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*2002 U. Ill. J.L. Tech. & Pol'y 435***LENGTH:** 16775 words**NOTE: SELLING THE STEM CELL: THE LICENSING OF THE STEM CELL PATENT AND POSSIBLE ANTITRUST CONSEQUENCES**

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SUMMARY:

... The isolation of human stem cells has generated considerable excitement, creating the possibility of medical cures for many of mankind's greatest illnesses and afflictions. ... Third, the exclusive license from the inventive entity behind the stem cell patent to a biotechnology company and this company's proposed licensing practices have caused concern over the possible restrictive effect on stem cell research. ... While the broad scope of the stem cell patent as written may cause considerable concern as to the availability of the technology to others, scientists may still find a way to design around the patent in order to conduct their research, assuming that the patentee refuses to license to them. ... In other words, Geron could insert a licensing provision providing them with either a sole exclusive license to, or the assignment of, all future patented technologies arising from the stem cell patent. ... An example of a proposed equitable compulsory licensing system would provide a reasonable licensing fee (which would depend on the commercial value of any products developed from the research allowed under the stem cell patent) to Geron and grant the licensee the ability to pursue stem cell research. ...

HIGHLIGHT: The isolation of human stem cells and subsequent patenting of the stem cell technology has caused considerable scientific excitement and moral outrage. Ignored, however, has been the very powerful position in which the exclusive licensee of the stem cell patent, Geron Corp., sits. Geron's position is powerful because the stem cell patent is very broad in scope. In addition, federal funding limitations on stem cell research established by the Bush Administration have placed Geron in the position to potentially control all stem cell research and development. Several commentators have expressed concern over a single corporate entity having such power and control over this groundbreaking biotechnology, which has the possibility of affecting everyone's health and well-being. This Note discusses the background of patent and antitrust laws and the tension among law, stem cell technology, and the stem cell patent. Further, this Note explores several licensing provisions Geron may wish to utilize in selling the stem cell patent and the possible antitrust consequences. All of the licensing provisions examined are analyzed in light of the Department of Justice and Federal Trade Commission's Antitrust Guidelines for the Licensing of Intellectual Property. The Note concludes by analyzing possible solutions espoused by several commentators and then recommends that no court or Congressional action be taken to ensure that Geron licenses the stem cell patent. Instead, this Note recommends that the market dictate which terms Geron will or will not be able to include in any licensing of the stem cell patent.

TEXT:

[*435] I. Introduction

The isolation of human stem cells has generated considerable excitement, n1 creating the possibility of medical cures for many of mankind's greatest illnesses and afflictions. At the same time, this [*436] development has generated controversy among those concerned with the ethical and moral dangers of embryonic science. Receiving less attention

are issues concerning the licensing of the intellectual property to this discovery. Scientists see one of the greatest medical breakthroughs of mankind, church leaders see scientists playing God and creating life simply for use as a medical tool, but what about the patent attorneys? Patents, typically ignored by the general public, have become a central force in the development and licensing of biomedical inventions that affect each and every member of the general public on a daily basis. However, certain uses of a patent may run afoul of the antitrust laws. For example, should the stem cell patent owner decide to choose one or a combination of several licensing provisions in order to "sell the stem cell," a number of interesting antitrust issues arise.

This Note deals with neither the excitement over the medical possibilities arising from the stem cell nor the ethical and moral controversy surrounding stem cell or embryonic science. Rather, this Note focuses on the possible antitrust issues that may arise should the stem cell patent owner decide to employ one of several licensing provisions. This Note concludes that most of the possible licensing provisions discussed in "selling the stem cell" will be found legal and that the stem cell patent owner will have several options in licensing the technology. However, the use of grantback provisions in an unreasonably restrictive manner will likely violate the antitrust laws.

In addition, this Note addresses two possible "solutions" to past licensing issues surrounding patents, and more specifically, biotechnology patents. Specifically, this Note examines whether the stem cell patent should be invalidated on public policy grounds, as several commentators have argued, or whether a court or Congress should enforce a compulsory licensing regime. However, the ultimate conclusion is that neither of these proposed "solutions" are applicable to the stem cell patent, as the cost of enacting either of these "solutions" will outweigh any benefit derived. Therefore, it is the author's perspective that, difficult as it may be for those who wish to see unrestricted, free access to the stem cell technology, our established market system should be allowed to perform as it always has and that no court or Congressional action is required for our medical technology to continue to advance.

II. Background on Stem Cells, the Patent Law System, and the Antitrust Laws

The controversy at issue lies at the intersection of three broad areas, namely science, patent law, and antitrust law. One basic purpose of science, and more specifically biotechnology, is to prolong and improve our lives. A purpose of the patent laws is to encourage innovation by [*437] exchanging a time- and scope-limited monopoly for the disclosure of new innovations to the public. The antitrust laws are designed to protect the public from the adverse economic effects of trust activity. However, these three areas can interfere with each other's purposes. For example, should a medical innovation that could possibly save or improve millions of lives be stifled by a single patent in the hands of one who wishes the technology to remain largely unavailable for the term of the patent? Or should the government step in with the antitrust laws and interfere with our long-established patent system to prevent such an occurrence? In the interest of finding a solution to this very real and very severe problem, one must first understand each of these areas.

A. A Brief Background to the Stem Cell

A stem cell is the primordial master cell in the human body; it has the potential to develop into any one of the human body's tissues or organs. n2 This ability to develop into any one of the body's tissues or organs is known as pluripotentiality. n3 One of the great scientific features of stem cells is the ability to divide for indefinite periods of time while giving rise to the special cells that will form human tissues and organs. n4

The aspect of stem cell technology that has caused considerable religious and moral controversy is the source of stem cells. While stem cells may be obtained from a variety of locations, n5 embryonic stem cells are obtained from the inner cell mass of a human embryo. n6 The embryos from which these stem cells are taken are left over from in vitro fertility treatments. n7 This has caused considerable controversy and consternation among opponents of abortion, as the embryos are destroyed in the process of obtaining the stem cells. n8 Once the stem cells have been isolated, they are placed into a culture dish with various growth factors and chemicals. n9 Eventually, the stem cells are harvested and placed into another culture where they may be grown into the desired cells, tissues, or organs. n10

The stem cell technology has an outstanding medical potential. Many human diseases are caused by the disruption of cellular function or [*438] tissue failure. n11 This disruption causes diseases such as diabetes, which, for example, may possibly be cured by a transplant enabled by stem cell technology. n12 Stem cells, when grown into specialized tissues and organs, may be used to repair or replace tissues and organs damaged by diseases. n13

However, at this early stage in the research process, stem cells are useful as research tools in many facets of human

cells. n14 For example, stem cell research may provide medical assistance in the fight against various diseases such as diabetes, Alzheimer's, Parkinson's, heart disease, spinal injury, stroke, burns, osteoarthritis, rheumatoid arthritis, and other diseases. n15 Stem cell research may even help in the fight against cancer. n16 While an organ transplant may treat some of these diseases, the number of Americans suffering from these diseases is far greater than the number of organs available for transplant. n17 Therefore, the full utilization of stem cell technology could curtail this organ demand.

Proponents of the use of stem cell technology have tremendous excitement over these possible benefits. The development of the ability to isolate human stem cells "holds the very real potential to have a substantial impact on the welfare of almost every human on the planet" n18 As stated by the White House, the possible benefits of stem cell research "may eventually lead to therapies that could be used to treat diseases that afflict approximately 128 million Americans." n19

B. Overview of the Scope and Purposes of the Patent Law System

The purposes of the U.S. patent system are basically two-fold: to promote innovation and the "progress of science and the useful [*439] arts," and, correspondingly, to benefit the U.S. economy. n20 Patent rights confer on the patentee an exclusive right to exclude others from practicing the invention for a term of years, which currently stands at twenty years. n21 These rights may be licensed or assigned to another, similar to any other form of personal property. n22 The protections afforded by the patent laws encourage innovation by providing rights that act to subsidize investments in innovation. n23

The scope of legal protection conferred by the patent is determined by the claims of the patent. n24 The practicing of an invention that does not fall within the claims of the patent or their equivalents does not infringe the patent. A patent infringer may be liable for damages plus increased damages, court costs, attorney fees, and may be bound by an injunction against further production of infringing products. n25

C. Antitrust Laws and Intellectual Property

The antitrust laws in the United States have purposes similar to the patent laws. n26 The antitrust laws are primarily intended to foster competition by removing unreasonable restraints on trade, thereby forcing competitors to compete to seek new innovations. n27 Patents are a [*440] legally granted monopoly that could otherwise be used to cause unreasonable restraints on trade. Naturally, the patent system of granting scope-and-time-limited monopolies may be in tension with the antitrust purpose of preventing unreasonable monopolies. n28 In addition, certain methods of licensing patent rights, particularly with the licensing practices of biomedical patents with broad scopes of protection, may interfere with the antitrust laws. n29 In general, as long as a patentee enforces his or her patent within his or her statutorily granted rights, there would be no antitrust violation. n30 However, moving away from this "shield" use of the protection afforded by the patent laws to a "sword" [*441] use to unreasonably restrain competition may cause the patentee to be liable for antitrust violations. n31

III. The State of the Stem Cell Patent

The intersection of antitrust and patent laws with the stem cell patent is of significant interest and controversy due to three main factors. First, the scope of the stem cell patent is very broad and has the potential to affect the subsequent use of the majority of stem cells in medicinal research. Second, the White House limitation on federal funding for stem cell research will place significant restrictions on fundamental stem cell research. Third, the exclusive license from the inventive entity behind the stem cell patent to a biotechnology company and this company's proposed licensing practices have caused concern over the possible restrictive effect on stem cell research.

