8-6-2008

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Minnesota Law Review (forthcoming 2008)

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According to well-established principles, one cannot patent natural laws or phenomena per se*, but one can patent new and useful applications of those laws and phenomena. Justice Breyer's opinion in* Laboratory Corp. v. Metabolite Labs., Inc. *applies this distinction to inventions exploiting natural relationships, such as a method of diagnosing a vitamin deficiency by observing elevated levels of an amino acid in a patient's blood. Justice Breyer concludes that patenting a method based on observation and reasoning amounts to patenting the natural relationship itself – a result contrary to policy because it denies others a "basic tool of research." In fact, the traditional dichotomy of principle and application suggests the opposite conclusion. But there is a danger in such patents because of the critical role that knowledge plays in infringement. The difficulty of avoiding infringement – except by embracing ignorance – could force the abandonment of activities having substantial noninfringing uses, thereby conferring on the patent owner market power beyond the intended scope of the grant. Rather than condemn all patents based on useful observations of natural laws or phenomena, one should concentrate on those with undesirable and unavoidable spill-over effects.*

INTRODUCTION.

In 2006, the Supreme Court granted certiorari, and then dismissed it as improvidently granted, in *Laboratory Corp. v. Metabolite Labs., Inc.*[1] The plaintiff's patent claimed a method of diagnosing a vitamin deficiency by observing the level of the amino acid homocysteine in a patient's blood. Justice Breyer, joined by Justices Stevens and Souter, dissented from the dismissal and voiced his concern that the patent violated the long-standing rule that principles of nature are unpatentable.

Scientists who contribute to our understanding of nature, adding to the sum of knowledge but nothing more, cannot secure the property rights that convert insight into wealth. Patents encourage technical achievements through the promise of reward, but natural phenomena and principles of nature *per se* exceed the scope of patentable subject matter.[2] Only those who apply their understanding in the form of new structures,

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[1] 126 S. Ct. 2921 (2006) (hereinafter *Lab. Corp.*).

[2] Diamond v. Diehr, 450 U.S. 175, 185 (1981).

compounds, or processes can secure a patent,[3] and with the patent the exclusive right to make, use, or sell the fruits of their discoveries.[4] In short, where patents are concerned it is better to be an Edison than an Einstein.

While inconclusive, Justice Breyer's *Lab. Corp.* opinion highlights a kind of invention that lies in the netherworld between natural principles and the practical application of those principles – an invention that relies upon observation, reasoning, and a newly-discovered natural relationship. The patent did not claim the relationship between homocysteine and vitamin deficiencies as such; the patent claimed a method of diagnosis – a method potentially new and useful, and a product of human ingenuity. Nevertheless, Justice Breyer included the method within the traditional prohibition against patenting nature. Laws of nature, Justice Breyer reminds us, are the "basic tools of research,"[5] so fundamental to technological progress that to grant exclusive rights would have the effect of stifling, rather than promoting, advancements in the useful arts. The homocysteine relationship may be one of those "basic tools," but the patent claimed only the *use* of the relationship, as many other patents claim the use of natural phenomena for practical ends. Is a method of diagnosis really a foundation for further research? If so, how can it be distinguished from a novel measurement apparatus, where the potential of the invention as a research tool raises no barrier to patentability? Something in the traditional dichotomy between principle and application breaks down in Justice Breyer's analysis.

What is different and dangerous about the *Lab. Corp.* patent is not its potential for hindering fundamental research but the role of knowledge in distinguishing those who infringe. An ignorant physician does not observe the forbidden correlation. An informed physician, reading a lab report, cannot avoid it. This has two consequences. First, it discourages the spread of knowledge by penalizing those who receive it. Second, the potentially involuntary nature of the infringement threatens to broaden the patentee's market power beyond the intended limits of the grant. An unlicensed physician might be forced to abandon legitimate activity – like performing blood tests for other purposes – simply to avoid unintended infringement. These are serious concerns and should be the focus of inquiry for patents based on observation and analysis. While the traditional rules governing the patentability of natural laws and phenomena are useful in other contexts, they fail, in this instance, to separate the harmless sheep from the economically-menacing wolves.

