Harvard Journal of Law & Technology
Volume 19, Number 1 Fall 2005

INVERTING THE LOGIC OF SCIENTIFIC DISCOVERY: APPLYING COMMON LAW PATENTABLE SUBJECT MATTER DOCTRINE TO CONSTRAIN PATENTS ON BIOTECHNOLOGY RESEARCH TOOLS

*Peter Yun-hyoung Lee**

TABLE OF CONTENTS

---

* Law clerk for the Honorable Barry G. Silverman, U.S. Court of Appeals for the Ninth Circuit. I would like to thank Professor Arti K. Rai and the members of the Fall 2004 seminar *The Public and the Private in High Technology* at Yale Law School.

I. INTRODUCTION

Although patent law aims to promote progress,[1] recent scholarship suggests that some patents may actually inhibit basic research and thereby impede progress. This phenomenon appears to be particularly true in biotechnology,[2] where patents on research tools — products and processes that are vital inputs of scientific experimentation — can effectively create individual property rights that impinge upon broad areas of scientific inquiry.[3] For example, patents on recombinant gene technology, oncogenic non-human animals, and human embryonic stem cells allow patent holders to exclude others from using technologies that are vital for further exploration of basic biological questions.[4] Concerns over research tool patents have heightened in light of the narrowing of the experimental use exception, which had traditionally allowed free, unlicensed use of patented material for noncommercial, academic pursuits.[5]

---

1. *See* U.S. CONST. art. I, § 8, cl. 8 (authorizing Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"). Interestingly, Malla Pollack has argued that "progress" in the Constitution is actually best read to mean "spread" or "diffusion" rather than some notion of substantive innovation. Malla Pollack, *What Is Congress Supposed To Promote?: Defining "Progress" in Article I, Section 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause*, 80 NEB. L. REV. 754, 755 (2001). She concedes, however, that the authors of this clause understood that wide dissemination of technical knowledge was a prerequisite for qualitative improvement of arts and sciences. *Id.* at 773. Ultimately, then, even Pollack's reading of "progress" as "spread" leads to a conclusion that the constitutional framers intended for patents to contribute to scientific progress in the sense of qualitative innovation.

2. *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

3. The National Institutes of Health ("NIH") defines research tools as "tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999).

4. *See, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1079 (1989); David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 110 (2001); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 293 (2003).

5. *See infra* Part II.B.

The potential for patents on research tools to stifle scientific progress arises from a crucial distinction between "upstream" and "downstream" assets that lies at the heart of the patent system. Traditional patent law is predicated on a scheme in which innovators apply freely available upstream knowledge to develop patentable downstream technologies. In a prototypical example, a pharmaceutical researcher applies basic principles of biochemistry to develop new medicines. Within this system, scientific progress depends on the simultaneous existence of two property regimes: an expansive public domain of freely-accessible knowledge and a robust system of exclusive patent rights to reward innovation. Patent law establishes both of these regimes by denying patents on foundational elements such as basic knowledge while creating exclusive property rights that encourage innovators to produce new technologies. Traditional patent doctrine promotes innovation by maintaining both upstream accessibility to basic tools and knowledge as well as downstream privatization of products and processes.

Research tools, however, invert this paradigm because they are a specialized class of technologies that lie anterior to, and produce, basic knowledge. Examples of research tools include proton accelerators, compound microscopes, and the "artificially-bred" *Drosophila* fruit fly,[6] technologies that are all "upstream" to basic knowledge. Whereas the traditional paradigm involves the application of basic knowledge to create new technology, in the case of research tools, technology ultimately helps create new basic knowledge. Analogously, whereas most patents cover the *outputs* of scientific investigation, patents on research tools cover the *inputs* of that investigation. Allowing strict property rights over such research tools permits propertization near the beginning of the development chain and threatens to establish individual control over broad areas of scientific research. Unlike patents on the vast majority of end-product technologies, patents on research tools present a fundamental conflict between maintaining the free availability of basic knowledge and encouraging innovation by granting property rights over new technologies. If knowledge itself is not patentable, should one be able to patent the technological fountain from which it springs?

Advancing technology and evolving doctrine that liberally construes patentable subject matter raise concerns that patenting of research tools will increase. This increase could lead to deeper encroachment of individual property rights into the tradition of "open science"[7] that has historically pervaded biomedical research. Propo-

6. *See, e.g.*, ROBERT E. KOHLER, LORDS OF THE FLY: *DROSOPHILA* GENETICS AND THE EXPERIMENTAL LIFE (1994) (illustrating that the common fruit fly, *Drosophila melanogaster*, has served as a remarkably productive research tool in genetics).

7. *See* Rai & Eisenberg, *supra* note 4, at 291.

nents of strong intellectual property rights might argue that such patents actually help accelerate research and development. On the contrary, this Article argues that such encroachments upset the central balance between basic and applied knowledge that drives scientific progress. However, rather than advocating a change in patent law to exempt research tools from patentability, this Article argues that the common law prohibition against patenting natural laws, natural phenomena, and abstract principles already provides a prudential and legal basis for narrowing patents on certain types of biomedical research tools.

Underlying this common law prohibition is a policy interest in keeping knowledge and other foundational elements of research freely available in the public domain. Recent developments in patent law appear to undermine this objective. For example, the most influential contemporary statement of patentable subject matter doctrine, *Diamond v. Chakrabarty*,[8] fundamentally misconceives the relevant distinctions animating patent law. *Chakrabarty* holds that the distinction between naturally-occurring and non-naturally-occurring separates the spheres of unpatentable and patentable subject matter.[9] The more appropriate distinction for determining patentability, however, is that between upstream, enabling resources (whether natural or artificial) and downstream, end-product applications.

This Article will focus on human embryonic stem cells ("HESCs"), which are prime examples of upstream assets whose unique knowledge-enabling properties warrant differential treatment in the patent system. HESCs are indispensable for conducting biological research, and patenting them threatens to privatize access to broad areas of basic investigation. While this Article focuses on HESCs, its claims are applicable to other similarly-situated research tools. Many research tool patents are effectively creating exclusive property rights in resources vital to the generation of basic knowledge. These patents disrupt the balance between freely available basic knowledge and privatized applied knowledge that is crucial to driving innovation.

Although scholars have argued against patenting HESCs on a variety of grounds,[10] this Article posits that existing patent doctrine already possesses the solution to this problem. A new layer of patent doctrine to "liberate" research tools is unnecessary because the real failure of patent law is the courts' inability to appropriately apply existing doctrine to novel technologies.

---

8. 447 U.S. 303 (1980).

9. *Id.* at 309.

10. *See, e.g.*, Christopher D. Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157, 198 (2002).

This Article does not attempt to conclusively define the relationship between patents and scientific progress.[11] Elsewhere, I have suggested that in certain contexts, patents on research tools may help spark the rare paradigm shifts that fundamentally advance scientific theory.[12] On an everyday level, however, progress within a particular paradigm depends on the ready availability of the basic tools of science, which common law patentable subject matter doctrine helps to ensure.

Part II of this Article describes how patents on research tools can create exclusive rights over basic scientific knowledge and theory, a phenomenon exacerbated by the narrowing of the experimental use exception. Part III explores the science and patenting of HESCs, explaining how patents on these resources threaten to stifle investigation in a broad area of basic science. Part IV examines the common law prohibition against patenting natural laws, natural phenomena, and abstract principles as well as the policies underlying this doctrine. Part V applies this doctrine to argue that patents on HESCs should be restricted. Part VI argues that since the Constitution's Intellectual Property clause expresses a policy objective, courts have greater flexibility to engage in policy-oriented interpretation when determining whether patents on research tools should be granted.

II. THE EFFECTS OF PATENTS ON SCIENTIFIC RESEARCH

A. Potential Downstream Effects of Patenting Research Tools

Although common law patent doctrine has long held that natural laws, natural phenomena, and abstract principles are not patentable, scientists can patent the technological devices that are necessary to discover, explore, and apply them. Depending on the nature of the scientific inquiry in question, patents on research tools can effectively create ownership rights that restrict access to scientific knowledge. For example, if Newton had patented prisms in a sufficiently broad manner, he might have achieved a monopoly over the study and application of basic optical properties. Though this hypothetical may sound far-fetched, the modern trend of patenting biotechnology research tools raises this type of concern. Research tools are unique interfaces between the realms of technology and basic knowledge. As such, they are focal points in the tension between rewarding technological innovation with patents and preserving free access to basic knowledge.