A. The Scope of the Stem Cell Patent

The Wisconsin Alumni Research Foundation ("WARF") holds the patent for the embryonic stem cells isolated by the University of Wisconsin biologist James A. Thomson. n32 The stem cell patent is very broad. n33 The patent covers both the method for isolating stem cells and the method for transplanting the stem cells into a human being. n34 The scope of the patent also encompasses human embryonic stem cells, regardless of their "creator." n35 The claims are allegedly so broad and powerful that stem cells within and outside the federal funding limitations imposed by the Bush Administration n36 will be within the scope of the patent. n37

In most every instance, a broad patent over a fundamental innovation is a powerful patent, with the patentee possibly having the ability to control subsequent developments or improvements arising [*442] from the patent. n38 Such power in the hands of a patentee may hinder the patentee's desire to license the broad patent, because withholding licenses could preclude competitors from developing competing technologies or from designing around the patent, which would likely require use of the patent. n39 Such resistance to licensing could also result from a desire to gain scientific fame (and, thus, additional investors) and future intellectual property rights arising from the original patent. n40

Several commentators have postulated that such broad patent rights actually cause innovation to be slowed down due to the inability of the patentee to license the technology effectively. n41 These fears of the ill effects of broad patent rights on future innovation are amplified when speaking about biotechnology, as in the case of the stem cell patent. n42 [*443] This amplification of concerns arises for two main reasons. First, as the term "biotechnology" refers to the application of biological science and technology to life, typically to prolong or improve life, it has a tremendous effect on everyone. Second, the biotechnology industry is considered one of the fastest growing segments of the American economy. n43 Third, when considering exclusive rights in the realm of genetic research, as in stem cells, "the thought of a large biotechnology company holding an exclusive right to research and manipulate human genetic material provokes many reactions – from moral revulsion to enthusiasm about the possibilities for therapeutic advancement." n44

Given the considerable breadth of the stem cell patent, the promising subject matter of the stem cell patent, n45 and the exclusive nature of the rights owned over the process of isolating stem cells, the sheer power of the stem cell patent becomes clear. In essence, any scientist or laboratory wishing to conduct any research involving human stem cells must use the stem cell patent. The ultimate effect is a virtual bottleneck of patent rights. If the holder of broad patent rights (required for further research in the relevant field) refuses to use or license the patented technology, then a "bottleneck" of innovation will occur. No further development of technologies based on the patent will occur. This problem will also result from the inability of the patentee to effectively develop the basic patented technology, while refusing to license to competitors. This places considerable power in the hands of WARE, both in an "economic innovation market sense" n46 and in a "research-controlling sense."

Combine these fears of broad, exclusive biotechnology patent rights with the added twist of the exclusive patent rights relating to a process by which all future related research and development will be required to use, and the severity of concerns and fears becomes apparent. n47 For example, the suppression of broad patent rights to a fundamental technology will invariably cause future research and development in the relevant field to be slowed until such technology is either licensed or the [*444] patent expires. These fears lead to unease over the future of research and development in the related biotechnology fields:

A license that provides complete exclusivity to a technology that is also a research tool may result in some product development in the short-term, but it will close off opportunities to advance science and develop other products in the long-term. The only way to maximize the benefit to the public is to ensure that both research use and the potential for commercial development are preserved. n48

In addition, these fears lead to concern over the possible antitrust issues, where "there may be many situations in which the biotechnology rights cover processes for producing unpatented end-products. Any attempt to grant one licensee any exclusive rights to sell raises antitrust and misuse questions." n49 Yet, it is important to remember that the possible ill effects of the stem cell patent arise not from the considerable scope of the patent, but from how this powerful patent is used and licensed.

While the broad scope of the stem cell patent as written may cause considerable concern as to the availability of the technology to others, scientists may still find a way to design around the patent in order to conduct their research, assuming that the patentee refuses to license to them. However, given the Bush Administration's limitations on federal funding of stem cell research, this stem cell "thicket" has become even more entangled and controversial.

B. The Funding Issues

While the stem cell patent already grants a considerable economic and research monopoly, the Bush Administration's announcement that federal funding of stem cell research would be limited n50 has further increased both the power and possibility of misuse of the stem cell patent. n51 On August 9, 2001, President George W. Bush announced that federal

funding for stem cell research would be limited to the then-existing stem cell lines. n52 This decision was primarily made in response to [*445] the clash of ethical concerns and the push for unrestrained embryonic research. n53 The National Institutes of Health ("NIH") has phrased the federal funding limitation more specifically:

Federal funds [may] be used for research on existing human embryonic stem cell lines as long as prior to [President Bush's] announcement (1) the derivation process (which commences with the removal of the inner cell mass from the blastocyst) had already been initiated and (2) the embryo from which the stem cell line was derived no longer had the possibility of development as a human being. In addition, the President established the following criteria that must be met: The stem cells must have been derived from an embryo that was created for reproductive purposes; The embryo was no longer needed for these purposes; Informed consent must have been obtained for the donation of the embryo; [and] No financial inducements were provided for donation of the embryo. n54

The effects of this federal funding limitation in conjunction with the scope of the stem cell patent cannot be overstated. While the patent system is designed to foster innovation, basic research that provides such innovation requires basic funding dollars to provide patentable subject matter. Although not all research funding results in profitable gains, the main driving force in the biotechnology industry for providing research dollars is the possibility of gaining a larger piece of the multi-billion dollar biotechnology market. n55

There are three "key players" in the realm of biotechnology research and development, namely, the government, universities, and industry. n56 Each one of these players has a unique and individualized interest. The government is primarily interested in "advancing the 'national interest' in scientific and technological progress," n57 which it principally achieves through the NIH. n58 Universities seek a similar "public interest" goal, while "seeking the freedom to pursue the reputational and grant-winning gains that come from having a recognized capacity to perform front-line science." n59 Finally, private industry seeks [*446] the most self-centered interest, which is to "advance their capacity to generate revenues." n60

So where do funding dollars for universities come from? Although private industry and the federal government both contribute to university research, their contributions are clearly skewed in relation to each other. For basic scientific research, in total, "although industry accounts for about sixty percent of total funding for research and development, the federal government dominates the provision of funding for basic science, and most basic science, including most publicly funded basic science, is done at the university." n61 In the context of pure university research and development, "industry's contribution ... accounted for less than seven percent of total annual university funding." n62 These percentages lead to an assumption of university independence from private industry however, "although university royalties from patent protection remain relatively small compared to federal funding for research, individual university researchers have increasingly established research-related ties with private industry, a development that has led to concerns about conflicts of interest that might corrupt the truth-making mission of the academic enterprise." n63 Otherwise stated, concerns have arisen due to the relationship between biotechnology companies and research universities where funding dollars are exchanged for intellectual property rights arising from this research. In the context of private industry research and development, "the federal government is still the pre-eminent funder of the basic research upon which the biotechnology industry relies." n64

The Bush Administration's federal funding limitation on stem cell research, taken in conjunction with the large role that federal funding has in biotechnology research and development, has severely limited the scope and ability of many entities, whether industrial or academic, to conduct stem cell research. This limitation has basically confined all those who wish to conduct stem cell research to use the stem cell patent. This, in turn, has effectively increased the power, and hence the value, of the already broad stem cell patent. n65 The funding limitations, however, are not the only restraints on the freedom of stem cell research and development. A licensing arrangement has made the situation much more complicated.

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C. The Stem Cell Licensing Mess

The possible problems with the stem cell patent (and the licensing of it) arise from the very powerful situation in which Geron Corp. ("Geron") sits. Geron is the exclusive licensee of WARF. While the stem cell patent was obtained through the research and development efforts of the University of Wisconsin, WARF originally held the patent rights. n66 Geron

privately funded the initial human embryonic stem cell derivation at the University of Wisconsin in exchange for an exclusive license to any patent that the University of Wisconsin developed and assigned to WARF. n67

WARF agreed to license exclusive commercialization rights to six types, or lines, of stem cells to Geron. n68 Within this license is an option that grants Geron access to additional cell lines under the same exclusive agreement. n69 This puts Geron in a very powerful position:

President Bush's decision may have strengthened the hands of the Wisconsin group [WARF] and Geron. By refusing to allow taxpayer money to finance creation of new cell lines in this country, Mr. Bush reduced the chances that scientists would derive and patent cells that might challenge Wisconsin's dominance in the field ...

... .

[The exclusive rights granted to Geron], coupled with the Wisconsin patent, might mean that anyone seeking to develop commercial applications of stem cells in these six areas must negotiate with Geron first. n70

On July 26, 2001, Geron attempted to exercise this option, but WARF sued in federal court seeking a finding that the exercise of the option was invalid. n71 As the situation currently stands, Geron's exclusive licensed rights to develop the six stem cell lines, combined with the scope of the stem cell patent and President Bush's limitations on federal funding, require that any party wishing to develop stem cells must first deal with Geron. n72

Note: On January 10, 2002, Geron announced that it would be content to retain its exclusive rights under its exclusive licensing agreement with WARF to only three types of stem cells. n73 Geron also agreed that it does not have the option to gain exclusive rights to additional cell types, [*448] contrary to the initial licensing agreement. n74 Geron has additionally agreed to freely license the stem cell patent rights for research-only uses. n75 However, there still remains the possibility of stifling innovation as "some researchers might not want to begin research if there is a chance they would be blocked from commercial development of their results." n76 While this agreement, which was the result of a federal lawsuit, n77 does relieve some of the antitrust concerns over the possible licensing practices, it does not affect the analysis of this Note. The possible antitrust violations that could arise from the licensing restrictions of such a broad biotechnology patent apply equally well to stem cells and other biotechnological developments. n78

The remainder of this Note's focus will be on the unique situation created by the stem cell patent. The situation is unique for several reasons. First, the stem cell patent is new, groundbreaking, and broad intellectual property. Second, the federal funding limitations placed by President Bush have essentially forced the hands of all possible researchers into using or infringing the stem cell patent. Third, WARF, the owner of the stem cell patent, has granted an exclusive license to Geron. Such a situation has given rise to several possible scenarios where an antitrust violation or violations could occur through Geron's possible licensing provisions or practices. The Note will now focus on several, but not all, of these possible licensing practices and provisions and examine how the situation may be dealt with considering the unique situation of the stem cell patent.