Part I of this Article examines the long-standing prohibition against patenting natural laws and natural phenomena *per se*. Part II discusses the special case of inventions based on observation and analysis of natural phenomena. Here several threads converge, including disputed definitions of "process," the tortuous history of the "mental

[3] Id. at 187-88; Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); *see also* 35 U.S.C. § 101 (patents granted to whoever "invents or discovers any new and useful process, machine, manufacture, or composition of matter").

[4] *See* 35 U.S.C. § 271(a) (infringement by anyone who, without the patent owner's authority, makes, uses, sells, offers to sell, or imports the patented invention).

[5] *Lab. Corp.*, 126 S. Ct. at 2923.

steps" doctrine, and conflicting ideas about the interaction between patentable subject matter and novelty. Part II also critiques Justice Breyer's *Lab. Corp.* opinion. Part III discusses the economic spill-over effects of patents based on observing nature, and suggests that these effects, rather than the issues discussed in Parts I and II, are the key to singling out the patents that may do serious harm. A patent that grants market power beyond the inventive contribution of the patentee imposes unjustified costs. It takes from the public without corresponding benefit. This, in the end, is a more serious concern than whether a patent embraces a law of nature or a tool of research.

I. NATURAL LAWS AND PATENTABLE SUBJECT MATTER.

Article 1 of the United States Constitution gives Congress the 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."[6] With respect to the "useful Arts," Article 1 confers the authority to issue patents. "Useful arts" is an 18th Century term for what today we would call "technology."[7] Patents encourage the development of technology by allowing inventors exclusive rights to their discoveries for a period ending 20 years after the filing date of the patent application.[8] Although the Constitution refers to "science," historians conclude that the framers meant knowledge of all kinds, rather than the narrower field to which we apply the term "science" today.[9] The balanced structure of the clause links "science" with "authors" and their "writings" – the province of copyright law, not patent law.[10] Hence patent law concerns itself not with scientific inquiry, as some jurists have mistakenly believed,[11] but with the useful arts – knowledge, scientific or otherwise, applied in practical ways for the benefit of mankind.

An invention may be patented only if it is novel[12] and "nonobvious" in comparison to the "prior art" inventions that preceded it[13] It must also be useful, meaning that it must provide some practical benefit, even if it is not superior to existing alternatives.[14] An inventor must describe the patented invention in a series of claims, and those claims must be definite enough to inform others skilled in the art of the metes and bounds of the patentee's exclusive rights.[15]

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[6] United States Constitution, Article 1, Section 8, Clause 8.

[7] *See Alan L. Durham, "'Useful Arts' in the Information Age,"* 1999 B.Y.U.L. Rev. 1419, 1437-1444 (1999).

[8] 35 U.S.C. § 154(a)(2).

[9] *See* Karl B. Lutz, *Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution,* 18 Geo. Wash. L. Rev. 50, 51 (1948).

[10] Id.; Edward C. Walterscheid, To Promote the Progress of Useful Arts: American Patent Law and Administration, 1798-1836, at 60-61 (1998).

[11] *See, e.g.,* Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 154-58 (1950) (Douglas, J., concurring).

[12] 35 U.S.C. § 102.

[13] 35 U.S.C. § 103; KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, ___ (2007).

[14] 35 U.S.C. § 101; Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1390 (Fed. Cir. 1988).

[15] 35 U.S.C. § 112 ¶ 2; All Dental Prodx, LLC v. Advantage Dental Prods., Inc., 309 F.3d 774, 779-80 (Fed. Cir. 2002).

