businesses with ownership of patents arising from federally-funded R&D, offers an incentive for cooperative work and commercial application. Royalties derived from intellectual property rights provides the academic community an alternative way to support further research and the business sector a means to obtain a return on their financial contribution to the endeavor.

In enacting P.L. 96-517, the Congress accepted the proposition that vesting title in a contractor will encourage commercialization and that this should be used to foster innovation in specific segments of the economy. As stated in the law:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally-supported research and development; . . . to promote collaboration between commercial concerns and nonprofit organizations, including universities; . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [and] to ensure that the Government obtains sufficient rights in federally-supported inventions to meet the needs of the

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[54]*National Institutes of Health (NIH) Update on Existing Human Embryonic Stem Cells*, 27 August 2001 available at : [http://www.nih.gov]. See also: Congressional Research Service, *Stem Cell Research*, by Judith A. Johnson, CRS Report RL31015, 10 August, 2001.

[55]For a more detailed discussion of the Bayh-Dole Act and related legislation see: Congressional Research Service, *Patent Ownership and Federal Research and Development: A Discussion on the Bayh-Dole Act and the Stevenson-Wydler Act*, by Wendy H. Schacht, CRS Report RL30320, 11 December 2000.

[56]House Committee on Science and Technology, *Government Patent Policy*, 95th Cong., 2nd sess., May 1978, H.Rept. Prt. 4.

[57]Ibid., 5.

> Government and protect the public against nonuse or unreasonable use of inventions. . . .[58]

The anticipated paybacks to the country through increased revenues from taxes on profits, new jobs created, improved productivity, and economic growth were seen by Congress as a balance for the initial cost of the technology to the government or any potential unfair advantage to any recipient.

Each nonprofit organization (including universities) or small business is permitted to elect (within a reasonable time frame) to retain title to any "subject invention" made as a result of R&D funded by the federal government; except under "exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter."[59] The owner of the intellectual property must commit to commercialization of the patent within a predetermined time frame agreed to by the supporting agency and the performing organization. As stated in the House report to accompany the bill (H.R. 6933), "the legislation establishes a **presumption** [emphasis added] that ownership of all patent rights in government funded research will vest in any contractor who is a nonprofit research institution or a small business."

Certain rights are reserved for the government to protect the public interest. The government retains ". . . a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world. . . ." The government also retains "march-in rights" that enable the federal agency to require the contractor (whether he owns title or has an exclusive license) to ". . . grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants. . ." with due compensation, or to grant a license itself under certain circumstances. The special situation necessary to trigger march-in rights involves a determination that the contractor has not made efforts to commercialize within an agreed upon time frame or that the "action is necessary to alleviate health or safety needs. . ." that are not being met by the contractor (15 U.S.C. §203).

The Bayh-Dole Act also addresses the licensing of inventions to which the government retained title typically because of past agency practices or because of a public interest. Title 35 U.S.C. §209 proscribes the licensing of this type of invention (except under certain conditions). The law permits federal departments to offer nonexclusive, exclusive, or partially exclusive licenses under certain conditions and with specific rights retained by the government. These include the right to terminate the license if commercialization is not pursued as provided in the business plan or if the government needs the license for public use. The agencies are required to inform the public about the availability of a patent for licensing. In providing licenses, small businesses are given preferences and licensees must agree that ". . .any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States."

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[58]35 U.S.C. §200

[59]Ibid.

Issues and Observations

The policy articulated by the Bush Administration limits federal research funding to a discrete number of human embryonic stem cell lines. At least some of these cell lines are subject to patent protection. Scientists who wish to use federal financing to explore certain research possibilities thus may have few alternatives but to employ a patented cell line. With federal policy arguably limiting research options, some attention might be paid to how patents on exploitable stem cell inventions are used by their proprietors. Licensing policies and practices may be especially appropriate for consideration.

One possible option is an examination of the propriety of reach-through agreements. According to opponents of reach-through agreements, owners of patents on fundamental biotechnological research tools could use their proprietary position to influence or hold back competing innovations resulting from stem cell research. The persistence of this commentary suggests that the use of reach-through agreements in the biotechnology industry might be subject to review. If reach-through agreements were viewed unfavorably, legislative options include declaring such agreements unenforceable or calling for their scrutiny by the relevant antitrust and competition authorities.