IV. Possible Licensing Provisions and the Application of the Antitrust Guidelines

This Note will address four possible licensing provisions in which the licensing of, or failure to license, the stem cell patent, under the exclusive licensing arrangement and President Bush's limits on federal funding, may raise antitrust concerns. These licensing provisions are: tying arrangements, "suppression of technology" licensing techniques (both refusals to use or to license), exclusive licenses, and grantbacks. All of the possible licensing provisions and practices will be examined under the Department of Justice ("DOJ") and Federal Trade Commission's ("FTC") Antitrust Guidelines for the Licensing of [*449] Intellectual Property. n79 In addition, the stem cell patent licensing agreements must be examined in light of the fact that the stem cell market is an innovation market under the Antitrust Guidelines. n80 Upon examination of each of these licensing techniques, it will be shown that it is unlikely for most of the provisions to violate any antitrust laws. However, an overly broad application of a grantback provision may cause antitrust concerns to arise.

Additionally, several commentators have proposed possible solutions applicable to the situation of the stem cell patent. Two of these proposed solutions are to invalidate the stem cell patent on public policy grounds or to force a compulsory licensing regime for the stem cell patent. However, this Note concludes that none of these solutions would be the most efficient and economical manner in which to proceed. Instead, the existing patent and antitrust laws should remain as they are to allow market pressures to compel the open licensing of the stem cell patent.

A. The Licensing of Intellectual Property

The DOJ and the FTC have attempted to assist intellectual property owners in distinguishing between questionable and allowable licensing practices in the Antitrust Guidelines. n81 In the Antitrust Guidelines, three basic principles of any intellectual property licensing are stated, namely: intellectual property is treated as any other form of personal property; n82 no presumption of market power arises as a result of intellectual property licensing; n83 and, in general, the licensing of intellectual property is procompetitive and consistent with the purposes and principles of the antitrust laws. n84

The Antitrust Guidelines are a major step by the DOJ and FTC in recognizing the procompetitive aspects of the licensing of intellectual property. n85 Frequently, intellectual property owners will include [*450] restrictive provisions in their licensing agreements. n86 In order to evaluate the possibility of these licensing provisions violating antitrust laws, the Antitrust Guidelines assert that such restrictions are generally evaluated under the rule of reason. n87 The Antitrust Guidelines are not a rhetorical or theoretical guide and should not be taken lightly due to the serious consequences of antitrust violations. n88 As a general guideline, "licensing arrangements raise concerns under the antitrust laws if they are likely to affect adversely the prices, quantities, qualities, or varieties of goods and services either currently or potentially available." n89

1. The Rule of Reason and Per Se Illegality

The rule of reason inquiry asks "whether the restraint is likely to have anticompetitive effects and, if so, whether the restraint is reasonably necessary to achieve procompetitive benefits that outweigh those anticompetitive effects." n90 However, some licensing restrictions are so plainly anticompetitive in nature that they are deemed illegal per se. n91

Part of the rule of reason inquiry is an analysis of the relationship between the licensor and licensee. These parties will either be in a horizontal or vertical relationship. A horizontal relationship is evidenced by the ability of the two parties to compete with each other in the absence of any licensing restrictions. n92 Antitrust concerns are more likely to be raised in a situation involving a horizontal relationship for the simple fact that the restrictive license may be impeding competition n93 between likely competitors. n94 A vertical relationship is evidenced by the [*451] complementary nature of the interactions between the licensing entities, such as supplier and producer. n95 In examining the licensing restrictions in a vertical relationship, the rule of reason inquiry will focus on the likelihood of harm to other entities in horizontal relationships with any of the licensing parties and to other relevant markets. n96

2. Innovation Markets

A new feature of the Antitrust Guidelines is the consideration by the DOJ and FTC of the possible anticompetitive effects of licensing restrictions on innovation markets. n97 An innovation market is defined as a market "consisting of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development." n98 An analysis of a licensing restraint on an innovation market will consist of an assessment of the restraint's effect on competition in future development of new processes or goods. n99 Additionally, the DOJ and FTC will only examine licensing restrictions in the context of an innovation market when the ability of the licensing parties to engage in the pertinent research and development is "associated with specialized assets or characteristics of specific firms." n100

However clear the above analysis may appear to be, some commentators have voiced concern over the vague language employed by the DOJ and FTC. n101 For example, it is difficult to delineate what constitutes a "specialized asset." n102 Nevertheless, from this new feature, the "innovation market," it appears that licensing restrictions that result in restrictions on research and development - the bedrock of innovation - will be closely examined. As defined, an "innovation market consists of the research and development directed to particular new or improved goods or processes and the close substitutes for that research and development." n103 This is in line with the purposes of the patent law [*452] system, which is to promote innovation. n104 Giving a more critical examination of restrictive licensing provisions as they apply to markets directed to research and development of new goods and processes, therefore, clearly assists in furthering the

purpose of the patent system – to promote innovation.

The stem cell market is an innovation market as defined in the Antitrust Guidelines. n105 The stem cell patent market has its "research and development directed to particular new or improved goods or processes." n106 Currently, there are no "close substitutes for [stem cell] research and development," which makes the patent all the more powerful. n107 Therefore, any analysis of stem cell licensing restrictions will examine the effect of the restraint on competition in future development of new stem cell processes or goods. n108 For the purposes of this Note, it will be assumed that the "specialized assets or characteristics of specific firms," n109 a required element of the innovation market analysis, is the ability of biotechnology firms to engage in stem cell research. However, these biotechnology firms (that is, every biotechnology firm except for Geron, the exclusive licensee of WARF) do not have access to the stem cell patent rights without Geron's permission. Therefore, the DOJ and FTC will examine Geron's possible licensing restrictions of the stem cell patent in the context of an innovation market. n110

B. Possible Licensing Provisions and Antitrust Analysis

There are many different types of licensing restrictions. The types of licensing (or refusal to license) restrictions that are relevant to the scope and topic of this Note are tying arrangements, suppression of technology through refusals to use or license, exclusive licenses, and grantback provisions. In general, restrictive licensing provisions are not violative of the antitrust laws and are considered part and parcel of the patent holder's rights. n111 Additionally, a comparison of the outputs with and without the restrictive license is an improper basis upon which to determine its legality. n112

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1. Tying Arrangements

Tying, or tie-in, licensing arrangements have been defined by the Supreme Court as "an agreement by a party to sell one product ... on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that [tied] product from any other supplier." n113 The DOJ and FTC have stated that they "would be likely to challenge a tying arrangement if: (1) the seller has market power in the tying product, (2) the arrangement has an adverse effect on competition in the relevant market for the tied product, and (3) efficiency justifications for the arrangement do not outweigh the anti-competitive effects." n114 An essential characteristic of illegal tying arrangements is the selling entity's exploitation of its market control over the tying product to force a buyer to also purchase a tied product that the buyer did not want. n115

Tying arrangements are treated as per se illegal if four elements are found: "(1) two distinct products are involved; (2) sale of one product is conditioned on purchase of another; (3) the seller has 'appreciable economic power' over the tying product sufficient to restrain trade; and (4) the tie-in affects a not insignificant amount of interstate commerce." n116 The requirement that the two products are distinct means exactly what it states: the two products must be separate. The two products must be such that buyers would want to purchase each without having to purchase the other. n117 However, an economic justification for joint packaging may prevent a tying arrangement from being found illegal. n118 If the two products may be separately purchased, the selling entity's decision to give buyers a "package deal" does not unreasonably restrain trade in the market. n119 The market power of the selling entity is a key feature of tying arrangement illegality: if the seller can force a [*454] buyer to do something the buyer would not want to do in a competitive market due to the seller's power in the relevant market, such a tying arrangement will be illegal. n120

In the realm of patent licensing, tying arrangements will be found illegal if an entity has "licensed a patented device on condition that unpatented materials be employed in conjunction with the patented device." n121 This constitutes an improper attempt to enlarge the scope of the patent:

Any effort to enlarge the scope of the patent monopoly by using the market power it confers to restrain competition in the market for a second product will undermine competition on the merits in that second market. Thus, the sale or lease of a patented item on condition that the buyer make all his purchases of a separate tied product from the patentee is unlawful. n122

A possible tying arrangement that Geron might wish to pursue with the stem cell patent is an arrangement that requires

licensees to purchase, in exchange for permission to practice the patented stem cell technology, a related product, such as an actual stem cell culture. Such a proposed tying arrangement will not be found to be per se illegal. This is a result of the failure to satisfy the four requirements for per se illegality. n123 The conditioned allowance of use of the stem cell patent on a directly related product, such as a stem cell culture, fails to satisfy the first requirement, that "two distinct products are involved" n124 Also, it makes economic sense to attach a stem cell culture along with the rights to use the stem cell culture. For example, Geron would not be tying the sale of Internet browser software to the licensed use of the stem cell patent, which would be more likely to raise antitrust concerns.

In addition, such a tying arrangement is unlikely to raise concerns of the DOJ and FTC. It is unlikely that Geron has considerable market power in the stem cell cultivation market. n125 Also, it is doubtful that the arrangement would have an adverse effect on competition in the market for cultivation of stem cell cultures, as it is unlikely that Geron is the only biotechnology firm with the capability of cultivating stem cells in a culture. n126 As for the third requirement for raising DOJ and FTC concerns, there are doubtless efficiency justifications for providing stem cell cultures along with the rights to use the cultures. n127 This manner of giving a "package deal," instead of just providing use rights through the [*455] license, surely would be an example of "efficiency justifications ... outweighing the anti-competitive effects." n128

2. Suppression of Technology Through Refusals to Use, Sell, or License

Another type of licensing restriction involves the suppression of the technology claimed by the patent. n129 This may occur through a refusal to license or to practice the technology. The suppression of technology most commonly arises in one of two situations: first, where an owner of some intellectual property unilaterally refuses to either license or sell his or her intellectual property rights to another competitor; or second, where the intellectual property owner refuses to use the intellectual property rights at all. n130 In general, neither practice is likely to constitute an antitrust violation. n131 In certain situations, however, such a refusal by a patent holder has been found to violate the antitrust laws. n132 Such violations have been limited to situations where the refusal "harms the competitive process in the absence of a legitimate business justification." n133 In other words, if a patent holder provides any valid justification for refusing to license, sell, or use the intellectual property, the refusal will not violate the antitrust laws. n134

The patentee's virtually unilateral right to refuse to license, sell, or use the intellectual property is further supported by the DOJ and FTC's comparison of intellectual property rights to any other form of personal property in the Antitrust Guidelines. n135 For a simple analogy, imagine a landowner's right to refuse access, lease, or use of his or her property to [*456] another. In the overwhelming number of scenarios, the landowner (like the patentee) possesses this absolute right of refusal.