Perhaps the most basic requirement of a patentable invention is that it must fall within the bounds of patentable subject matter, defined in § 101 of the Patent Act. Section 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[16] Patentable subject matter under § 101 may be narrower in scope than the Constitution's general reference to "discoveries," but it is nevertheless exceedingly broad.[17] As the Supreme Court observed in *Diamond v. Chakrabarty*,[18] where it found living things created in the laboratory to be within the scope of patentable subject matter, "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."[19] Indeed, the Committee Reports suggest that the subject matter of patents "include[s] anything under the sun that is made by man."[20]

Notwithstanding the general expansiveness of § 101, the courts have identified certain "discoveries" that lie beyond its scope, including laws of nature, natural phenomena, and "abstract ideas."[21] These exceptions, rooted in more than 150 years of patent law jurisprudence, resist precise definition. The difficulty stems from the close relationship between understanding the workings of the natural world and applying them in useful ways. The scope of a patent should corespond, as nearly as possible, to the inventor's contribution to society. Moreover, if the goal of the patent system is to enhance public welfare by promoting technological advancement,[22] the rights conferred must be broad enough to provide the necessary incentives, but not so broad that they deny the public the benefit of new technologies or discourage further innovation.[23] This balancing act accounts for many of the problematic distinctions in patent law,[24] and it sparked debate in some of the earliest cases dealing with the patentability of inventions based on natural principles.

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[16] 35 U.S.C. § 101. Earlier versions of the Patent Act employed similar language, but used the term "art" in place of "process." See Chakrabarty, 447 U.S. at 308-09. The change is not substantive, and "art" maintains a presence in the definition of "process" as a "process, art or method." 35 U.S.C. § 100(b).

[17] *See* J.E.M. AG Supply v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 130 (2001).

[18] 447 U.S. 303 (1980).

[19] Id. at 308.

[20] S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).

[21] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[22] *See* Id. at 307 ("The authority of Congress is exercised in the hope that '[the] productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.'" (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480(1974))).

[23] *See* Smithkline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1351 (Fed. Cir. 2005, Gajarsa, j., concurring) ("[A]ll patents are capable of discouraging at least some innovation . . . . This discouragement, however, is simply part of the cost that the public bears to promote an overall patent system whose goal is to motivate more innovation than it deters.").

[24] An example of such a problematic distinction is the scope of patent claims under the "doctrine of equivalents." A literal reading of patent claims exposes patentees to minor variations that rob them of their monetary reward; on the other hand, disregarding claim limitations may stifle innovation through uncertainty. *See* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 732 (2002).

A. Natural Laws in the Golden Age of Invention.

Modern cases on natural laws and patentable subject matter still cite a number of 19th Century opinions, some involving such illustrious inventors as Samuel Morse and Alexander Graham Bell.[25] Few question now, or questioned then, the importance of the contributions made by those inventors. But patent claims, by their nature, do not confer rights to *specific* items (e.g., Morse's telegraph apparatus in all of concrete details) but rather to *classes* of items (e.g., any telegraph one might construct, if it includes elements corresponding to each element listed in the claim). A claim so detailed that it precisely described Morse's own mechanism would have been worthless because it could be avoided by minor changes. A valuable claim, and one corresponding to Morse's insights, would generalize to some extent, including what was new and useful in Morse's telegraph, but omitting what was nonessential. The questions raised in these early cases concern the extent to which patent claims can generalize, and whether they can do so by reference to the natural law on which the invention relies.

In 1852, the Supreme Court in *Le Roy v. Tatham*[26] discussed whether one could patent a "principle." The patentee discovered that sections of lead pipe could be securely joined if forced together, using conventional machinery, under extreme pressure and heat. Rather than claiming the novel method as such, the patentee claimed the machinery when used in the manner described.[27] Discovering a new use for an existing apparatus does not permit one to patent the apparatus, so the manner in which the patentee characterized the invention proved fatal.[28] However, because the trial judge had emphasized the new "principle" at work, the court offered some observations on that point. While cautioning that the word "principle" had been used by courts and scholars with such imprecision that it was likely to mislead,[29] the court explained that principles, as such, cannot be patented:

> 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. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known. Through the agency of machinery a new steam power may be said to have been generated. But no one can appropriate this power exclusively to himself, under the patent laws. The same may be said of electricity, and of any other power in nature, which is alike open to all, and may be applied to useful purposes by the use of machinery.[30]

[25] *See* O'Reilly v. Morse, 56 U.S. 62 (1854) (Samuel Morse); The Telephone Cases, 126 U.S. 1 (1887) (Alexander Graham Bell).

[26] 55 U.S. 156.

[27] Id at 172.

[28] Id. at 177.

[29] Id. at 174.