---

11. For a discussion of different views of this relationship, see Peter Lee, Note, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659, 686 (2004).

12. *See id.* at 692–93.

Two primary factors affect whether a patent on a certain technology will effectively create an exclusive right to investigate particular scientific phenomena and theories. The first factor involves the breadth of patent claims. The further a patent moves away from claiming a specific device and towards claiming a general effect, the broader the patent's scope. This in turn creates a greater potential for establishing exclusive rights to the exploration of a particular natural law, natural phenomenon, or abstract principle. For example, a patent on a specific compound microscope design would do little, even assuming the absence of licensing opportunities, to frustrate exploration of the germ theory of disease, as researchers could use other microscopes to study bacteria. However, a patent claiming the principle or effect of microscopy could fundamentally frustrate this type of research.

The second factor to consider is whether a particular kind of technological device is absolutely necessary for exploring a certain scientific question and has no adequate substitutes. A patent claiming the effects of an entire class of technology would not hinder research if substitute classes of technologies were available. For example, a broad patent on functional magnetic resonance imaging technology would not frustrate investigation of the correlation between brain activity and function, since researchers could use other technological frameworks, such as positron emission tomography, to study the same phenomenon. The more essential a technology is for exploring a particular subject matter, the greater the potential for patents on that technology to effectively privatize basic knowledge. Considering both of these factors together, if a patent broadly claims a research technology for which there are no substitutes, then that patent is more likely to lead to a monopoly of knowledge.

Ultimately, the extent to which patents help or hinder innovation in contemporary biomedical science is a complex empirical question that this Article does not attempt to resolve.[13] Studies focused on this question have produced conflicting results. Robert Merton's influential research claims that a deep-seated norm of communalism encourages scientists to share results and discoveries.[14] More recently, interviews with dozens of intellectual property attorneys, scientists, business representatives, and government officials have led others to conclude that patents on research tools rarely prevent scientists from pursuing worthwhile projects.[15] Rebecca Eisenberg has described a

13. *See, e.g.*, Iain M. Cockburn, *The Changing Structure of the Pharmaceutical Industry*, 23 HEALTH AFF. 10, 17–20 (2004) (presenting arguments both for and against strong patenting of upstream research tools).

14. ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 273–75 (1973).

15. *See* John P. Walsh et al., *Working Through the Patent Problem*, 299 SCIENCE 1020, 1021 (2003).

model where scientists freely exchange findings while university lawyers haggle over rights and licensing agreements.[16] In addition, patent-holding scientists and pharmaceutical companies do not always assert their full exclusionary rights.[17]

However, others have suggested that patents on research tools undermine scientific exchange, and ultimately, progress. One survey found that twenty-seven percent of geneticists cited the need to honor an industrial sponsor's demands as an important reason for withholding useful research results, techniques, and materials from fellow academic scientists, and twenty-one percent cited the need to protect the commercial value of results as a reason for withholding data and materials from others.[18] In addition to encouraging withholding by researchers, patents can discourage legitimate and permitted uses of patented technologies by those who are nevertheless concerned about infringement suits. In 1988, Cetus, a private biotechnology firm, publicly stated that it would aggressively enforce its patent on polymerase chain reaction technology.[19] Even though the company planned to exempt academic researchers, this announcement raised concerns that scientists would refrain from fully adopting and realizing the potential of this technology.[20] Some have argued that patenting research tools, such as gene fragments and receptors, could create a "tragedy of the anticommons" that would drastically hinder downstream research.[21] Christopher Hazuka warns that the Wisconsin Alumni Research Foundation's patents on stem cells could "limit exploration of the properties and potential uses" of those cells,[22] a problem examined in greater depth below.

The potential for patents to inhibit innovation has led to arguments for stricter constraints on the patenting of upstream experimen-

---

16. Rebecca S. Eisenberg, *Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 223, 242 (Rochelle Cooper Dreyfuss et al. eds., 2001).

17. *See, e.g.*, Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, 13 SOC. PHIL. & POL'Y 145, 150 (1996); Rai & Eisenberg, *supra* note 4, at 296 ("[P]atent holders practice an informal regime of price discrimination in favor of nonprofit researchers, primarily by not enforcing their patents against such researchers for non-commercial uses."); Leon Rosenberg, *Perspectives from Different Sectors: Major Pharmaceutical Company*, *in* INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 63 (Nat'l Research Council ed., 1997).

18. Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 JAMA 473, 478 (2002). The most common reasons cited for withholding information and materials include the effort required to produce the requested items (eighty percent) and the need to protect a junior colleague's ability to publish findings (sixty-four percent). *Id.*

19. *See Cetus to Exact Royalties from PCR Sales; Probe Absolves Convicted Rapist*, BIOTECHNOLOGY NEWSWATCH, Sept. 5, 1988, at 7.

20. *See id.*

21. *See, e.g.*, Heller & Eisenberg, *supra* note 2, at 699.

22. Hazuka, *supra* note 10, at 157–58.

tal methods and products.[23] For example, the National Institutes of Health ("NIH") has proposed remedial measures to address the fact that "[m]any scientists and institutions involved in biomedical research are frustrated by growing difficulties and delays in negotiating the terms of access to research tools."[24] While more empirical work is needed to clarify these problems, studies indicate that research tool patents have the potential to stifle downstream research. The recent narrowing of the experimental use exception further exacerbates this problem.

B. The Narrowing of the Experimental Use Exception

The experimental use exception has historically functioned as a safety valve in patent law, allowing the unlicensed use of patented material for academic, noncommercial purposes. Justice Story laid the foundation for this doctrine in the 1813 case of *Whittemore v. Cutter*, where he stated, "[I]t could never have been the intention of the legislature to punish a man, who constructed such a[n allegedly infringing] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[25] Under this formulation, purely academic uses of a patented machine for experimental purposes do not result in infringement liability. William Robinson's widely influential *The Law of Patents for Useful Inventions* asserted that where patented material "is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized."[26] In its original form, the experimental use exception sharply distinguished between the unlicensed use of patented technology for commercial as opposed to noncommercial uses and generally permitted the latter.[27]

Contemporary courts, however, have severely narrowed the experimental use doctrine.[28] In a 2000 case rejecting a defense of ex-

---

23. *See, e.g., id.* at 220.

24. NAT'L INSTS. OF HEALTH, REPORT OF THE WORKING GROUP ON RESEARCH TOOLS (1998), http://www.nih.gov/news/researchtools (last visited Oct. 21, 2005).

25. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

26. 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898, at 56 (1890).

27. *See* Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391) (defining infringing use as "the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification"); Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279) ("An experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee.").

28. In response to the Federal Circuit's 1984 decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), Congress passed the Hatch-Waxman Act, which introduced a limited experimental use exception to patent law. Drug Competition and Patent Term Restoration (Hatch-Waxman) Act, Pub. L. No. 98-417, § 202, 98 Stat.

perimental use, Judge Rader of the Federal Circuit offered his concurring opinion that "the Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement."[29] In the seminal 2002 case of *Madey v. Duke University*, the Federal Circuit held that Duke University's use of patented laser technology in academic, noncommercial research constituted patent infringement.[30] The court noted that the laser technology helped Duke advance its institutional goal of education and allowed it to attract research grants, students, and faculty.[31] It therefore concluded that Duke was liable for patent infringement, since "so long as the [suspect] act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense."[32] Under the *Madey* reasoning, an absolute defense of experimental use is no longer available to universities, the historic paragons of disinterested research.[33]

In the face of an eroded experimental use exception, increased patenting of research tools becomes more alarming. The experimental use defense had long balanced the interests of academic researchers seeking access to basic materials and patent holders seeking protection for their investments. Now, however, even noncommercial uses are not necessarily exempt from infringement liability. Consequently, patents on research tools have greater potential to narrow access to basic scientific knowledge, a phenomenon clearly demonstrated in the case of human embryonic stem cells.

1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1) (2000)). The Hatch-Waxman exception allows firms to use patented material to conduct FDA-mandated tests when developing generic versions of patented drugs. *Id.* While policy and academic commentators often refer to the Hatch-Waxman Act as establishing an experimental use exception, this is a mischaracterization. The protected use is commercial in nature, as the exception was designed to facilitate testing legally required to market new generic drugs. Thus, it is not a true experimental use exception of the kind Justice Story articulated in *Whittemore*, which would protect strictly philosophical, noncommercial uses of patented material. *See supra* note 25 and accompanying text.

29. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1352 (Fed. Cir. 2000) (Rader, J., concurring).

30. 307 F.3d 1351 (Fed. Cir. 2002).

31. *Id.* at 1362.

32. *Id.*

33. *See* Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 84 ("[R]ecent decisions from the U.S. Court of Appeals for the Federal Circuit threaten to shrink the experimental-use exemption to extinction."). *See also Roche Prods.*, 733 F.2d at 863 ("We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."); Applera Corp. v. MJ Research, Inc., 311 F. Supp. 2d 293, 296 (D. Conn. 2004) (affirming *Madey's* "very narrow" and "strictly limited" interpretation of the experimental use exception).

III. THE SCIENCE AND PATENTING OF HUMAN EMBRYONIC STEM CELLS

A. The Science of Embryonic Stem Cells

Two defining characteristics render human embryonic stem cells ("HESCs") invaluable subjects of basic scientific investigation: (1) they are unspecialized entities that renew themselves for long periods of time through cell division, and (2) they can be induced to become differentiated cells with specific functions.[34] In this latter regard, embryonic stem cells are considered pluripotent because they retain the ability to differentiate into most kinds of body tissue.[35] While adult stem cells exhibit some of the properties of embryonic stem cells, they do not have the ability to differentiate into as many kinds of tissue and have been difficult to isolate and purify.[36] The immense importance of HESCs lies in their unique value in investigating human biology and in their potential as treatments for a host of currently intractable diseases.[37]

Stem cell research promises to advance fundamental knowledge of human developmental biology and cell regeneration. Understanding the processes by which stem cells remain unspecialized and self-renewing can lead to greater insights into how the human body repairs and replaces old and degenerated cells, as well as how it "preprograms" the lifespan of certain cells.[38] Identifying the signals that induce HESCs to become specialized cells may illuminate the complex processes of differentiation that allow simple multicellular forms to develop into highly specialized and inter-coordinated tissues.[39] Comparative studies of HESCs and other cell types may reveal the factors driving cell senescence and death.[40] In short, "[s]tem cells are one of the most fascinating areas of biology today."[41]

HESCs also hold great promise as a basis of new therapies. Scientists are investigating the ability of stem cells to regenerate damaged tissue when injected into target areas of the human body.[42] Stem cells are a potential therapy for a wide range of diseases predicated on cell

---

34. *See* NIH, STEM CELL INFORMATION 1 (2002), http://stemcells.nih.gov/staticresources/info/basics/StemCellBasics.pdf.

35. *See id.* at 5.

36. *See id.* at 4–5 (explaining that adult stem cells have limited plasticity relative to embryonic stem cells).

37. *See id.* at 1, 5–6.

38. *See id.* at 1–2.

39. *See id.* at 5.

40. *See id.*

41. *Id.* at 1.

42. *See, e.g.*, Richard Guerra, Comment, *Therapeutic Cloning as Proper Subject Matter for Patent Eligibility*, 43 IDEA 695, 698 (2003).

death, such as Parkinson's disease, diabetes, and heart disease.[43] According to Jennifer Enmon, "Pluripotent stem cells are the future of treatments for currently incurable diseases."[44]

B. Patents on Human Embryonic Stem Cells

HESCs are also the subject of broad patent claims. James Thomson of the University of Wisconsin at Madison first isolated HESCs in 1998 and received three patents related to his discovery. They claim, respectively: (1) primate embryonic stem cells,[45] (2) a purified preparation of human embryonic pluripotent stem cells,[46] and (3) methods of hematopoietic differentiation of human embryonic pluripotent stem cells.[47] The Thomson patents were assigned to the Wisconsin Alumni Research Foundation ("WARF"), a non-profit organization that manages the intellectual property assets of the University of Wisconsin at Madison. WARF has granted an exclusive license for these patents to Geron Corporation, a private biotechnology firm that had sponsored Thomson's research; this license allows Geron to commercialize products based on six cell types that Thomson has developed.[48]

An examination of WARF's patents reveals their immense breadth. Claim 1 of the patent on a purified preparation of HESCs covers:

> A purified preparation of pluripotent human embryonic stem cells which (i) will proliferate in an in vitro culture for over one year, (ii) maintains a karyotype in which the chromosomes are euploid and not altered through prolonged culture, (iii) maintains the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) is inhibited from differentiation when cultured on a fibroblast feeder layer.[49]

Because of its breadth, this claim relating to the purification and culturing of HESCs effectively encompasses all HESCs that can live in

---

43. *See* Hazuka, *supra* note 10, at 164–65; NIH, *supra* note 34 at 1.

44. Jennifer L. Enmon, *Stem Cell Research: Is the Law Preventing Progress?*, 2002 UTAH L. REV. 621, 647 (2002).

45. U.S. Patent No. 5,843,780 (filed Jan. 18, 1996).

46. U.S. Patent No. 6,200,806 (filed June 26, 1998).

47. U.S. Patent No. 6,280,718 (filed Nov. 8, 1999). Hematopoietic cells are a type of cell normally found in blood and bone marrow.

48. *See* Amy Ligler, *Egregious Error or Admirable Advance: The Memorandum of Understanding That Enables Federally Funded Basic Human Embryonic Stem Cell Research*, 2001 DUKE L. & TECH. REV. 37 (2001), http://www.law.duke.edu/journals/dltr/articles/pdf/2001DLTR0037.pdf.

49. '806 Patent.

culture for over one year, maintain the normal (euploid) number of chromosomes for the human species, and retain the pluripotent capacity to differentiate into any type of tissue. In short, this claim encompasses virtually all HESCs of significant research value.

Though Thomson's inventive step was discovering the method for isolating and culturing HESCs, his patents also cover the stem cells themselves. Furthermore, the patents' claims cover all HESCs, and not just the cell lines that Thomson isolated.[50] Therefore, "any researcher must negotiate with WARF before using [HESCs], even if that researcher isolates new [HESCs] or uses a new method to do so."[51] Even foreign biotechnology companies and research institutions fear potential infringement suits that could arise from selling their stem cell lines in the United States.[52] If those cells match the claims contained in WARF's patents, potential importers who wish to distribute their cells in the United States must obtain a license in order to avoid potential infringement.[53] As Christopher Hazuka observes, the HESC patents "cede a remarkable amount of territory to WARF."[54]

The patent on the method for isolating and culturing these cells also creates potential barriers to future research. A technique for maintaining undifferentiated cells in laboratory environments is critical in attempts "to use these cells to make mature cells, organs, and tissues that can be used therapeutically."[55] Therefore, even if another party were able to derive useful stem cells without infringing a patent claim, it would likely be forced to infringe WARF's patent on the only known method for maintaining the cells' viability.

An agreement between HESC patent holders and NIH has somewhat eased concerns over access to HESCs for research purposes. In October 1999, WARF established WiCell Research Institute, Inc., a non-profit organization that now holds the licenses to WARF stem cells.[56] Under the terms of a Memorandum of Understanding ("MOU"), WiCell agreed to offer WARF cells to scientists at NIH laboratories at only the cost of preparation.[57] Furthermore, WiCell agreed to allow other federally-funded non-profit researchers access to the stem cell lines upon negotiating similar arrangements.[58] Although the MOU grants NIH researchers rather liberal use of Wiscon-

50. *See, e.g.*, Hazuka, *supra* note 10, at 173.

51. *Id.* at 158.

52. *See* Ligler, *supra* note 48, at 7.

53. *See id.*

54. Hazuka, *supra* note 10, at 174.

55. *Id.* at 158.

56. *See* WiCell Research Institute, Inc.: About Us, http://www.wicell.org/aboutus (last visited Nov. 21, 2005).

57. *See* Memorandum of Understanding Between WiCell Research Institute, Inc., and Public Health Service, U.S. Department of Health and Human Services 5 (Sept. 5, 2001), *available at* http://ott.od.nih.gov/pdfs/WiCellMOUhuman.pdf.