Another approach would be to consider the possibility of an award of a compulsory license on patents for embryonic stem cell inventions. A compulsory license allows a competitor of the patent owner to use the patented invention without the patent owner's permission.[60] Although compulsory licenses have played only a minor role in the United States patent system,[61] many foreign patent statutes include such provisions.[62] These statutes typically require an interested party formally to request the compulsory license from the foreign government. Competent authorities then decide whether to grant the license as well as the terms of any granted license. Grounds for granting a compulsory license include the abusive exercise of patent rights, lack of domestic manufacture of the patented product, commercialization of the patented good that does not satisfy the needs of the local market and national emergencies.[63] While some accounts suggest that formal compulsory licensing proceedings are commenced only infrequently, the mere existence of a compulsory licensing statute may do much to encourage bargaining between patentees and would-

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[60]Robert Sherwood, "Intellectual Property and Investment Stimulation: The Ratings of Systems in Eighteen Developing Countries," 37 *IDEA* (1997), 261.

[61]*Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176 n.21 (1980).

[62]Gianna Julian-Arnold, "International Compulsory Licensing: The Rationales and the Reality," 33 *IDEA* (1993), 349.

[63]*Ibid.* For studies of specific compulsory licensing provisions of individual nations, see, for example, Rafael V. Baca, "Compulsory Patent Licensing in Mexico in the 1990's: The Aftermath of NAFTA and the 1991 Industrial Property Law," 8 *Transnational Lawyer* (1995), 33; Robert E. Rosenthal, "The Chinese Patent System," 17 *Law and Policy in International Business* (1985), 907; John M. Wechkin, "Drug Price Regulation and Compulsory Licensing for Pharmaceutical Patents: The New Zealand Connection," 5 *Pacific Rim Law & Policy Journal* (1995), 237.

be users of the patented invention.[64] It should be noted that World Trade Organization agreements, to which the United States has acceded, to some degree restrict the ability of signatories to enact laws authorizing compulsory license awards.[65]

From a broader perspective, the issue of whether living organisms are merely unpatentable products of nature or whether ethical or policy considerations should bar their patenting continues to command public attention. Two principal issues have arisen regarding biotechnology patenting. First, observers have fundamentally questioned whether patents should be granted for living inventions, genetic materials and other biotechnologies. Ethical issues and concerns over genetic diversity animate many of these objections. Supporters of biotechnology patenting counter that trade secret protection is a less attractive social alternative, observe that patents have long been granted for biotechnologies, and question whether the patent law is the appropriate vehicle for technology assessment.

Commentators have also differed over the extent to which an inventor must show a specific, practical use for a biotechnology in order to be awarded a patent. Some observers favor a strict view of the utility requirement due to concerns over overlapping upstream patents that discourage research and commercialization. Others believe that the utility requirement should be applied leniently, stating that a strict view of utility will only lead to industry concentration and that biotechnology research tools cannot be meaningfully distinguished from other sorts of inventions.

At this point it is unclear if federal research will generate new embryonic stem cell patents subject to the Bayh-Dole Act. If so, the way the provisions of the statute are applied may be of interest given the specific parameters of the Bush plan. Under these research limitations, might the government exercise the rights conferred in a way different from current practice? Will the government use its license ". . .to practice or have practiced for or on behalf of the United States any subject invention throughout the world. . . . " to expand access for scientists? Might the research constraints create a situation where the government utilizes march-in rights, although to date they have not been invoked?

The Bayh-Dole Act is intended to provide ownership of intellectual property derived from government funding in return for the commercialization of the results of this work. However, as the environment within which R&D and innovation are performed changes, and given the specifics of the Bush plan relating to embryonic stem cell research, new issues may have to be addressed. Disputes have arisen over competing claims to intellectual property developed under government-industry ventures. Concerns have been expressed regarding the rights of companies to set prices on pharmaceuticals and therapeutics that were developed in part with federal funding or in collaboration with federal agencies. Problems have been encountered in obtaining technologies for research use by federal laboratories because of

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[64]Sarah Boseley, "Opinion: Pharmaceuticals move their battleground to Brazil to stem the tide of cheaper drugs," *Irish Times* (20 April 2001), 14.

[65]Congressional Research Service, *HIV/AIDS Drugs, Patents and the TRIPS Agreement: Issues and Options*, Thomas, John R., RL31066, 27 July 2001.

apprehensions over diminished effectiveness of intellectual property if new applications are discovered. As these and other related issues continue to be explored, the information contained in this paper and the additional referenced reports are presented as background for any additional congressional interest and oversight.