[30] Id. at 175.

Invention lies not in the discovery of natural principles, but in devising ways to apply those principles to practical ends. Only the latter may be patented.[31] Moreover, one may not generalize one's invention so far as to claim any means of producing the desired effect. A monopoly of such scope "would discourage arts and manufactures, against the avowed policy of the patent laws."[32] One must leave room for others to devise new ways to achieve similar results.[33]

Two years later, the Supreme Court covered some of the same ground in O'Reilly v. Morse.[34] The eighth claim of Morse's telegraph patent embraced any use of electromagnetism, then known or later developed, for transmitting written characters.[35] The majority rejected Morse's claim as too broad.[36] Anticipating further developments in the field of communications, the court observed that "[f]or aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification."[37] The discovery of a subsequent inventor might improve on Morse, but if Morse's claim were upheld the inventor of the improvement would need Morse's permission to proceed.[38] Like the inventor in *Le Roy*, Morse must confine himself to the means he had devised for harnessing electromagnetism, because policy would not tolerate a patent limited only by the effect he had achieved.[39]

Justice Greier supplied the dissent. "The mere discovery," he wrote, "of a new element, or law, or principle of nature, without any valuable application of it to the arts, is not the subject of a patent."[40] However, "he who takes this new element or power, as yet useless, from the laboratory of the philosopher, and makes it the servant of man; who applies it to the perfecting of a new and useful art, or to the improvement of one already known, is the benefactor to whom the patent law tenders its protection."[41] One who discovers how a law of nature can be put to work is "a discoverer and inventor of the highest class," who may have invested "more labor, expense, persevering industry, and ingenuity than the inventor of any machine."[42] Regarding the application of the claim to

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[31] Id.

[32] Id.

[33] Justice Nelson penned a lengthy dissent in which he argued that the patentee had discovered a new and valuable "property of lead." Id. at 181. The patentee did not claim the property as such, but a mode of applying that property to produce superior manufactures. Although a principle could not be patented in the abstract, a practical application of a principle could be; and unless the patentee had "tied himself down" to the particulars of the mode he employed, the patentee should be entitled to claim "all modes by which the same result is produced, by an application of the same law of nature or property of matter." Id. at 186.

[34] 56 U.S. 62 (1854).

[35] Id. at 112.

[36] Id. at 113.

[37] Id. The "specification" is the part of a patent including a detailed disclosure of the inventor's preferred embodiments. *See* Alan L. Durham, Patent Law Essentials: A Concise Guide § 3.3 (2d ed. 2004).

[38] Id.

[39] Id. at 119.

[40] Id. at 132.

[41] Id. at 132-33.

[42] Id. at 132.

improvements which might themselves be patentable, Greier did not find that this effect had interfered with the development of machines and found no reason to fear the effect as applied to "arts."[43]

Although the court rejected patent claims as broad as Morse's claim 8, it did not altogether prohibit inventors from generalizing, or seeking to capture what Morse called the "essence" of the invention. The court cited with approval *Neilson v. Harford*,[44] an English case concerning an improved furnace. Neilson discovered that a furnace would operate more efficiently if the air used for combustion were pre-heated. In order to take advantage of this principle, Neilson invented, and patented, a "hot-blast" furnace including an air-heating receptacle located between the blowing apparatus and the combustion chamber.[45] The court did not force Neilson to limit his claims to a heating receptacle of the same size, shape or materials as the one he had devised; any competent workman could fashion a suitable receptacle, and the effect would be similar whatever the variations in the apparatus.[46] Admitting that the court found it difficult to distinguish Neilson's patent from "a patent for a principle," it concluded that the invention claimed was a machine for applying the principle, even if the patent did not limit Neilson's rights to precisely the apparatus he had described.[47] The United States Supreme Court, recalling the *Neilson* case, observed that the inventor could not have patented the discovery that hot air produced superior combustion, because "the discovery of a principle in natural philosophy or physical science, is not patentable."[48] But what Neilson had invented was a mechanism for applying that principle to an improved furnace by interposing a heating receptacle between the blower and the combustion chamber. Whoever used such a vessel used Neilson's invention, because the same results were achieved, to some extent, regardless of the size or shape of the receptacle.[49] In contrast, Morse had not discovered that electromagnetism would successfully transmit characters at a distance in all cases. His patent must be limited to what he had discovered – a particular method of harnessing electromagnetism to produce the sought-after result.[50]