58. *See* Ligler, *supra* note 48, at 5.

sin stem cells for research purposes, the agreement includes strict reach-through provisions for commercial applications.[59] Researchers using WARF HESCs may patent any discoveries made in the course of research, but they may not commercialize these discoveries without first negotiating a license with WARF.[60]

Although WiCell's agreement with NIH has allowed relatively liberal and inexpensive access to HESCs for research purposes, it is important to note that this MOU is a voluntary agreement. WiCell still retains broad legal rights over the WARF HESCs: it may exclude any party from using the HESCs, charge whatever license fee it desires for their use, or pursue infringement suits against those who use the HESCs without its permission. The only limitation on these rights arises from the march-in provisions of the Bayh-Dole Act, which apply because of the federal government's funding of Thomson's original primate research.[61] The march-in provisions require entities who patent the results of federally-funded research to grant a license to a party of the government's designation. These provisions, however, pertain only to federally-funded research and will not apply to all patents on research tools, particularly given the declining growth of public financing for research.[62] The MOU is particularly advantageous to WiCell, which retains all rights to commercialize any discoveries arising from federally-funded basic research. Indeed, scholars have criticized WiCell's apparent "largesse" by noting that "the federal government is funding the expanded basic research of two private companies [(WiCell and Geron)] that already have a legal monopoly on a broad set of stem cell products and methods."[63] WiCell's apparent generosity in allowing at-cost access to its patented cells may ultimately prove quite self-rewarding.

Setting aside the voluntary MOU, the broad patent grant over HESCs raises the question of how such expansive patents can affect basic research. As noted, Hazuka has warned that WARF's broad patents could constrain exploration of the properties of these cells.[64] A

---

59. Interestingly, some reach-through provisions, depending on their structure, may run afoul of the "limited [t]imes" element of the constitutional authorization of patent power. U.S. CONST. art. I, § 8, cl. 8. A "viral" reach-through provision that attaches and renews itself with every new generation of subsequent patented discoveries has the potential to persist indefinitely, in contravention of the finite term prescribed in the Intellectual Property clause.

60. *See* Ligler, *supra* note 48, at 5.

61. *See* Bayh-Dole University and Small Business Patent Procedures Act, Pub. L. No. 96-517, 94 Stat. 3019 (codified as 35 U.S.C. §§ 200–212 (2000)). Contrary to previous law, the Bayh-Dole Act permits and encourages universities to patent inventions and discoveries arising from publicly-funded research.

62. *See* NAT'L RESEARCH COUNCIL, INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 2 (1997), *available at* http://books.nap.edu/html/property/1.html#chap1.

63. Ligler, *supra* note 48, at 1.

64. *See* Hazuka, *supra* note 10, at 157–58.

patent on this upstream research tool creates an extremely wide zone of exclusivity, since "[d]ecades of discoveries, innovations, and inventions remain in determining how HESCs may be utilized."[65] HESCs are critical to achieving fundamental new insights into basic biology, and granting individual property rights over them seems contrary to the policy objective of keeping basic scientific knowledge freely available to the public. It is against this background that this Article will explore a common law doctrine that protects this kind of access: the prohibition against patenting natural laws, natural phenomena, and abstract principles.[66]

IV. THE COMMON LAW PROHIBITION AGAINST PATENTING NATURAL LAWS, NATURAL PHENOMENA, AND ABSTRACT PRINCIPLES

A. Statutory Foundations

While the prohibition against patenting natural laws, natural phenomena, and abstract principles developed primarily through common law, it is instructive to first explore its statutory foundations. The Constitution states that "[t]he Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[67] While the framers did not explicitly define "discoveries," early patent statutes indicate that patentable discoveries had to be of a tangible, rather than conceptual, nature in order to be patented. The first Patent Act, enacted in 1790, established a system of letters patents for the invention or discovery of "any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used."[68] The Patent Act of 1793 extended this definition of patentable subject matter to include "any new and useful

65. *Id.* at 183.

66. In addition, another common law doctrine may be applicable to the patenting of research tools: the prohibition against patenting inventions that serve immoral or illegal purposes. As Justice Story observed:

> 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.

Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568). Though this common law doctrine is declining in relevance, attempts to cordon off broad areas of significant scientific inquiry for private exploitation could arguably run afoul of this "immoral purposes" test, though it is the act of patenting that would be considered immoral, rather than the invention to be patented.

67. U.S. CONST. art. I, § 8, cl. 8.

68. Act of Apr. 10, 1790, ch. 33, § 1, 1 Stat. 109, 110.

art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter, not known or used before the application."[69] Amendments to the federal patent laws during the nineteenth and twentieth centuries largely preserved this requirement of tangibility for patentable subject matter.[70] The present patent act, enacted in 1952, maintains this principle by stating, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[71] From a textual perspective, patents seem to be available only for tangible discoveries, such as a process or machine, and not for intangible concepts, such as natural laws and basic knowledge. However, because the patent laws only define patentable subject matter affirmatively, they do not explicitly enumerate that which is not patentable.

B. The Common Law Prohibition Against Patenting Natural Laws, Natural Phenomena, and Abstract Principles

The prohibition against patenting natural laws, natural phenomena, and abstract principles is largely a product of common law, although court opinions have frequently invoked statutory text and intent in their reasoning. As the Supreme Court has observed, a literal reading of current patent law does not "suggest that § 101 [of the Patent Act] has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable."[72]

Early cases focused on the invalidity of patents claiming general principles or effects. In 1842, the Supreme Court narrowly construed a patent on a process for fastening a rib to a cotton gin, holding that "the end to be accomplished is not the subject of a patent."[73] Rather, it is the "new and useful means" for obtaining that end which constitute the proper scope of a patent.[74] The Court thus crucially distinguished between a patentable means and a non-patentable result or effect.

In *Le Roy v. Tatham*, the Court affirmed a patent on a process for manufacturing lead pipes but refused to construe the patent as cover-

---

69. Act of Feb. 21, 1793, ch. 49, § 1, 1 Stat. 318, 319.

70. *See* Act of Apr. 17, 1800, § 1, 2 Stat. 37; Act of July 4, 1836, § 6, 5 Stat. 117, 119; Act of July 8, 1870, ch. 230, § 24, 16 Stat. 198, 201; Act of March 3, 1897, ch. 391, § 1, 29 Stat. 692; 35 U.S.C. § 31 (1948); Sam S. Han, *Analyzing the Patentability of "Intangible" Yet "Physical" Subject Matter*, 3 COLUM. SCI. & TECH. L. REV., at 12 (2002), http://www.stlr.org/cite.cgi?volume=3&article=2.

71. 35 U.S.C. § 101 (2000).

72. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

73. Carver v. Hyde, 41 U.S. 513, 519 (1842).

74. *Id.*

ing the general principle of creating lead pipe.[75] The Court reasoned, somewhat tautologically, "[A] principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."[76] In *O'Reilly v. Morse*, the Court similarly held that a telegraph patent was overly broad because it "claim[ed] the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing [of] intelligible characters, signs, or letters at a distance."[77] Such a claim sought to cover the general principle of using electromagnetic force to send and receive communications and was therefore impermissibly wide in scope, leading the Court to restrict it to a specific physical method for achieving that end.

As *O'Reilly* suggests, the prohibition against patenting general effects is conceptually related to a prohibition against patenting natural phenomena. In the *Telephone Cases*, the Court held that a patent on telephony was valid, distinguishing electricity from a method for applying electricity to communicate sound: "[E]lectricity, left to itself, will not do what is wanted. The art consists in so controlling the force as to make it accomplish the purpose."[78] While all technologies apply properties of nature in some manner, patent laws did not historically permit the patenting of these properties.[79]

In the twentieth century, courts continued to enforce the prohibition against patenting theories and principles. In 1944, the Second Circuit stated, "Epoch-making 'discoveries' of 'mere' general scientific 'laws,' without more, cannot be patented."[80] In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Supreme Court addressed a patent claiming a combination of various naturally-occurring nitrogen-fixing bacteria.[81] In holding the patent invalid, the Court explained, "He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end."[82] *Funk Bros.* highlights an important connection between prohibiting patents on natural phenomena and maintaining a robust public domain of knowledge.