Geron may wish to suppress the stem cell patent technology either through a refusal to practice, sell, or license the rights of the stem cell patent. As long as Geron has a legitimate business justification for suppressing the stem cell technology, antitrust violations are unlikely to be found. n136 Geron may have a legitimate business justification in its refusal to sell or license the stem cell patent in wishing to wait until economic conditions improve. With the extremely high costs of research and development in such a drastic new medical and scientific development as the stem cell, there will be a considerable economic "learning curve." Geron would be economically justified in waiting until market conditions improve to increase the possibility of additional investors. Such a justification surely will not harm competition in the long term and, conversely, may improve development by allowing Geron to ensure that sufficient research and development investment dollars are spent efficiently. Otherwise, rushing to conduct the stem cell research and development in a piecemeal fashion (due to insufficient research funding) may cause an overall slowdown in stem cell therapy development.

However, it would be entirely unrealistic for Geron to otherwise unilaterally refuse to use, license, or sell the patent rights. Geron is not known on Wall Street as a large "money-maker" in the realm of biotechnology. n137 In the American capitalistic system, it is highly unlikely that Geron will choose to not earn money by licensing or practicing its exclusively licensed patented stem cell technology. As previously discussed, the stem cell patent is an incredibly valuable piece of intellectual property. While Geron will want to maintain considerable control over its intellectual property and the research and development of the stem cell technology, it will also wish to capitalize on its property. In all likelihood, Geron will wish to license the stem cell patent, albeit at a high price, either by actual dollars or through other licensing restrictions.

Even though it is more likely than not that Geron will license the patent, Geron may still wish to refuse to license, sell, or use the stem cell patent for other, non-business justifications. For example, Geron may wish to suppress the stem cell technology in order to force other biotechnology firms out of the stem cell market. This would clearly be restraining trade in the stem cell innovation market without any business justification. Any antitrust action is likely only if Geron

refuses to sell or license the patent in order to unreasonably restrain trade against their horizontal counterparts in the stem cell innovation market. However, [*457] such an action would be difficult, if not impossible, to maintain. Therefore, any choice by Geron to withhold the stem cell patent through an outright refusal to use, license, or sell is highly unlikely to establish an antitrust action.

3. Exclusive Licenses

Exclusive licenses contain provisions restricting "the right of the licensor to license others and possibly ... to use the licensed technology itself." n138 The licensor could give up his rights to the patented technology for the term of the license (or the patent, whichever is shorter) through an exclusive licensing provision. The "exclusive" nature of the license or licensing provision does not mean that it is the only existing license, as many exclusive licenses may exist. n139

An exclusive license will be evaluated under the rule of reason. n140 While exclusive licenses "have been closely scrutinized over the years," n141 the courts have generally upheld them. n142 Antitrust concerns usually will be raised by exclusive licenses between entities in a horizontal relationship. n143 These licenses benefit society by "providing the licensee with the security necessary to develop and market an intellectual property." n144

An example of an exclusive license is the exclusive license granted to Geron on behalf of WARF in exchange for research and development funding (which ultimately led to the stem cell patent). This exclusive license is very unlikely to raise any antitrust concerns, as such a license is doubtful to raise any anticompetitive concerns unless it binds two entities in a horizontal relationship. n145 Geron is in the biotechnology market. WARF is in the business of obtaining intellectual property protection for advances in academic research at the University of Wisconsin and transferring such advances to the marketplace in order to benefit both the public and to obtain more research funding. n146 Clearly, Geron and WARF do not compete as horizontal entities, even though their efforts ultimately may achieve similar ends. Therefore, it is highly unlikely that [*458] the DOJ or FTC will challenge the parties' exclusive license of the stem cell patent.

Conversely, assuming that the DOJ or FTC were concerned by this exclusive license, the license would still be found in compliance with the antitrust laws. As evaluated under the rule of reason, any anticompetitive effects of the exclusive license will be deemed to be outweighed by the procompetitive effects. While the inability of WARF to freely license the stem cell patent to other biotechnology firms does invoke some anticompetitive concerns, the resulting situation in which Geron sits may actually have procompetitive effects. With the exclusive license, Geron effectively controls all research and development of the stem cell patent within the United States. Therefore, Geron may act as the "overseer" of all stem cell research. This position puts Geron in the procompetitive position to ensure that research is not duplicated and that information is shared among the licensees. n147 Instead of having several companies "re-invent the wheel," Geron could ensure a more efficient development of the technologies arising from the stem cell patent. Surely this result would not unreasonably restrain competition in the stem cell market.

4. Grantback Provisions

A grantback licensing provision is "an arrangement under which a licensee agrees to extend to the licensor of intellectual property the right to use the licensee's improvements to the licensed technology." n148 However, grantback provisions may go so far as to require the licensee to assign any intellectual property protection obtained on improvements to the licensed technology to the licensor. n149 In general, grantbacks are "subject to scrutiny because they may be seen as discouraging invention by licensees; however, they are not illegal per se." n150 Therefore, grantbacks are evaluated under the rule of reason, n151 and are generally [*459] considered legal. n152 In evaluating grantbacks, the DOJ and FTC will consider the licensor's market power in the relevant market. n153

Grantbacks can have both pro- and anticompetitive effects. If the grantback provision is non-exclusive, it is more likely to have procompetitive effects. n154 Patent protection for subsequent improvements of the licensed technology will help to increase consumer demand for both the licensed and improved technologies. n155 The anticompetitive effects of grantback provisions may arise if the restrictions "substantially reduce the licensee's incentives to engage in research and development and thereby limit rivalry in innovation markets," n156 or "where a patentee who wishes to acquire or retain significant power in a relevant market combines a grantback clause with territorial limitations or restraints on use." n157 If the grantback provision is likely to significantly reduce the licensee's incentives to invest in improvements of the licensed technology, the DOJ and FTC will consider the existence of any offsetting procompetitive effects. n158 These procompetitive effects may include the resultant promotion of the licensee's improvements of the licensed technology, the change in incentives to the licensee to disseminate the licensed technology, or any increase in competition and output in

the relevant market. n159 Additionally, other factors may assist in the determination of the possible antitrust violations of grantback provisions. n160 Grantbacks are most attractive to a licensor with a broad patent, as the licensor is "able to license a sufficiently large percentage of sources of substitute developments to make it worthwhile." n161

[*460] Perhaps the most problematic licensing provision that Geron could utilize would be the employment of a grantback provision. These grantback provisions could be structured to give Geron intellectual property protection or licensed rights to any and all advancements made in stem cell therapy through use of the stem cell patent. In other words, Geron could insert a licensing provision providing them with either a sole exclusive license to, or the assignment of, all future patented technologies arising from the stem cell patent. As the stem cell patent is such a broad "pioneer" patent, a series of exclusive, broad grantback provisions would effectively give Geron control over any and all advancements in stem cell research and development. Again, the "bottleneck" effect of the stem cell patent becomes a concern. Since basically all future stem cell research and development depends on this patent, grantback provisions would give Geron some measure of control over all future developments in stem cell technologies. This, in turn, could effectively lengthen Geron's legal patent monopoly indefinitely by "tacking on" multiple patents on top of the basic stem cell patent.

Clearly, the anticompetitive effects of such a licensing regime would raise antitrust concerns. Under the rule of reason, such grantback provisions are unlikely to have any procompetitive effects that would outweigh the anticompetitive effects. While grantback provisions may have procompetitive effects in patents that are not as "pioneering" as the stem cell patent, there are few procompetitive effects to allocating all future developments of stem cell research in the hands of one biotechnology firm. Again, the "bottleneck" effect of the stem cell patent could force all subsequent innovations in stem cell technology (which arise from the stem cell patent) to be in some way controlled by Geron.

This conclusion is further supported under the Antitrust Guidelines with respect to the stem cell innovation market. The stem cell innovation market is defined by the market consisting of the research and development of stem cell therapies, which have commercial application and value. As the FTC and DOJ analyses of licensing restrictions in the stem cell innovation market will involve an assessment of the effect of the grantback restrictions on the development of future processes or goods, such complete control of future stem cell developments and innovations in one biotechnology firm will certainly raise antitrust concerns. Geron would effectively be the only entity with control over substantially all of the innovation market defined by stem cell research and development.

In addition, such a broad grantback provision would have severe anticompetitive effects due to its likely effect of reducing the incentives of other entities to engage in stem cell research and development. If licensees were forced to assign or exclusively license their intellectual property rights arising from improvements on the stem cell patent, there [*461] would be little to no incentive for these entities to engage in research and development. These licensees would effectively be performing research and development on the stem cell patent on Geron's behalf. Geron would, in effect, be receiving free assistance in increasing its product base and market share, as Geron would rely on the licensees to improve upon the stem cell patent without having to place considerable financial emphasis on its own research and development.

C. Proposed Solutions

While only a few of the possible licensing restrictions are likely to raise antitrust concerns, the possibility of broad grantback provisions giving Geron control over substantially all of the stem cell research and development innovation market could form the basis for an antitrust action. Even if these provisions are insufficient for an antitrust action, several commentators have expressed concern over Geron holding such great power in the stem cell research and development market. n162 Two possible "solutions" to the problematic licensing provisions (or even to the concern of Geron having too much power in the stem cell research and development market) that may provide a more favorable result in the eyes of the public are to invalidate the stem cell patent on public policy grounds or to enact a compulsory licensing regime for the stem cell patent.