Both *Neilson* and *Morse* are notable for commingling what could be considered separate issues: first, whether the patent claims eligible subject matter (the application of a natural principle rather than the principle in the abstract); and second, whether the patent if enforced would be unacceptably broad, failing to correspond with what the inventor had discovered and inhibiting the efforts of subsequent innovators. Although there are means today to deal with over-broad claims that do not rely on patentable subject matter,[51] the early conceptual link between breadth and subject matter has never been broken.[52]

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[43] Id. at 133-34.
[44] 8 M. & W. 806 (Ct. of Exchequer 1841).
[45] Id. at 823.
[46] Id. at 824-26.
[47] Id. at 823.
[48] *Morse*, 56 U.S. at 116.
[49] Id. at 116.
[50] Id. at 117.
[51] Alternative means include the requirements that the patent specification describe the patented invention and enable its practice. *See* 35 U.S.C. § 112 ¶ 1; Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555,

B. Enduring Principles.

The early cases laid the foundation for a number of enduring principles concerning the relationship of natural phenomena and patentable inventions. These may be summarized as the following: (1) natural laws, in the abstract, cannot be patented; (2) natural phenomena, in their natural state, cannot be patented; (3) scientific explanations for phenomena already in use cannot be patented; (4) inventions incorporating natural principles or phenomena, or based on new understandings of natural law, may be patented.

1. Natural Laws in the Abstract.

Computer software – a product of human ingenuity that is useful, valuable, but inherently intangible – accounts for many of the modern cases dealing with the limits of patentable subject matter. The Supreme Court's contribution to this evolving body of law is largely through the trilogy consisting of *Gottschalk v. Benson*,[53] *Parker v. Flook*,[54] and *Diamond v. Diehr*.[55] Each of these cases supports the venerable rule that natural laws cannot be patented in the abstract.

The patent applicant in *Benson* devised a series of mathematical steps (an "algorithm") for converting one form of representing a number (binary-coded decimal) into another form (pure binary).[56] Although Benson clearly intended to apply the mathematics in a programming context,[57] the claims did not limit him to any particular computer hardware or any particular use of the technique.[58] In a notoriously cryptic opinion, the court rejected the claims as unpatentable subject matter. Three concerns dominate the court's discussion. First, the claims were "abstract" [59] because not tied to any tangible process or machinery.[60] "[A]bstract intellectual concepts," the court held, "are not patentable."[61] Second, because they were abstract, the claims were also exceedingly broad, covering every use of the algorithm that had been or might later be

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1561 (Fed. Cir. 1991) (the written description requirement "guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation"); Leibel-Flarsheim Co. v. Medrad, 481 F.3d 1371, 1379-80 (Fed. Cir. 2007) (specification must enable the full scope of the claim).

[52] *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 67-68 (1972).

[53] 409 U.S. 63 (1972).

[54] 437 U.S. 584 (1978).

[55] 450 U.S. 175 (1981).

[56] 409 U.S. at 64-65.

[57] *See* id. at 65 ("The patent sought is on a method of programming a general-purpose digital computer . . . .")

[58] Id. at 64.

[59] *See* id. at 68 (characterizing the applicant's claims as "abstract and sweeping").

[60] *See* id. (the applicant's process might be performed "through any existing machinery or future-devised machinery or without any apparatus." One of the cryptic aspects of the opinion are the nearly contradictory statements on whether a patentable "process" must involve a *physical* transformation.