Subsequent decisions also considered statutory requirements in the context of broader public interests in preventing dangerous "mo-

---

75. 55 U.S. 156 (1853).
76. *Id.* at 175.
77. 56 U.S. (15 How.) 62, 112 (1854).
78. 126 U.S. 1, 532 (1888).
79. *See id.*
80. Katz v. Horni Signal Mfg. Corp., 145 F.2d 961, 961 (2d Cir. 1944) (footnote omitted).
81. 333 U.S. 127 (1948).
82. *Id.* at 130.

nopolies of knowledge" over foundational research elements. In *Brenner v. Manson*, the Supreme Court held that a process for creating chemical compounds of no known utility was not patentable.[83] Noting that the patent applicant had not established the usefulness of the process because he had not established the usefulness of the end products, the Court held that the statutory requirement of utility had not been met.[84] The Court reasoned:

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates *a monopoly of knowledge* which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to *block off whole areas of scientific development*, without compensating benefit to the public.[85]

Grounding its reasoning in the statutory requirement of utility, the *Brenner* Court identified a valuable policy interest in maintaining the free availability of knowledge unless sufficient public benefit could justify granting a patent monopoly.[86]

In contemporary times, rapid advances in computer science and biotechnology have presented new challenges to courts applying the prohibition against patenting theories and principles. In *Gottschalk v. Benson*, the Supreme Court considered a patent claiming the programmed conversion of numerical information in digital computers, and concluded that the patent claimed an idea and was therefore invalid.[87] In *Parker v. Flook*, the Court addressed a patent on a process — which included an algorithm — for determining an "alarm limit," a number that indicates suboptimal functioning of a catalytic converter.[88] The Court conceded that "[t]he line between a patentable

---

83. 383 U.S. 519 (1966).

84. *Id.* at 531–32.

85. *Id.* at 534 (emphases added) (footnote omitted).

86. *See* Hazuka, *supra* note 10, at 204 (arguing that the *Brenner* Court recognized the use of the utility requirement in distinguishing upstream from downstream research).

87. 409 U.S. 63 (1972).

88. Parker v. Flook, 437 U.S. 584, 584–85 (1978).

'process' and an unpatentable 'principle' is not always clear,"[89] but nevertheless held that the patent attempted to claim a general mathematical formula and was therefore invalid.[90] Because the algorithm could be considered within prior art, the process did not contain an "inventive concept" and therefore was not patentable.[91]

Subsequent cases have widened the scope of patentable subject matter in the field of computer science. In the aftermath of *Gottschalk* and *Parker*, the Court of Customs and Patent Appeals developed the *Freeman-Walter-Abele* test.[92] The *Freeman* court applied a two-step analysis to determine whether a patent impermissibly claimed an abstract algorithm.[93] The patent claim was invalid if it: (1) directly recited an "algorithm," and (2) wholly preempted that algorithm.[94] In *Walter*, the court rephrased the second step of the *Freeman* test and held that a claim was valid as long as the "algorithm is implemented in a specific manner to define structural relationships between the physical elements of the claim . . . or to refine or limit claim steps."[95] In *Diamond v. Diehr*, the Supreme Court held that a process for curing synthetic rubber was not unpatentable simply because it involved a mathematical formula.[96] In 1994, the Federal Circuit in *In re Alappat* took a step toward setting aside the requirement of physical transformation altogether and identified utility as the lynchpin of patentability.[97] In short, patent doctrine has evolved from generally prohibiting patents on algorithms, to allowing them if they are part of a physical transformation, to permitting them based on the algorithm's utility.

Several cases have also widened the scope of patentable subject matter in biotechnology. Here, patent doctrine has emphasized the distinction between artificially modified natural products and truly natural products. In 1964, the Fourth Circuit held that purifications or isolations of natural products were patentable.[98] In 1977, the Court of

89. *Id.* at 589.

90. *Id.* at 595.

91. *Id.* at 594.

92. *See In re* Freeman, 573 F.2d 1237 (C.C.P.A. 1978); *In re* Walter, 618 F.2d 758 (C.C.P.A. 1980); *In re* Abele 684 F.2d 902 (C.C.P.A. 1982). This test has also been adopted by the Federal Circuit. *See* State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1374 (Fed. Cir. 1998) ("First, the claim is analyzed to determine whether a mathematical algorithm is directly or indirectly recited. Next, if a mathematical algorithm is found, the claim as a whole is further analyzed to determine whether the algorithm is 'applied in any manner to physical elements or process steps.'").

93. *Freeman*, 573 F.2d at 1245.

94. *Id.*

95. 618 F.2d at 767.

96. 450 U.S. 175, 184 (1981) (emphasizing that the process in question rendered a transformation or reduction of an article "to a different state or thing").

97. 33 F.3d 1526, 1544 (Fed. Cir. 1994) (citing *Diehr's* emphasis on focusing the patentability analysis on whether an innovation produces "a useful, concrete and tangible result").

98. Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156 (4th Cir. 1958).

Customs and Patent Appeals similarly held that purifications of naturally occurring products constituted patentable subject matter under § 101 of the Patent Act, reasoning that "[t]he biologically pure culture [claimed in the patent application] clearly does not exist in, is not found in, and is not a product of, 'nature.' It is man-made and can be produced only under carefully controlled laboratory conditions."[99]

This distinction between modified and natural products found further expression in the seminal 1980 decision, *Diamond v. Chakrabarty*.[100] There the Supreme Court held that a live, man-made microorganism was patentable,[101] a decision that "opened the door to patenting the organisms, molecules, and research techniques emerging from biotechnology."[102] The Court distinguished earlier precedent, differentiating between the "nonnaturally occurring manufacture or composition of matter" at issue in *Chakrabarty* and the naturally occurring bacteria considered in *Funk Bros.*[103]

The expansion of patentable subject matter, even over abstract principles, approached its contemporary zenith with the Federal Circuit's decision in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*[104] In affirming a business method patent on a process for managing mutual fund investments, the Federal Circuit disregarded physicality requirements for process patents.[105] Instead, it held that patentability analyses should focus on "the essential characteristics of the subject matter, in particular, its practical utility."[106] *State Street Bank* raises the prospect of rather expansive interpretations of patentable subject matter, and the academic community has roundly criticized its breadth.[107]

Even in this more permissive patenting environment, however, purely abstract general principles are not eligible for patent protection. In denying a patent that claimed a method of illustrating asset values by plotting them on a chart, the Patent and Trademark Office reasoned, "The abstract idea which forms the heart of the invention . . . does not become a technological art merely by the recitation in the claim of 'transforming physical media into a chart' . . . and 'physi-

---

99. *In re* Bergy, 563 F.2d 1031, 1035 (C.C.P.A. 1977).

100. 447 U.S. 303 (1980).

101. *Id.*

102. David C. Mowery & Arvids A. Ziedonis, *Academic Patent Quality and Quantity Before and After the Bayh-Dole Act in the United States*, 31 RES. POL'Y 399, 415 (2002).

103. *Chakrabarty*, 447 U.S. at 309–10.

104. 149 F.3d 1368 (Fed. Cir. 1998).

105. *Id.* at 1375.

106. *Id.*

107. *See, e.g.*, Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263 (2000); Alan L. Durham, *"Useful Arts" in the Information Age*, 1999 B.Y.U. L. REV. 1419 (1999); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139 (1999).

cally plotting a point on said chart.'"[108] While the computer and business method cases reveal some latitude in patenting naked ideas, the same expansive spirit has not extended to patenting the basic knowledge and natural phenomena that give rise to it. Intellectual property law has never allowed private ownership of basic factual knowledge, and the prohibition against patenting natural laws, natural phenomena, and abstract principles remains a solid foundation for judicial decision-making.