1. Invalidate the Stem Cell Patent on Public Policy Grounds

The argument for invalidating the stem cell patent on public policy grounds is based on one of two concerns. First, there are those who would wish to invalidate the stem cell patent due to the moral and ethical controversies surrounding embryonic science. Second, others are simply concerned over a single, profit-driven biotechnology firm having such widespread intellectual property control over stem cell research and development. However, the stem cell patent should not be invalidated on the basis of either argument.

In general, it is extremely rare to invalidate a patent on public policy grounds; however, some precedent for doing so does exist. n163 In *Lowell v. Lewis*, the plaintiff sued the defendant for patent infringement of a new and improved method of constructing water pumps. n164 The defendant claimed that the patented invention was not a useful invention [*462] and therefore the plaintiff was not entitled to patent protection. n165 Justice Story rejected defendant's claim that in order for plaintiff to be entitled to patent protection the invention must "supersede the pumps in common use." n166 However, in Justice Story's discussion of the utility requirements of the patent laws, he stated that patents may be found invalid if the invention contravenes public policy or morals:

All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word "useful," therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention. n167

More recently, the United States Patent and Trademark Office ("PTO") has stated in a press release that a patent may be invalidated on the grounds of public policy. n168

With respect to those who would invalidate the stem cell patent due to the moral and ethical controversies surrounding embryonic science, doing so would only do considerable harm to a system continually attempting to maintain clear standards. What is bad in the eyes of public policy today may be beneficial to later generations. Most patented technologies in their early stages (much like the stem cell patent) have not realized their full potential. Invalidating patents before they have achieved their true worth would be poor practice. In any event, in terms of the stem cell patent, with all of the medical therapies that may be possible given enough research and development, invalidation would be a mark of pure shortsightedness.

Likewise, to those who would invalidate the stem cell patent due to the broad power it grants to Geron, such invalidation would also be unfounded in both logic and practicability. First, invalidating a patent due to its breadth would do great harm to the consistency of the patent system. How would one determine when a patent is too broad for the relevant market? Patents, whether they are broad or narrow with respect to the relevant market, should not be invalidated because the patentee could possibly misuse the patent. Second, it would be very difficult to invalidate a patent on such grounds, especially considering the Federal Circuit's generally positive approach towards patent validity. n169 [*463] Third, such invalidation should be conducted by the PTO and not the courts. It is the province of the PTO to determine which inventions satisfy the utility requirement and deserve patent protection. n170

2. Compulsory Licensing Regime

Another possible solution is a compulsory licensing system of the stem cell patent. In general, a court-ordered compulsory license is rare and only ordered in extreme situations. n171 Courts generally disfavor such actions, especially with respect to the biotechnology industry. n172 However, there are several examples of compulsory patent licensing. n173 Several commentators have recommended compulsory licensing as a possible solution to a problem where the licensor controls, through one or several patents, a significant portion of the relevant market. n174

If Geron were to license the stem cell patent in an anticompetitive manner and, in turn, effect a great societal cost, a federal court could enact a compulsory licensing regime. This compulsory licensing system could be established to look out for the best interests of all parties involved. An example of a proposed equitable compulsory licensing system would provide a reasonable licensing fee (which would depend on the commercial value of any products developed from the research allowed under the stem cell patent) to Geron and grant the licensee the ability to pursue stem cell research. n175 This system could benefit all involved parties: Geron would receive a reasonable royalty from the [*464] stem cell patent, licensees would be able to conduct their stem cell research, and society would benefit from any therapeutic advancements achieved as a result of the stem cell research.

However, in reality, such a compulsory licensing system would ultimately fail to achieve its purposes. First, it would be difficult to establish a reasonable royalty rate for use of the stem cell patent. A reasonable royalty is traditionally established by determining "an amount "which a person, desiring to manufacture and sell a patented article, as a business proposition, would be willing to pay as a royalty and yet be able to make and sell the patented article, in the market, at a reasonable profit." n176 As of yet, the stem cell patent encompasses technology best utilized as a research tool, with the

availability of marketable "articles" at least several years away. Therefore, how would a court establish what the royalty would be? As one author suggests, a reasonable royalty dependent upon subsequent commercial applications combined with an experimental use exception for research and development would be fair and equitable to all parties. n177 For example, company X, a licensee of Geron, would not have to pay any royalties to Geron for use of the stem cell patent until company X develops and sells a finished product. Geron's royalty would be in proportion to company X's profit on the sale of the finished product. Yet, this does little to settle the difficulties in establishing a reasonable royalty rate. What "finished products" would be subjected to the royalty? Would "finished products" also encompass stem cell developments that are only useful as research tools? Would there be any allowance made for start-up production costs, including, for example, the very expensive and time-consuming approval process of the Federal Drug Administration ("FDA")? If no allowance is made for these costs, there would be less incentive for a licensee to spend the extra money required for these start-up costs where a full royalty rate would still be due upon public sale of the "finished products." While many of these questions could be answered through prolonged negotiations after a compulsory licensing regime were enacted, the transaction costs of doing so would simply be too great. One could imagine the situation that would arise. Several stem cell therapy treatments become available after considerable research and development and FDA approval, but the treatments are "placed on the shelf" while Geron and the licensees begin or continue to litigate the details of the reasonable royalty. Such a regime would be an inefficient and improper means for licensing the stem cell patent.

[*465]

V. Recommendation

The stem cell patent should be subjected to traditional market forces to determine Geron's licensing practices. If Geron attempts to require broad grantback provisions in its licenses, Geron will find itself with few, if any, licensees. Few biotechnology companies would choose to invest considerable research and development dollars in a venture where they will never realize a full profit-generating potential. These companies simply would not be willing to spend such great amounts with considerable risk, only to grant Geron a sole exclusive license or assignment of patented improvements on the stem cell patent. It simply would not make economic sense. The end result is that all parties are harmed: Geron would find its use of the stem cell patent inefficient; biotechnology companies in the United States would pass up the opportunity to improve on the stem cell patent; and, perhaps worst of all, the general public would find the medical treatments and therapies derived from the stem cell technology delayed.

Therefore, Geron and possible licensees must be given the opportunity to establish, outside of court orders or supervision, a licensing agreement that is beneficial to all parties involved. n178 While Geron is in a very powerful position, it is not in an absolutely powerful position. Other biotechnology companies will refuse to be forced into licensing provisions that are, in effect, unconscionable. Of course, Geron will seek to maximize its benefit from any licensing agreement. However, this will more likely occur in the form of increased prices or non-exclusive grant-back provisions. Geron and its possible licensees should be left to arrange a license that is satisfactory to both, without any outside influence. This will ensure that the stem cell technology will continue to be improved in an efficient manner. Simply forcing Geron into a compulsory licensing regime before any opportunity is given for the bargaining parties to reach a mutual agreement would be contrary to the interests of all involved.

VI. Conclusion

The current state of the stem cell patent has left the exclusive licensee, Geron, in an extremely powerful position. The scope of the stem cell patent, the fact that the stem cell patent is a "pioneer" patent, and the federal funding limitations laid down by the Bush Administration have increased the already powerful position of the owner of the stem cell patent. However, while Geron may be in an economically powerful position, the FTC and DOJ will not likely bring [*466] antitrust claims unless certain licensing restrictions are employed, such as a tying arrangement to an unrelated product, a suppression of the stem cell patent with no legitimate business justification, or overly broad grantback provisions. Even if Geron's licensing practices were to raise antitrust concerns, a court invalidation of the stem cell patent on public policy grounds would be highly unlikely. In addition, forcing Geron into a compulsory licensing system would be an inefficient method of maximizing the potential of the stem cell patent. Instead, Geron and the possible licensees should be left to reach a mutually agreeable license.

FOOTNOTES:

n1. All this excitement began with the announcement that University of Wisconsin biologist James A. Thomson had isolated human stem cells. Jason Gertzen, *Stem Cell Patents Put UW Agency in Spotlight*, Milwaukee Journal Sentinel, Aug. 26, 2001, at 1A.

n2. Sheryl Gay Stolberg, *Suit Seeks to Expand Access to Stem Cells*, N.Y. Times, Aug. 14, 2001, at C2.

n3. Press Release, The White House, *Fact Sheet on Embryonic Stem Cell Research* (Aug. 9, 2000), available at <http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html>.

n4. National Institutes of Health, *Stem Cells: A Primer* (May 2000), available at <http://www.nih.gov/news/stemcell/primer.htm>.

n5. Sara Chartrand, *Patents; Amid the Debate on Stem Cell Studies, a Small but Growing Number of Patents are Issued in the Field*, N.Y. Times, Aug. 13, 2001, at C2.

n6. See *supra* notes 2-3.

n7. Nicholas Wade, *U.S. Approves Labs with Stem Cells for Research Use*, N.Y. Times, Aug. 27, 2001, at A1.

n8. *Id.*

n9. Chartrand, *supra* note 5.

n10. *Id.*

n11. National Institutes of Health, *supra* note 4.

n12. As stated by the National Institutes of Health,

In people who suffer from type I diabetes, the cells of the pancreas that normally produce insulin are destroyed by the patient's own immune system. New studies indicate that it may be possible to direct the differentiation of human embryonic stem cells in cell culture to form insulin-producing cells that eventually could be used in transplantation therapy for diabetics.