[61] 409 U.S. at 67.

discovered.[62] If a patent were allowed, it would "wholly preempt the mathematical formula."[63] Third, although the court did not explicitly characterize mathematics as a manifestation of nature, the court's seamless transition from discussing natural phenomena to Benson's algorithm suggests that point of view.[64] "[P]henomena of nature," wrote the court, "though just discovered . . . are not patentable."[65] Echoing decisions of the previous century,[66] *Benson* concludes with the ambiguous warning that "one may not patent an idea."[67]

In *Flook*, the second case of the trilogy, natural law played a more obvious part. The invention concerned the catalytic conversion of hydrocarbons, a process requiring careful monitoring of conditions such as temperature and pressure. Problems arise when those conditions exceed certain limits, known as "alarm limits." Flook's idea was to update the alarm limits as the reaction took place, to account for the dynamic nature of the process.[68] His claims described a sequence of taking measurements, calculating new alarm limits using the measured values, and updating the alarm limits to reflect the calculations.[69] The only thing that distinguished Flook's invention from the prior art was the computer-implemented mathematical algorithm used to calculate the new figures.[70] Flook's invention differed from Benson's in important respects. Flook limited his claims to a particular field of use, [71] and his invention was not as abstract as Benson's, linked as it was to a physical process. Nevertheless, the court rejected Flook's patent as outside the scope of § 101.

Although Flook claimed a "process" in the general sense of the term, the Court fell back on the dictate of *Le Roy* that "'[a] principle, in the abstract, is a fundamental truth [and] . . . cannot be patented.'"[72] While "[t]he line between a patentable 'process' and an un-patentable 'principle' is not always clear,"[73] Flook's invention fell on the side of "principle." The court treated the mathematical formula as though it were already

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[62] Id. at 68 ("Here the "process" claim is so abstract and sweeping as to cover both known and unknown uses of the [algorithm]. The end use may (1) vary from the operation of a train to verification of drivers' licenses to researching the law books for precedents . . . .").

[63] Id. at 72.

[64] *See e.g.*, id. at 67-68 ("As we stated in *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 130, 'He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes . . . .' We dealt there with a 'product' claim, while the present case deals with a 'process' claim. But we think the same principle applies."). In *Flook*, the court interprets *Benson* as treating a mathematical formula or algorithm "*like* a law of nature." 437 U.S. at 589 (emphasis supplied).

[65] Id. at 67.

[66] *See, e.g.*, Rubber-Tip Pencil Co. Howard, 87 U.S. 498, 507 (1874) ("[a]n idea of itself is not patentable").

[67] The warning is ambiguous because every patent claim expresses an idea. In *Rubber-Tip Pencil*, the idea was that one could attach a rubber eraser to the end of a pencil. In spite of its practical application, the court reduced the invention to an "idea" about the natural ability of rubber to adhere – an idea that was useful but not new. 87 U.S. at 507.

[68] 437 U.S. at 585.

[69] Id.

[70] Id. at 585-86, 588.

[71] Id. at 586.

[72] Id. at 589 (quoting *Le Roy*, 55 U.S. at 175).

[73] Id. at 589.

known, an approach, suggested by *Neilson v. Harford*, for ignoring the principle itself in order to determine if the applicant, like Neilson, had invented an *application* of the principle.[74] Because the catalytic conversion process was already known, and the court treated the formula as though it too were already known, the combination was "comparable to a claim that the formula $2\pi r$ can be usefully applied in determining the circumference of a wheel."[75] To the extent that Flook had made a discovery, it was not a discovery that the law allowed him to patent.[76]

Diehr, the final case of the trilogy, had a different outcome. Diehr devised an improved process for molding synthetic rubber. In order to determine the optimum time to stop the curing process, Diehr continuously measured temperatures inside the mold and used the data in a mathematical algorithm based on the well-known Arrehnius equation. When the calculated ideal matched the cure time that had actually elapsed, a signal from the computer directed the opening of the mold.[77] The court held Diehr's claims to be patentable subject matter. It distinguished *Flook* on the narrow ground that Flook's claims, like Benson's, ended with the calculation of a number (Flook's "alarm limit").[78] In contrast, Diehr claimed an industrial process of curing rubber, one *part* of which happened to employ mathematics. A process of curing rubber is, unquestionably, patentable subject matter.[79]