C. Conceptual Parallels Between Patentable Subject Matter Doctrine and the Idea-Expression Dichotomy in Copyright

To understand the prohibition against patenting natural laws, natural phenomena, and abstract principles, it is instructive to examine a conceptually analogous doctrine from copyright law: the idea-expression dichotomy. Copyright protection is not available for a general or abstract idea (e.g., a love story in general), but a specific expression of the idea (e.g., the text of *Romeo and Juliet*) is copyrightable. Thus in the seminal case of *Baker v. Selden*, the Supreme Court held that a copyright on a book that facilitates double-entry accounting could not be interpreted as granting copyright protection over the idea of such bookkeeping.[109] In *Nichols v. Universal Pictures Corp.*, Judge Learned Hand offered a classic formulation of the distinction between an uncopyrightable idea and a copyrightable expression:

> Upon any work, and especially upon a play, a great number of patterns of increasing generality will fit equally well, as more and more of the incident is left out. The last may perhaps be no more than the most general statement of what the play is about, and at times might consist only of its title; but there is a point in this series of abstractions where they are no longer protected, since otherwise the playwright could prevent the use of his "ideas," to which, apart from their expression, his property is never extended.[110]

Patentable subject matter doctrine parallels the copyright dichotomy in that a general effect (e.g., using electromagnetism to communicate signals at a distance) is not patentable, while a specific method of

108. *Ex parte* Bowman, 61 U.S.P.Q.2d 1669, 1671 (B.P.A.I. June 12, 2001).
109. 101 U.S. 99 (1879).
110. 45 F.2d 119, 121 (2d Cir. 1930) (discussing an archetypical theatrical play).

achieving the effect (e.g., the design for a particular telegraph machine) may be protected by patent.[111]

The idea-expression dichotomy is intimately related to the doctrine of merger, or the principle that "[w]hen there is essentially only one way to express an idea, the idea and its expression are inseparable and copyright is no bar to copying that expression."[112] In *Morrissey v. Procter & Gamble Co.*, the First Circuit relied on *Baker* to hold that an "expression" consisting of the rules of a sweepstakes contest was inseparable from the idea of the contest itself, and that because the idea was not copyrightable, the rules were not copyrightable either.[113]

Recently, the idea-expression dichotomy has played a prominent role in defining the scope of copyrights on computer software. In *Computer Associates International, Inc. v. Altai, Inc.*, the Second Circuit articulated a three-step abstraction-filtration-comparison test to determine whether a computer program and an alleged copy were "substantially similar," thus indicating copyright infringement.[114] The court differentiated between the unique, particularized elements of a software program, which are copyrightable, and general algorithms, which are not.[115] In so doing, the court defined a satisfactory balance between protecting innovative works and ensuring "that non-protectable technical expression remains in the public domain for others to use freely as building blocks in their own work."[116] This balance is also a primary policy concern in patent doctrine.[117]

Underlying the idea-expression dichotomy and the merger doctrine is the principle that basic knowledge and abstract ideas are so fundamental, unparticularized, and widely applicable that they are unsuitable for copyright protection. Instead, they should reside in the public domain for all to use in their creative endeavors. As the *Baker* Court observed, "[T]he truths of a science or the methods of an art are the *common property* of the whole world, and [the] author has the right to express the one, or explain and use the other, in *his own way*."[118] The Supreme Court has continued to adhere to the idea-expression dichotomy in more recent cases.[119] The Court's decisions

---

111. *See supra* notes 75–77 and accompanying text.

112. Concrete Mach. Co. v. Classic Lawn Ornaments, Inc., 843 F.2d 600, 606 (1st Cir. 1988).

113. 379 F.2d 675, 678–79 (1st Cir. 1967).

114. 982 F.2d 693, 706–12 (2d Cir. 1992).

115. *Id.* at 712–26.

116. *Id.* at 721. *See also* Lotus Dev. Corp. v. Borland Int'l, Inc., 49 F.3d 807, 814–15 (1st Cir. 1995) (refusing to find infringement of Lotus's menu command hierarchy, thus illustrating copyright law's reluctance to privatize "upstream" assets of sufficiently widespread applicability).

117. *See infra* Part IV.D.

118. Baker v. Selden, 101 U.S. 99, 100–01 (1879) (emphases added).

119. *See, e.g.*, Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 344 (1991) ("This case concerns the interaction of two well-established propositions. The first is that facts are not copyrightable; the other, that compilations of facts generally are."); Harper & Row

and that of the Second Circuit in *Computer Associates* reflect a commitment to the principle — which is also central to patent law — that keeping basic knowledge, facts, and ideas in the public domain provides the optimal foundation for facilitating innovative works.

Despite their parallels, copyright and patent law do not have identical conceptual underpinnings. Because of its more rigorous and mechanized tests for determining novelty, nonobviousness, and utility, patent law may extend more appropriately into the domain of propertizing ideas.[120] Nonetheless, the copyright doctrines of idea-expression dichotomy and merger are useful in understanding the policy of open access to basic knowledge that underlies the prohibition against patenting theories and principles.

D. Rationales Underlying the Common Law Prohibition Against Patenting Natural Laws, Natural Phenomena, and Abstract Principles

The rationales for prohibiting patents on natural laws, natural phenomena, and abstract principles generally fall into two categories. First, courts may deny patents on this subject matter because they fail to meet a statutory or doctrinal requirement. Second, courts may reject these patents for policy reasons, particularly the prudential interest in keeping such subject matter in the public domain in order to enable downstream research and application.[121]

Doctrinally, theories and principles fail to satisfy the novelty requirement of patent law; they are not new and thus the patent applicant did not actually invent anything. The *O'Reilly* Court, in denying a patent on using electromagnetism to send and receive communications, noted that the applicant in that case "claims an exclusive right to use a manner and process which he has not described and indeed had not invented."[122] Similarly, over a century later in *Parker*, the Court invalidated a patent claiming a mathematical algorithm because "[t]he rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of 'dis-

---

Publishers, Inc. v. Nation Enters., 471 U.S. 539, 556 (1985) ("No author may copyright his ideas or the facts he narrates.").

120. *See, e.g.*, *Baker*, 101 U.S. at 102 ("To give to the author of the book an exclusive property in the art described therein, when no examination of its novelty has ever been officially made, would be a surprise and fraud upon the public. That is the province of letters-patent, not of copyright.").

121. The relationship between doctrine and policy is, of course, more complex than this statement might suggest. Policy considerations regarding the best mode for promoting progress often form the substantive basis for the doctrinal requirements of patentability. Therefore, it is a somewhat artificial distinction to separate "doctrinal" and "policy" justifications for prohibiting patents on certain subject matter. I simply wish to highlight and distinguish *implicit* invocations of policy (as articulated through doctrinal requirements) and *explicit* invocations of policy considerations that do not fit into any formal doctrinal category.

122. O'Reilly v. Morse, 56 U.S. (15 How.) 62, 113 (1854).

coveries' that the statute was enacted to protect."[123] The Court reasoned that "[t]he underlying notion is that a scientific principle, such as that expressed in respondent's algorithm, reveals a relationship that has always existed."[124] In short, because natural laws and general principles fail to satisfy the novelty requirement of patent doctrine, they are outside the scope of patentable subject matter. Some courts have also held that abstract laws and principles cannot be patented because they are not useful until reduced to some practical application.[125]

The second set of rationales for prohibiting patents on basic scientific principles emanates more from an overarching policy interest in keeping the basic tools of science in the public domain than explicitly from doctrine. While references to these policy objectives frequently appear in dicta, they nevertheless form a consistent line of judicial reasoning concerning the proper scope of patentable subject matter, and judges frequently intertwine them with references to doctrinal and statutory authorities. In holding that a patent failed to satisfy the novelty requirement, the *Parker* Court recognized, "There is a very compelling reason for this rule. The reason is founded upon the proposition that in granting patent rights, the public must not be deprived of any rights that it theretofore freely enjoyed."[126] As the *Funk Bros.* Court explained, products and phenomena of nature such as "[t]he qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."[127] The distinction between basic and applied knowledge is critical to the policy interest in keeping this "storehouse of knowledge" open to all. Patent law may permit a monopoly over certain forms of applied knowledge as a necessary incentive to encourage its production. However, as the *Brenner* Court observed, courts and prospective patent holders should not extend the patent system to enable a "monopoly of knowledge" over basic intellectual assets that could "block off whole areas of scientific development, without compensating benefit to the public."[128]

These arguments revolve around the principle that elements with foundational roles in scientific investigation — such as knowledge, nature, and abstract concepts — should not be patented. As the *Gottschalk* Court observed, "Phenomena of nature, though just dis-

123. Parker v. Flook, 437 U.S. 584, 593 (1978).

124. *Id.* at 593 n.15 (analogizing an algorithm to the law of gravity, as both are relationships that existed prior to the discovery of the phenomenon and thus cannot be patented).

125. *See, e.g.*, *In re* Alappat, 33 F.3d 1526, 1543 (Fed. Cir. 1994).

126. *Parker*, 437 U.S. at 593 n.15 (1978) (quoting PETER ROSENBERG, PATENT LAW FUNDAMENTALS § 4, at 13 (1975)).

127. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

128. Brenner v. Manson, 383 U.S. 519, 534 (1966) (footnote omitted).

covered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."[129] This policy is also evident in courts' interpretations of the statutory requirements of patentability; courts have articulated a presumption that basic tools of science are elements of the prior art, regardless of whether they were previously known. Quoting *Gottschalk*, the *Parker* Court stated, "Whether the algorithm was in fact known or unknown at the time of the claimed invention, as one of the 'basic tools of scientific and technological work,' . . . it is treated as though it were a familiar part of the prior art."[130] The Supreme Court has thus expanded the definition of prior art to include items that, although not chronologically prior to recent discoveries, are nonetheless logically prior as necessary predicates for conducting basic scientific and technological work.