Id.

n13. Andrew Pollack, *The Promise in Selling Stem Cells*, N.Y. Times, Aug. 26, 2001, 3, at 1; see Gertzen, *supra* note 1.

n14. *Stem Cell Research: Hearing Before the Committee on Appropriations, Senate Subcommittee on Labor, Health, and Human Services, Education and Related Agencies, 106th Cong. (1999)* (statement of Maria C. Freire, Ph.D., Director, Office of Technology Transfer, National Institutes of Health), available at <http://www.hhs.gov/asl/testify/t990112a.html> [hereinafter Freire] ("Stem cells provide the research community a springboard to launch numerous inquiries into the most fundamental processes of cellular growth and differentiation that underlie human development.")

n15. See *supra* notes 4 and 7.

n16. See *supra* notes 2 and 13.

n17. See National Institutes of Health, *supra* note 4.

n18. John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 *Emory L.J.* 101, 102 (2001).

n19. Fact Sheet on Embryonic Stem Cell Research, *supra* note 3.

n20. U.S. Const. art. I, 8, cl. 8; see also *Int'l Wood Processors v. Power Dry, Inc.*, 792 F.2d 416, 426 (4th Cir. 1986) ("Congress enacted the patent laws ... to stimulate invention and to reward innovation by granting a successful patentee the right to exclude others from making, using, and selling the invention for a period of seventeen years."); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 *U. Chi. L. Rev.* 1017 (1989); Moses Abramovitz, *Resource and Output Trends in the United States Since 1870*, 46 *Am. Econ. Rev.* 5 (1956); Robert M. Solow, *Technological Change and the Aggregate Production Function*, 39 *Rev. of Econ. & Stat.* 312, 320 (1957); Edward F. Denison, *The Sources of Economic Growth in the United States and the Alternatives Before Us* 271-72 (1962); Edward F. Denison, *Accounting for United States Economic Growth: 1929-69*, at 128 (1974); F. M. Scherer, *Inter-Industry Technology Flows and Productivity Growth*, 64 *Rev. of Econ. & Stat.* 627 (1982).

n21. 35 U.S.C. 154(a)(2) (2002).

n22. 35 U.S.C. 261.

n23. Robert Pitofsky, *Antitrust and Intellectual Property: Unresolved Issues at the Heart of the New*

Economy, Remarks at the Antitrust, Technology and Intellectual Property Conference (Mar. 2, 2001), available at <http://www.ftc.gov/speeches/pitofsky/ipf301.htm> ("Intellectual property rights subsidize investments in innovation by granting substantial but time-limited market power.").

n24. See, e.g., *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). In addition, courts use the specification and prosecution history (or file wrapper) of the patent as evidence in construing the scope of the various claims. *Id.* at 980. Courts may, but are hesitant to, consider extrinsic evidence such as the testimony of experts. *Id.*

n25. 35 U.S.C. [283-85].

n26. Pitofsky, *supra* note 23 ("It is clear that both intellectual property protection and reasonable antitrust enforcement will encourage innovation."); see also John T. Soma et al., *Antitrust Pitfalls in Licensing*, in 2 *Intellectual Prop. Antitrust 1996*, at 351, 353 (PLI Intellectual Prop. Antitrust Course, Handbook Series No. G-449, 1996) ("Since the first antitrust and intellectual property laws were enacted, their goals have been: 1) to promote innovation and 2) to enhance consumer welfare.") (emphasis added).

n27. Pitofsky, *supra* note 23 ("Antitrust [laws] ensure[] that firms compete, and by competing, seek new roads to innovation.").

Antitrust enforcement confers great benefits on American consumers in terms of price, output, quality, and diversity. Producers also receive benefits, if not always comfort, from a climate of economic rivalry that spurs innovation and efficiency. Antitrust policy has served to preserve economic opportunity, an important element of American freedom that continues to attract people daily to this country.

Anne K. Bingaman, Department of Justice Antitrust Enforcement, *Some Initial Thoughts and Actions*, in *Intellectual Prop. Antitrust 1994*, at 175, 194 (PLI Pat., Copyright, Trademarks & Literary Prop. Course, Handbook Series No. G4-3920, 1994).

However, some commentators have argued that monopolies may actually foster innovation. See Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 *Berkeley Tech. L.J.* 813, 823-24 (2001) ("Monopolies foster innovation, particularly risky innovation, because they can appropriate fully (or at least more fully than competitive markets) the surplus generated by such investment.") (citing Joseph A. Schumpeter, *Capitalism, Socialism, and Democracy* 81-106 (1942)). In addition, competition between horizontal competitors in a market may not result in a "race" to produce a product into the market. A single monopolistic entity may be more efficient.

Although competition may lead to some duplicative investment, at least some of the redundancy may be more apparent than real... . Because the different possible goals of improvement are often unknown at the time such improvement starts, "racing" among competitors may yield results that would not have emerged if work on improvement had been restricted to a single party (or even to a few parties).

Rai, *supra* at 825 (citing Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 *Colum. L. Rev.* 839, 873-75 (1990)).

n28. The Antitrust Counterattack in Patent Infringement Litigation, 1994 A.B.A. Sec. Antitrust L. 47 (Elizabeth C. Benton et al. eds. 1994) [hereinafter Antitrust Counterattack].

Because a patent is a special grant of power to exclude competition, and exclusionary power has historically been scrutinized strictly under the antitrust laws, the patent and antitrust laws have historically coexisted in tension with one another. Reconciling the interrelationship between these two areas of law has long concerned the courts and legal commentators.

Id. (citing *Handgards, Inc. v. Ethicon, Inc.*, 897 F.2d 986, 992 (9th Cir. 1979) and *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1963)); see also supra note 27.

n29. See Freire, supra note 14.

A license that provides complete exclusivity to a technology that is also a research tool may result in some product development in the short-term, but it will close off opportunities to advance science and develop other products in the long-term. The only way to maximize the benefit to the public is to ensure that both research use and the potential for commercial development are preserved.

Id. See also, e.g., Mark F. Radcliffe, Antitrust Pitfalls in Licensing, in *Intellectual Prop. Antitrust 1994*, at 175, 177 (PLI Pat., Copyrights, Trademarks & Literary Prop. Course, Handbook Series No. G4-3920, 1994) ("Many significant new industries, ranging from computer software to biotechnology are dependent on intellectual property and its licensing."); Rai, supra note 27, at 813 ("In the context of the biopharmaceutical industry, broad patents, particularly on upstream invention, represent the main threat to competition.").

n30. Antitrust Counterattack, supra note 28, at 47.

n31. As stated by the Federal Circuit,

When a patent owner uses his patent rights not only as a shield to protect his invention, but as a sword to eviscerate competition unfairly, that owner may be found to have abused the grant and may become liable for antitrust violations when sufficient market power in the relevant market is present.

Atari Games Corp. v. Nintendo of Am., Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990).

n32. Gertzen, supra note 1; Pollack, supra note 13. Dan S. Kaufman is also listed as an inventor. U.S. Patent No. 6,280,718 (issued Aug. 28, 2001). WARF is a non-profit organization that handles the licensing of patents for the University of Wisconsin. Stephanie Ingersoll, *Biotechnology: Stem Cell Research Faces Legal Hurdles Over Patent Rights*, Daily Rep. for Executive (BNA) No. 60, at A-22 (Aug. 20, 2001).

n33. U.S. Patent No. 6,280,718 (issued Aug. 28, 2001).

n34. Id. at cl. 1, 4, 6, 9-10.

n35. Gertzen, *supra* note 1.

n36. For a discussion of the federal funding limitations, see *infra* Part III.B.

n37. Dr. Thomas B. Okarma, chief executive of Geron, has stated that "the Wisconsin [stem cell] patent [is] so fundamental that [stem cells under and outside of the federal funding limitations] would all infringe the Wisconsin patent." Pollack, *supra* note 13.

n38.

Market dominance for "only" 15 or 20 years can take enormous resources out of the economy and, by excluding innovative new entrants, foreclose alternative paths of technical development.

...

[Intellectual property protection] properly encourages and rewards innovation, and prevents misappropriation, but also prevents competition for a period of time within the zone of the [intellectual property] grant. For example, since much innovation consists of improvement on basic ideas, patent protection of the basic idea may preclude the very improvements that it is designed to encourage.

Pitofsky, *supra* note 23. See also Donna M. Gitter, International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption, 76 *N.Y.U. L. Rev.* 1623, 1680 (2001) (citing Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 *Yale L.J.* 177, 217-218 (1987)).

n39.

[A] patentee might refuse to license an invention in order to assemble a comprehensive patent portfolio that effectively would preclude others from working with competing technologies. Second, a patentee might attempt to preclude others from inventing around the patent, since the development of a noninfringing substitute would hurt the original patent's market value. Third, in the interest of gaining scientific renown and future intellectual property rights, a patentee might prefer to block the entry of others into the field.

Gitter, *supra* note 38, at 1680.

n40. Id.

n41.

In a variety of industries that relied on cumulative innovation, broad patents on initial invention could not be licensed effectively and hence hindered subsequent development. The exact nature of the failure to license differed by industry. In the field of incandescent lighting, Thomas Edison's broad patent covering the use of carbon filament as a source of light slowed down the development of the industry because Edison's company itself did not improve on the patent, and it used the patent to shut down competitors who had designed improved products. In the case of the Wright brothers' broad patent on a stabilizing and steering system, the patent holders sought to license their patent but could not, even after a period of ten years, work out licensing agreements.

Rai, *supra* note 27, at 831 (citing Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 *J.L. & Econ.* 265, 276 (1977)); Merges, *supra* note 27, at 886–87; Jacob A. VanderMeulen, *The Politics of Aircraft* 19 (1991)). "Although horizontal concentration may be useful for appropriating the value of a lengthy and expensive research and development process, a role for competition needs to be preserved. In the context of the biopharmaceutical industry, broad patents, particularly on upstream invention, represent the main threat to competition." Rai, *supra* note 27 at 813.

n42. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *Science* 698, 700 (1998) ("The lack of substitutes for certain biomedical discoveries ...may increase the leverage of some patentholders, thereby aggravating holdout problems.").

n43. Pitofsky, *supra* note 23.

n44. Gitter, *supra* note 38, at 1623.

n45. Again, as stated in Part I, this Note will not address any of the ethical or religious controversy surrounding stem cell research and is purely concerned with the antitrust issues associated with the stem cell patent and the possible licensing thereof.

n46. For a discussion of innovation markets, see Part IV.A.2.

n47. Freire, *supra* note 14.