Diehr differs substantially from *Flook* in its approach to the interaction between the patentable subject matter requirement of § 101 and the novelty requirement of § 102. We will revisit that subject in Part II(C). However, *Diehr* reaffirmed the essential rules laid out the previous century, even if it applied them differently than the court had in *Flook*. Section 101, broad as it is, excludes "laws of nature, natural phenomena, and abstract ideas."[80] A principle in the abstract is a "'fundamental truth'" to which no one can claim exclusive rights.[81] If there is a patentable invention to be derived from the discovery of a principle, "'it must come from the application of the law of nature to a new and useful end.'"[82] In subsequent cases, the Federal Circuit Court of Appeals, which usually takes a broad view of patentable subject matter,[83] has also acknowledged the unpatentability of natural laws or principles in the abstract.[84]

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[74] Id. at 592.

[75] Id. at 595.

[76] *See* id. at 593 ("the discovery of a law of nature cannot be patented" because natural phenomena "are not the kind of 'discoveries' that the statute was enacted to protect").

[77] 450 U.S. at 177-79.

[78] Id. at 186.

[79] Id. at 191-92.

[80] Id. at 185.

[81] Id. (quoting *Le Roy*, 55 U.S at 175).

[82] Id. at 188 n.11 (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).

[83] *See, e.g.,* State Street Bank & Trust Co. v. Signature Financial Gp., 149 F.3d 1368, 1375 (Fed. Cir. 1998) (rejecting the traditional business methods exception to patentable subject matter).

[84] *See e.g.,* id. at 1373 ("The Supreme Court has identified three categories of subject matter that are unpatentable, namely 'laws of nature, natural phenomena, and abstract ideas.'" (quoting *Diehr*, 450 U.S. at 185)).

2. Natural Phenomena in their Natural State.

A different question is whether one can patent concrete *things* discovered in nature – such as naturally-occurring substances, organisms or occurrences. *In re Latimer*,[85] one of the early cases to address the issue, refused a patent on the fibers extracted, essentially unchanged,[86] from the needles of the tree *Pinus Australis*. The court compared extracting the fibers from the needles to "gather[ing] the pebbles along the seashore, where the forces of nature have placed them."[87] Even if the applicant were first to appreciate the useful qualities of the needles, this did not entitle him to a patent monopoly. Patents that embrace "the trees of the forest and the plants of the earth" would be "unreasonable and impossible."[88]

Today, when we are accustomed to patents on plants,[89] bacteria,[90] and higher organisms,[91] rights to the trees of the forest and the plants of the earth do not seem so impossible. Yet the principle of *Latimer* is still sound. It is sustained not by the distinction between the living and the inanimate, but by the distinction "'between products of nature, whether living or not, and human-made inventions.'"[92] Modern science allows researchers to modify nature in subtle ways, but it is only in that modified form that the products of nature may be patented. Even if it qualifies as a discovery to reveal in nature a substance, plant, or organism previously unknown, such discoveries are not patentable subject matter.[93] The applicant in *Diamond v. Chakrabarty* prevailed because his hydrocarbon-metabolizing bacteria had been engineered in the laboratory.[94] In contrast, the applicant in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*[95] failed because he had only combined species of bacteria that already existed in nature. This

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[85] 1189 Comm'n Dec. 123 (1899).

[86] Id. at 125 ("Nature made them so and not the process by which they are taken from the leaf or needle.").

[87] Id. at 126.

[88] Id. at 126. Note the implication that the discovery of an entirely new species, or an entirely new gem, would also fail to qualify as a patentable discovery. *See* id. at 127 ("I am not aware of any instance in which it has been held that a natural product is the subject of a patent, although it may have existed from creation without being discovered.").

[89] *See* J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 127 (2001) (plants are patentable subject matter under § 101).

[90] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (bacteria qualify as "manufactures" and "compositions of matter" under § 101).

[91] In 1988, the Patent Office allowed Harvard University researchers to patent a mouse genetically engineered to be susceptible to cancer. *See* U.S. Patent No. 4,736,866.

[92] J.E.M., 534 U.S. at 130 (quoting *Chakrabarty*, 447 U.S. at 313).