An important consideration in prohibiting patents on basic tools of science is the practical effects of these patents, not just the formal characterization of the tools at issue. The *Gottschalk* Court, in denying a patent on an algorithm, did not limit its analysis to the facial claims of the patent. Rather, the Supreme Court reasoned:

> It is conceded that one may not patent an idea. But in *practical effect* that would be the result if the formula for converting BCD numerals to pure binary numerals were patented in this case. The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in *practical effect* would be a patent on the algorithm itself.[131]

This approach indicates that the rationales for prohibiting patents on theories and principles apply not only to patents on items actually prohibited, but also to patents that would have the same practical effect. In the case of HESCs, the WARF patents do not literally claim biological knowledge or scientific theory, but they effectively permit just that kind of propertization.

Patents on upstream research tools have greater potential to create monopolies over basic scientific knowledge than do patents on the products of other applied knowledge. Common law doctrine excludes basic intellectual resources such as knowledge and theory from the realm of patentable subject matter, but certain technologies are argua-

129. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).
130. *Parker*, 437 U.S. at 591–92 (quoting *Gottschalk*, 409 U.S. at 67).
131. *Gottschalk*, 409 U.S. at 71–72 (emphases added).

bly even more foundational than these truths themselves. As we will explore further, HESCs are a prime example of a class of research tools that can lie anterior to knowledge and theory.[132] Patents on this "machinery of knowledge" have the practical effect of creating monopolies over the knowledge that such machinery generates. In the case of contemporary biomedical research tools such as HESCs, common law doctrine counsels a narrowing of their patentability.

E. Assessing Common Law Patentable Subject Matter Doctrine

Before proceeding, it is instructive to consider the substantive merits and drawbacks of the common law prohibition against patenting natural laws, natural phenomena, and abstract principles. Based on the traditional rationales motivating the patent system, why not allow patents on scientific theories such as $E=mc^2$, and indeed the patenting of scientific knowledge itself? The prospect of monopoly ownership of scientific knowledge and all of its derivative applications would act as a powerful incentive to engage in basic scientific research. Individual property rights over ideas or parcels of scientific knowledge would help internalize the vast positive externalities that these intellectual assets provide;[133] the resulting incentives to discover would be enormous and might encourage vastly accelerated research into basic properties of nature. Furthermore, under Edmund Kitch's prospect theory,[134] permitting individual ownership of scientific theories could rationalize the allocation of resources devoted to developing those assets, thus reducing wasteful and duplicative effort.

However, patent-based incentive structures and prospect theory are inadequate analytical approaches for understanding and encouraging progress in the realm of basic science. The incentive-based model of patent rights may be unnecessary and ineffective for motivating researchers to produce basic scientific knowledge. Natural curiosity, an inherent desire to understand nature, and an altruistic drive to expand human knowledge may be sufficiently robust incentives for scientific research, rendering financial rewards unnecessary.[135] Such rewards may also be ineffective because values of universalism, communism, disinterestedness, and organized skepticism pervade the

---

132. *See infra* Part V.

133. *See* Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 348 (1967) ("A primary function of property rights is that of guiding incentives to achieve greater internalization of externalities.").

134. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266 (1977) (arguing that a patent system achieves an efficient allocation of resources by assigning exclusive rights to a prospect — an opportunity to develop a technology — to one individual or entity).

135. *See, e.g.*, Katz v. Horni Signal Mfg. Corp., 145 F.2d 961, 961 (2d Cir. 1944) (recognizing that "many scientists like Faraday care little for monetary rewards; generally the motives of such outstanding geniuses are not pecuniary").

scientific community,[136] and may lead researchers to regard monetary incentives with disdain rather than desire. The norm that scientific knowledge constitutes "a common heritage in which the equity of the individual producer is severely limited"[137] seems incompatible with individual property rights.

Prospect theory may also be ill-suited for justifying patents on theories and principles. A single firm might effectively develop a novel technological device such as a new windshield wiper. No single entity, however, could fully develop and apply the First Law of Thermodynamics. The potential applications are so vast that only ownership by the public at large, with a multiplicity of uncoordinated private actors acting in parallel, can ensure anything close to optimal exploitation. Kitch's prospect theory relies on the presumption that the potential uses for a particular prospect are either known ex ante or are easily discoverable by a single player. With fundamental concepts such as natural laws, however, it is unlikely that a single party could identify all of their potential uses, let alone exploit them. From the perspective of maximizing efficiency in scientific research, certain kinds of knowledge — basic rather than applied — appear better suited for public ownership than for private monopolization.

V. APPLYING COMMON LAW PATENTABLE SUBJECT MATTER DOCTRINE TO EVALUATE PATENTS ON HUMAN EMBRYONIC STEM CELLS

One of the primary goals of the patent system is to promote scientific progress.[138] As the prohibition against patenting natural laws, natural phenomena, and abstract principles reveals, patent doctrine reflects an underlying policy of encouraging innovation by keeping basic tools of science within the public domain and outside the realm of individual property. HESCs, which possess a unique potential to enable insights into fundamental biological processes, illustrate the importance of exempting basic research tools from patentability. WARF's patents on this basic tool of science contravene the principles underlying common law limitations on patentable subject matter, since patents on HESCs have the practical effect of conferring the ability to exclude others from exploring basic knowledge. Scientists can only evaluate theories about stem cells if they have access to them. The ability to investigate and develop theories regarding HESCs is therefore effectively the property of WARF.

Of course, in a formalistic sense, all patents can be construed as granting ownership over theories. The critical difference is that the

136. *See* MERTON, *supra* note 14, at 270–78.
137. *Id.* at 273.
138. *See* U.S. CONST. art.I, § 8, cl. 8.

novel information one can gain from most patented technologies is particularized and narrowly limited to that subject matter, whereas the novel information to be gained from investigating HESCs is generally relevant to a broad range of basic biological questions. It is this type of knowledge — general rather than particularized — that the common law has traditionally reserved for use in the public domain. Notwithstanding voluntary (and revocable) sharing agreements, WARF's patents on HESCs are effectively patents on biological knowledge, since they establish individual ownership of a research tool that is necessary for accessing that knowledge. Currently, academics and commentators debate whether increasing privatization in biotechnology promotes or inhibits the generation and dissemination of basic knowledge.[139] However, strong prudential concerns have consistently led courts to prohibit privatization of at least one class of research tools: natural laws, natural phenomena, and abstract principles.[140]

Some might contend that WARF's patents on HESCs are actually patents on technologies, and not on knowledge. However, in the context of prohibitions against patenting theories and principles, practical effects matter.[141] HESCs are a fountain from which vital scientific knowledge springs. Just as patent law prohibits property rights over that knowledge, it should also prohibit individual ownership of the source of that knowledge, the fountain itself.

Patent law generally promotes scientific progress by encouraging innovators to apply basic knowledge from the public domain to develop new technologies. Research tools, however, invert the normal relationship between knowledge and technology; scientists apply these technologies to produce basic knowledge. As a result, patents on research tools effectively confer rights to exclude others from accessing basic knowledge, especially given the restricted experimental use exception.

Some might worry that this analysis suggests increasing constraints on patenting technologies such as microscopes, which are also foundational research tools used to generate knowledge. However, as discussed earlier, whether a patent on a particular technology creates an exclusive right to basic knowledge depends on two factors: substitutability and breadth of patent claims.[142] Given a patent on a particular microscope design, other designs would still be available to

---

139. *See, e.g.*, Heller & Eisenberg, *supra* note 2.

140. *See supra* Part IV for a discussion on the evolution of the common law prohibition against the patentability of these concepts. In addition, some scholars have even posited a First Amendment "right to research." *See* John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203 (1978). Exclusive patents on basic research tools would arguably violate this right by closing off certain areas of research.

141. *See* Gottschalk v. Benson, 409 U.S. 63, 71–72 (1972). *See also supra* Part IV.D.

142. *See supra* Part II.A.

perform similar functions and achieve similar effects. HESCs, however, have no adequate substitute. Patenting HESCs is analogous to patenting the principle of optical magnification, which courts would certainly strike down as overly broad. Although HESCs are a technology, the practical effect of patenting HESCs is to constrain access to basic knowledge.