The concern arises when the patent holder chooses to exercise its rights through licensing in a manner inconsistent with the advancement of basic research. For example, many new inventions are not final products. The discovery may be a research material or a new method or procedure, primarily useful as the means to conduct further research. Such discoveries are commonly known as research tools. There is little doubt that these research tools may be patentable and that they are of economic value to the holder of these rights. There is also little doubt that the value to society is greatest when such research tools are widely available to scientists.

Id.

n48. Id.

n49. John W. Schlicher, *The Law and Economics of Licensing Biotechnology Patent and Related Property Rights in the United States*, in *The Law and Economics of Licensing Biotechnology Patent and Related Property Rights in the United States*, at 333, 352 (PLI Pat., Copyright, Trademarks & Literary Prop. Course, Handbook Series No. G4-3799, 1986).

n50. Wade, *supra* note 7.

n51. Sheryl Gay Stolberg, *Patent on Human Stem Cell Puts U.S. Officials in Bind*, N.Y. Times, Aug. 17, 2001, at A1.

n52.

As a result of private research, more than 60 genetically diverse stem cell lines already exist. They were created from embryos that have already been destroyed, and they have the ability to regenerate themselves indefinitely, creating ongoing opportunities for research. I have concluded that we should allow federal funds to be used for research on these existing stem cell lines, where the life and death decision has already been made.

President George W. Bush, August 9 Address to the Nation on Stem Cells (Aug. 9, 2001), at <http://www.whitehouse.gov/news/releases/2001/08/080901a.html>.

n53. See *id.*

n54. National Institutes of Health, *Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry* (Nov. 7, 2001), at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>.

n55. Golden, *supra* note 18, at 107 ("The United States' biotechnology industry generated \$18.6 billion in revenues in 1999") (citation omitted).

n56. "The government, the university, and industry are the three critical institutional players in the 'triple helix' of the United States' system of innovation. Each conducts its own research, and two of them, the government and industry, supplement their own work by funding research at the university." *Id.* at 132 (citing Henry Etzkowitz & Loet Leydesdorff, *The Dynamics of Innovation: From National Systems and "Mode 2" to a Triple-Helix of University-Industry-Government Relations*, 29 *Res. Pol'y* 109, 111 (2000)).

n57. Golden, *supra* note 18, at 132.

n58. See, e.g., *id.* at 132-33.

n59. *Id.* at 134.

n60. *Id.* at 133.

n61. *Id.* at 136 (citing National Science Board, Science and Engineering Indicators - 1996, at 4-5 to 4-6, 4-9 (1996)) (emphasis added).

n62. Golden, *supra* note 18, at 136 (citations omitted).

n63. *Id.* at 134.

n64. *Id.* at 141.

n65. See U.S. Patent No. 6,280,718 (issued Aug. 28, 2001).

n66. Ingersoll, *supra* note 32.

n67. Wade, *supra* note 7.

n68. The six stem cell lines are hepatocytes, myocytes, neural cells, pancreatic islet cells, hematopoietic cells, and osteoblasts. Ingersoll, *supra* note 32.

n69. *Id.*

n70. Stolberg, *supra* note 51.

n71. Ingersoll, *supra* note 32.

n72. Stolberg, *supra* note 51; Andrew Pollack, University Resolves Dispute on Stem Cell Patent License, N.Y. Times, Jan. 10, 2002, at C1.

n73. Pollack, *supra* note 72.

n74. *Id.*

n75. *Id.*

n76. *Id.*

n77. The basis of this lawsuit was WARF's desire to prevent Geron from exercising an option to the rights to gain exclusive rights to additional stem cell lines. *Id.*

n78. See, e.g., Andrew Pollack, "Politically Correct" Stem Cell is Licensed to Biotech Concern, N.Y. Times, Dec. 11, 2002, at C8 ("The granting of the [exclusive] license [to the new line of stem cells] to Athersys, which has been expected, could raise concerns similar to those that arose when the Geron Corporation was given the exclusive license for certain commercial uses of embryonic stem cells by the University of Wisconsin.").

n79. U.S. Department of Justice & Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (1995), available at <http://www.usdoj.gov/atr/public/guidelines/ipguide.pdf> [hereinafter Antitrust Guidelines] (last visited April 27, 2003).

n80. See *id.* at 10-13.

n81. Antitrust Guidelines, *supra* note 79.

n82. *Id.* at 3 ("The Agencies apply the same general antitrust principles to conduct involving intellectual property that they apply to conduct involving any other form of tangible or intangible property."). *Contra* Pitofsky, *supra* note 23 ("In my view, it is unduly simplistic to assert that intellectual property is like all other forms of property.") (citations omitted).

n83. Antitrust Guidelines, *supra* note 79, at 4 ("If a patent or other form of intellectual property does confer market power, that market power does not by itself offend the antitrust laws.").

n84. Id. at 5 (stating that the licensing of intellectual property allows firms to combine complementary factors of production, where "this integration can lead to more efficient exploitation of the intellectual property, benefiting consumers through the reduction of costs and the introduction of new products.").

n85. Doris Estelle Long, "Innovation Markets" and the 1995 Antitrust Guidelines for the Licensing and Acquisition of Intellectual Property, in 2 Intellectual Property Antitrust 1996, at 19, 21 (PLI Intellectual Prop. Antitrust Course, Handbook Series No. G-449, 1996).

n86. Some classic examples of licensing practices are exclusive licenses and grant-back provisions in the license agreement.

n87. Antitrust Guidelines, *supra* note 79, at 16.

n88. Soma et al., *supra* note 26, at 352 ("Compliance with these new [intellectual property] guidelines is critical because an antitrust violation can result in a DOJ or FTC investigation and complaint as well as a judgment to pay treble damages to a private plaintiff.").

n89. Antitrust Guidelines, *supra* note 79, at 7.

n90. Id. at 16 (citing *Fed. Trade Comm'n v. Indiana Fed'n of Dentists*, 476 U.S. 447 (1986); *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85 (1984); *Broadcast Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1 (1979); 7 Phillip E. Areeda, *Antitrust Law* 1502 (1986)); Soma et al., *supra* note 26, at 356 (noting that the rule of reason "requires a qualitative comparison of the risk of the anticompetitive effect of the license compared to the expected efficiencies to be gained.").

n91. Antitrust Guidelines, *supra* note 79, at 16 ("[A] restraint's 'nature and necessary effect are so plainly anticompetitive' that it should be treated as unlawful per se, without an elaborate inquiry into the restraint's likely competitive effect. Among the restraints that have been held per se unlawful are naked price-fixing, output restraints, and market division") (citations omitted); Soma et al., *supra* note 26, at 356 ("Among the restraints that have been held per se unlawful are naked price-fixing, output restraints, market division among horizontal competitors, certain group boycotts, and some resale price maintenance.").

n92. Antitrust Guidelines, *supra* note 79, at 14.

n93. Id. at 7 ("Antitrust concerns may arise when a licensing arrangement harms competition among entities that would have been actual or likely potential competitors in a relevant market in the absence of the license").

n94. Id. at 7 n.14 ("A firm will be treated as a likely potential competitor if there is evidence that entry by that firm is reasonably probable in the absence of the licensing arrangement.").

n95. *Id.* at 14 ("A licensing arrangement has a vertical component when it affects activities that are in a complementary relationship ...").

n96. *Id.* at 18 ("When the licensor and licensees are in a vertical relationship, the Agencies will analyze whether the licensing arrangement may harm competition among entities in a horizontal relationship at either the level of the licensor or the licensees, or possibly in another relevant market.").

n97. *Id.* at 10 ("If a licensing arrangement may adversely affect competition to develop new or improved goods or processes, the Agencies will analyze such an impact either as a separate competitive effect in relevant goods or technology markets, or as a competitive effect in a separate innovation market."); see also Soma et al., *supra* note 26, at 357 (stating that this is a new concept to be considered by the DOJ and FTC).

n98. Antitrust Guidelines, *supra* note 79, at 11.

n99. Soma et al., *supra* note 26, at 357.

n100. Antitrust Guidelines, *supra* note 79, at 11.

n101. See, e.g., Long, *supra* note 85, at 26–27 (stating that the Antitrust Guidelines offer no guidance as to determining what constitutes a "specialized asset").

n102. *Id.* at 27.

n103. Antitrust Guidelines, *supra* note 79, at 11.

n104. U.S. Const. art. I, 8, cl. 8.

n105. See Antitrust Guidelines, *supra* note 79, at 10–13.

n106. *Id.* at 11.

n107. *Id.*

n108. Soma et al., supra note 26, at 357.

n109. Antitrust Guidelines, supra note 79, at 11.

n110. Id.

n111. Antitrust Counterattack, supra note 28, at 75 ("Courts tolerate most of these restrictions as being within the patentee's legitimate rights granted by the patent monopoly."). It should also be noted that licensing of patent rights is also of extreme importance to the biotechnology field. Radcliffe, supra note 29, at 177 ("Many significant new industries, ranging from computer software to biotechnology are dependent on intellectual property and its licensing.").

n112. Schlicher, supra note 49, at 383 n.19 .

n113. Antitrust Counterattack, supra note 28, at 79 (quoting *Nothorn Pac. Ry. v. United States*, 356 U.S. 1, 5-6 (1958)); see also *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 461 (1992); Soma et al., supra note 26, at 367 ("Tie-ins are licenses which condition the sale or license of one product, service, or [intellectual property] desired by the licensee on the purchase or license of another product, service, or [intellectual property] that the licensee does not necessarily want.").

n114. Antitrust Guidelines, supra note 79, at 26.

n115. *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 12 (1984).

n116. Antitrust Counterattack, supra note 28, at 80.

n117. *Hyde*, 466 U.S. at 39

For products to be treated as distinct, the tied product must, at a minimum, be one that some consumers might wish to purchase separately without also purchasing the tying product. When the tied product has no use other than in conjunction with the tying product, a seller of the tying product can acquire no additional market power by selling the two products together.