This analysis seeks to clarify the terms of the debate over whether broad or narrow patent protection best promotes scientific progress. Though *Chakrabarty* hinged on the distinction between man-made and naturally-occurring, the truly pertinent distinction driving progress in the patent system is that between upstream, knowledge-enabling resources and downstream, particularized applications. The case of HESCs demonstrates that fidelity to this principle requires maintaining a robust public domain of basic tools of science, and consequently that certain knowledge-enabling technologies should be exempted from patentability.

VI. INTERPRETING "PROGRESS": RESEARCH TOOL PATENTS, THE INTELLECTUAL PROPERTY CLAUSE, AND POLICY-ORIENTED CONSTITUTIONAL INTERPRETATION[143]

Effective application of this prescription presents courts with two challenges. First, courts must determine whether a particular research tool is sufficiently necessary to the pursuit of a discrete set of scientific questions. Adequate technological substitutes may exist for conducting a particular line of research, or perhaps the research tool in question only enhances such investigations and is not strictly necessary for full exploration. Second, courts must determine whether granting a patent would confer rights to exclude others from a broad area of fundamental research, thus negatively affecting social welfare.

Courts may hesitate to engage in substantive measurements for two reasons: lack of scientific expertise and an institutional aversion to engaging in policy appraisals better left to legislatures.[144] A solu-

143. The following section is a preliminary exploration of ideas and analyses that I hope to further develop in a future publication.

144. From the perspective of institutional competence, this evaluation of substantive merit may, at first, seem inappropriate for courts to perform. Indeed, courts addressing the issue of patentable subject matter have expressed their own reluctance to engage in substantive evaluations of science. *See* Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980) ("The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot."). More recently, the Federal Circuit declined to consider "public policy considerations" in addressing a patent application for expressed sequence tags ("ESTs"), stating that Congress was the more appropriate forum for addressing these concerns. *In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005). Rather, the court denied the patent on the grounds that the patent applicant had not established the utility of the ESTs he wished to patent. *Id.* at 1379. I argue below that courts should not feel confined to the formal re-

tion to both of these concerns might involve establishing a specialized agency, such as a hybrid of the Patent and Trademark Office and the Federal Trade Commission, to screen patent applications for research tools based on the risk of creating monopolies of knowledge. Such novel institution-building, however, is unnecessary since the federal judiciary possesses the requisite resources and mandate to address the challenges of research tool patents. The establishment of the Federal Circuit reveals that courts can adopt and apply a high degree of technical expertise, and thus do not necessarily lack the competence to address scientific issues. Furthermore, the unique structure of the Constitution's grant of patent power provides the flexibility that courts require to properly apply the underlying policy rationales of common law patent doctrine in constraining patents on particular research tools.

The Intellectual Property clause is unusual among constitutional provisions in that it contains a policy rationale in its text. The Constitution established congressional authority to grant patents in order "[t]o promote the Progress of Science and useful Arts."[145] While the Supreme Court stated in *Eldred v. Ashcroft* that this preamble is not binding on Congress,[146] courts should still consider this explicit policy rationale in evaluating prospective patent claims.

It is well-settled doctrine that federal courts have the exclusive prerogative to "say what the law is."[147] This interpretive power is tantamount to possessing the authority to identify whether or not a particular factual predicate is consistent with a particular constitutional or statutory provision. In light of the Intellectual Property clause's policy rationale, courts have the power to interpret whether or not a particular factual predicate, namely a particular patent, is consistent with the constitutional policy of promoting scientific progress.[148] The Constitution's articulation of an overarching policy objective affords courts greater latitude to transcend statutory and doctrinal formalisms and engage in policy-oriented jurisprudence. As the foregoing analyses reveal, this articulation is particularly important because one must look beyond bright-line formalistic categories — such as the distinction between natural and man-made — to truly evaluate whether particular patents have the practical effect of privatizing upstream

---

quirements of patent doctrine in these types of cases, but have the flexibility to consider policy objectives when considering the patentability of a research tool.

145. U.S. CONST. art. I, § 8, cl. 8.

146. 537 U.S. 186, 211–12 (2003).

147. Marbury v. Madison, 5 U.S. 137, 177 (1803).

148. *See* Graham v. John Deere Co., 383 U.S. 1 (1966) (illustrating courts' ability and responsibility to interpret the policy objectives behind the constitutional grant of patent power). "The [Intellectual Property] clause is both a grant of power and a limitation [and] . . . Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose." *Id.* at 5–6.

intellectual resources and foreclosing wide streams of derivative applications.

Courts and commentators frequently cast constitutional provisions in terms of constitutional law, but the Intellectual Property clause also encompasses an almost sui generis example of constitutional policy.[149] Courts should construe government action, such as the granting of patents, not only in terms of consistency with the dictates of relevant law, but also in terms of whether or not it fulfills constitutional policy. They should have the power to deny patents that — although satisfying the literal "limited times" and "authors and inventors" strictures of the Intellectual Property clause — nevertheless undermine scientific progress by privatizing intellectual assets of broad applicability. Armed with this flexibility, courts may properly look beyond the fact that HESCs are doctrinally patentable and constrain patents on these cells in order to serve the prudential interest of maintaining wide accessibility to basic tools of science.

VII. CONCLUSION

Embryonic stem cells are a particularly fitting example of the type of research tool that should not be patentable. Basic knowledge, like a stem cell itself, is pluripotent — it represents potentiality that can specialize later into applied forms. To grant ownership rights over this knowledge would be to stifle the vast potential for its development in the hands of the public at large. For good reason, patent law has long kept general knowledge in the public domain while reserving monopoly protection for the specialized, concrete applications that arise from such knowledge. In order to give due credence to this doctrine, courts should consider the effects of particular research tool patents on the progress of science. Hazuka entertains the possibility that "Congress could, in general, declare broad areas of technology off-limits to patenting."[150] However, affirmative congressional action is not necessary in this regard because existing patent doctrine provides the mechanisms for disallowing or constraining patents based on the policy rationale of promoting scientific progress.

This Article has argued that common law doctrine provides a legal and prudential basis for restricting patents on research tools that have fundamental knowledge-generating properties. Patent law is predicated on the fundamental principle that scientific progress is best served by keeping foundational building blocks, such as knowledge,

149. The other constitutional provision that exhibits a prominent policy element is the Second Amendment. It contains a glimpse into constitutional intent in saying, "[a] well regulated militia, *being necessary to the security of a free state*, the right of the people to keep and bear arms, shall not be infringed." U.S. CONST. amend. II (emphasis added).

150. Hazuka, *supra* note 10, at 162.

in the public domain for all to use and by reserving the necessary evil of monopolies as an incentive to apply that basic knowledge to produce specialized technologies. This scheme reflects and supports an environment where basic knowledge is logically prior to technology. But research tools invert this paradigm because these technologies lie anterior to basic knowledge. Property rights in these assets create ownership rights in the knowledge streams to which they give rise and thus should be limited, particularly in light of a narrowed interpretation of the experimental use exception.

This Article has specifically argued for constraining patents on human embryonic stem cells. HESCs are research tools of immense theoretical interest and represent the key to understanding basic cellular and developmental processes. In this regard, they have no adequate substitute. WARF's patents on usable HESCs, as well as on the technologies for maintaining them in culture, create rights that exclude others from exploring broad areas of scientific research. While voluntary licensing agreements have allowed federally-funded non-profit scientists to access these vital research tools, the potential remains for patents on knowledge-generating resources such as HESCs to fundamentally frustrate the production of basic knowledge or, at the very least, to allow a single patent-holder broad power to determine the scope and contours of such research. Patent laws were never intended to facilitate this kind of privatization of control.

In the words of one patent commentator, "As time and science move forward, the law struggles to keep pace while, at the same time, resisting change in order to maintain stability."[151] Originating in an era of cotton gins and telegraphs, common law patentable subject matter doctrine offers intensely relevant solutions to the challenges posed by HESCs and other contemporary research tools. Fidelity to this doctrine demands that courts adapt it to the increasingly privatized interface between applied technology and basic knowledge by restricting patents on knowledge-generating research tools. The Intellectual Property clause grants courts the unique latitude to interpret patents' consistency not only with mechanical legal requirements, but also with the explicit policy objectives animating the patent system.

151. Han, *supra* note 70, at 1–2.