Id. at 39-40 (O'Connor, J., concurring) (emphasis in original).

n118. "When the economic advantages of joint packaging are substantial the package is not appropriately viewed as two products, and that should be the end of the tying inquiry." *Id.* at 40 (O'Connor, J., concurring).

n119. *Id.* at 11. "For example, ... "if one of a dozen food stores in a community were to refuse to sell flour unless the buyer also took sugar it would hardly tend to restrain competition if its competitors were ready and able to sell flour by itself." *Id.* at 11-12 (citations omitted).

n120. *Id.* at 13-14.

n121. *United States v. Columbia Steel Co.*, 334 U.S. 495, 522-23 (1948).

n122. *Hyde*, 466 U.S. at 16.

n123. Antitrust Counterattack, *supra* note 28, at 80.

n124. *Id.*

n125. *Id.*

n126. *Id.*

n127. *Id.*

n128. *Id.*

n129. "'Suppression of technology' can refer to any type of conduct or agreement that limits the availability, use, or development of a particular process or product, or that limits or chills the ability of others to create or exploit such an innovative process or product." Joel M. Cohen & Arthur J. Burke, An Overview of the Antitrust Analysis of Suppression of Technology, 66 *Antitrust* 421, 426 (1998).

n130. *Id.* at 425; *Image Technical Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1195 (9th Cir. 1997); *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147 (1st Cir. 1994).

n131. Cohen & Burke, *supra* note 129, at 424-25 n.9 (citing 35 U.S.C. 271(d)(4) ("No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of ... refusal to license or use any rights to the patent ...")); Ronald B. Coolley, Unilateral Refusal to License, in 2 *Intellectual Property Antitrust* 1996, at 379, 382 (PLI

Intellectual Prop. Antitrust Course, Handbook Series No. G-449, 1996) ("No court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in its patent the instant its patent affords a monopoly power over a relevant product market.") (citing *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981)); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 432-33 (finding no requirement that patentee license or use his or her patent); see generally Seungwoo Son, Selective Refusals to Sell Patented Goods: The Relationship Between Patent Rights and Antitrust Law, 2002 U. Ill. J.L. Tech. & Pol'y 109 (2002); *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908) (stating that patentee may refuse to license patent rights); *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984); *Service & Training, Inc. v. Data Gen. Corp.*, 963 F.2d 680, 686 (4th Cir. 1992); *United States v. Studiengesellschaft Kohle*, 670 F.2d 1122 (D.C. Cir. 1981).

n132. Cohen & Burke, supra note 129, at 425.

n133. *Image Technical Servs., Inc.*, 125 F.3d at 1209.

n134. Id.; Cohen & Burke, supra note 129, at 430.

n135. Antitrust Guidelines, supra note 79, at 3.

n136. See supra notes 133-134.

n137. Pollack, supra note 13.

n138. Soma et al., supra note 26, at 359; see also Antitrust Guidelines, supra note 79, at 27 (stating that an exclusive license "occurs when a license prevents the licensee from licensing, selling, distributing, or using competing technologies.").

N139. Soma et al., supra note 26, at 359-60.

n140. Antitrust Guidelines, supra note 79, at 27.

n141. Soma et al., supra note 26, at 360 (citing *E. Bement v. Nat'l Harrow Co.*, 186 U.S. 70 (1902); *United States v. E.I. duPont de Nemours & Co.*, 118 F. Supp. 41 (D. Del. 1953)).

n142. Soma et al., supra note 26, at 360.

n143. Id. ("A grant of exclusivity will raise antitrust concerns only where the license is between actual or

potential competitors.").

n144. Id.

n145. See id.

n146. Vicki Aken, UW–Madison Institutions Ensure Public Reaps Benefits of Research, at <http://www.cals.wisc.edu/wfsp/no-9/9-1a.html> (last visited Mar. 20, 2003).

n147. Rai, *supra* note 27, at 824 (citation omitted).

Broad patents, granted early in the developmental process, should give the patentee control over future development ... Absent patent protection of nascent invention, no one would invest in subsequent development of the invention for "fear that the fruits of the investment [would] produce unpatentable information appropriable by competitors."... Granting broad property rights on nascent invention will allow the rightsholder to coordinate subsequent development efficiently: because all potential developers will have to identify themselves to the rightsholder before they begin such development, the rightsholder will be able to eliminate duplicative investments in development and facilitate the exchange of information among developers.

Id.

n148. Antitrust Guidelines, *supra* note 79, at 30.

n149. Stephen N. Hollman, Antitrust Pitfalls in Licensing, in 2 Intellectual Prop. Antitrust 1996, at 541, 562–63 (PLI Intellectual Prop. Antitrust Course, Handbook Series No. G–449, 1996).

n150. Id. at 563 (citing *Transparent-Wrap Mach. Corp. v. Stokes & Smith Co.*, 329 U.S. 637, 646 (1947)).

n151. Antitrust Guidelines, *supra* note 79, at 30; *Transparent-Wrap Mach.*, 329 U.S. at 645–48.

n152. Radcliffe, *supra* note 29, at 184; see also Schlicher, *supra* note 49, at 376 ("The law is generally indifferent to a grant that includes rights developed in the future by the licensor.").

n153. Antitrust Guidelines, *supra* note 79, at 30.

n154. Id.

n155. Schlicher, *supra* note 49, at 374 ("It is never sensible for a licensor to discourage a licensee from developing improvements that the licensor will not develop. Such improvements only increase the derived demand for the licensor's rights by increasing demand for the final product or reducing production costs.").

n156. Antitrust Guidelines, *supra* note 79, at 30.

n157. Hollman, *supra* note 149, at 563 (citing *Transparent-Wrap Mach.*, 329 U.S. at 646).

n158. Antitrust Guidelines, *supra* note 79, at 30.

n159.

If the [DOJ and FTC] determine that a particular grantback provision is likely to reduce significantly licensees' incentives to invest in improving the licensed technology, the [DOJ and FTC] will consider the extent to which the grantback provision has offsetting procompetitive effects, such as (1) promoting dissemination of licensees' improvements to the licensed technology, (2) increasing the licensors' incentives to disseminate the licensed technology, or (3) otherwise increasing competition and output in a relevant technology or innovation market.

Id. at 30.

n160. Radcliffe, *supra* note 29, at 184 ("Issues [that] might make grantbacks a violation of antitrust law: a) Licensor is [a] dominant firm in the market, b) Assignment instead of non-exclusive license, c) Cartel behavior to allocate customers or territory, d) Ability of licensee to use his newly developed technology, [and] e) Duration of restrictions.").

n161. Schlicher, *supra* note 49, at 369.

n162. See, e.g., Stolberg, *supra* note 51.

n163. See, e.g., *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C. Mass. 1817) (discussing the ability to invalidate patents on public policy grounds). This section addresses the invalidation of the stem cell patent on purely public policy grounds, and is not concerned with other possible patent-invalidating causes. For the purposes of this Note, it has been assumed that the stem cell patent is valid and enforceable in all other respects, other than the possible public policy exception.

n164. *Id.*

n165. Id.

n166. Id.

n167. Id.

n168. Kojo Yelapaala, *Owning the Secret of Life: Biotechnology and Property Rights Revisited*, 32 *McGeorge L. Rev.* 111, 204 (2000) (citing *Lowell*, 15 *F. Cas.* at 1019).

n169. Richard J. Gilbert, *Antitrust Policy in High Technology Markets*, Address Before the Association of American Law Schools (Jan. 7, 1994), in *Antitrust Pitfalls in Licensing*, at 175, 223 (PLI Pat., Copyright, Trademarks & Literary Prop. Course, Handbook Series No. G4-3920, 1994).

Twenty years ago, about 70 percent of the patents that were contested in court were held to be invalid. Today, that figure has been reversed. Although such statistics may be difficult to interpret because they depend on the cases that actually go to court, the reversal appears to reflect a changed posture adopted by the Court of Appeals for the Federal Circuit toward the enforceability of patent rights.

Id.

n170. See generally *Manual of Patent Examining Procedure* 706.03(a) (8th ed.) (2000).

n171. Rai, *supra* note 27, at 843 ("Within patent law itself, compulsory licensing should be used only infrequently. Commercial improvers should not, as a routine matter, be putting courts in the institutionally awkward position of setting royalties for compulsory licenses.").

n172. Id.

Although some form of compulsory licensing for upstream research could be advisable in other industries, the use of compulsory licensing in the biopharmaceutical industry may not be wise. The biopharmaceutical industry is heavily dependent on patent law, and a compulsory licensing requirement may be too radical a departure from the existing regime, under which patent owners almost always have the ability to choose whether they want to license.

Id. Cf. Gitter, *supra* note 38, at 1679 (arguing in favor of a compulsory licensing regime coupled with an experimental use exception for the human DNA sequence patents).

n173. See Gitter, *supra* note 38, at 1682. The Bayh-Doyle Act requires federally funded patentees to license

others where the patentee has "failed to achieve sufficient practical application of the invention" or where action is required in light of health and safety needs. *Id.* (citing *35 U.S.C. 203(1)(a)* (1994)). The Atomic Energy Act allows non-exclusive licenses where the patent is concerned with the public interest. *Id.* (citing *42 U.S.C. 2183* (1994)). Also, the Clean Air Act allows the ordering of licenses for patents dealing with air pollution or prevention where a lack of patents could cause substantial downturns in competition or monopolistic tendencies. *Id.* (citing *45 U.S.C. 7608* (1994)).

n174. E.g., Rai, *supra* note 27, at 843 ("The only situation where a patent owner can plausibly be forced into compulsory licensing is if it accumulates enough narrow patents to confer monopoly power in a relevant market.").

n175. Gitter, *supra* note 38, at 1679.

n176. *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1157-58 (6th Cir. 1978).

n177. Gitter, *supra* note 38, at 1679.

n178. Rai, *supra* note 27, at 843 ("A conservative approach to compulsory licensing would encourage the improver to attempt in the first instance to secure a license through an ordinary market transaction.").