[93] *See Chakrabarty*, 447 U.S. at 309 ("a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter"). Judge Newman of the Federal Circuit may hold a contrary view. *See* Schering Corp. v. Geneva Pharmaceuticals, Inc., 348 F.3d 992, 994 (2003) (Newman, j., dissenting from denial of rehearing en banc) ("It was and is well understood that an inventor may discover something that already existed. . . . [A] previously unknown product does not become unpatentable simply because it existed before it was discovered.").

[94] 447 U.S. at 309-10 ("His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity 'having a distinctive name, character [and] use.'" (citation omitted)).

[95] 333 U.S. 127 (1948).

combination fell short of invention because it was "no more than the discovery of some handiwork of nature:"[96]

> The combination of species produces no new bacteria . . . and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.[97]

A researcher who discovered a *new use* for a naturally-occurring bacteria might obtain a patent; a new use is the handiwork of the inventor. But the patent would cover only the method of use, not the bacteria itself.[98]

3. Explanations of Natural Phenomena.

No one who discovers a scientific explanation for an existing phenomenon is entitled to exclusive rights.[99] In *Flook*, the court discussed Newton's law of gravitation, defining a relationship that had existed even before Newton revealed it.[100] The discovery of such a relationship "carries with it no rights to exclude others from its enjoyment."[101] In *Upsher-Smith Lab., Inc. v. Pamlan, L.L.C.*, the patentee discovered that antioxidants destroy vitamin B[12] and folate. The patent claimed vitamin supplements omitting destructive antioxidants.[102] While not discounting the value of the patentee's discovery, the court noted that B[12] and folate compositions free of antioxidants were already known.[103] The discovery of their advantages could not deny the public compositions they had already used.[104] Mankind had enjoyed the benefits of fire for thousands of years before understanding the role of oxygen in combustion; the discoverer of oxygen could not have monopolized the use of fire.[105] Similarly, the patentee's explanation of why antioxidant-free B[12] preparations were more effective than others did not entitle him to a patent.

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[96] Id.

[97] Id.

[98] *See In re* Shoenwald, 964 F.2d 1122, 1124 (Fed. Cir. 1992) (inventor of new use for a known compound is only entitled to patent the method of use).

[99] Markman v. Westview Instruments, Inc. 517 U.S. 370, 373 (1996) ("'A claim covers and secures a process, a machine, a manufacture, a composition of matter, or a design, but never . . . the scientific explanation of their operation'" (quoting 6 Lipscomb's Walker on Patents § 21:17, at 315-16)); *In re* King, 801 F.2d 1324, 1328 (Fed. Cir. 1986) (applicant is not entitled to a patent because he "sets out the scientific formulae for explaining what happens").

[100] 437 U.S. at 593 n.15.

[101] Id. As a New York district court expressed it, "the Constitution grants monopolies to inventors, not to analysts." CTS Corp. v. Electro Materials Corp., 469 F. Supp. 801, 821 (S.D.N.Y. 1979).

[102] *See* Upsher-Smith Lab., Inc. v. Pamlan, L.L.C., 412 F.2d 1319, 1323 (Fed. Cir. 2005).

[103] Id.

[104] Id.

[105] Id.; *see also* EMI Gp., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1351 (Fed. Cir. 2001) (the origin of the fire/oxygen analogy).

4. Inventions Incorporating Natural Phenomena or Based on Natural Laws.

Although one cannot patent natural materials or phenomena as such, one can patent inventions that incorporate them. If it were otherwise, one could not patent any process involving heat, any apparatus made of metal, or any composition formed of atoms.[106] Nature always supplies the elements of the patented invention; it is the use and combination of those elements that is inventive and patentable.[107] For example, even though Newton could not have patented his law of gravity, an inventor could patent a machine that takes advantage of gravity to achieve a superior result.[108] Similarly, inventors can apply their understanding of natural laws to create new and patentable machines, processes, or compositions of matter.[109] *Mackay Radio & Telegraph Co. v. RCA*[110] supplies a popular example.[111] The patentee began with a formula expressing the natural relationship between the length and angle of wires in a radio transmitting antenna and the radio activity produced.[112] The formula itself would have been unpatentable and, in any event, had been discovered by someone else.[113] The patentee, however, applied the formula to create an antenna with the directional characteristics he desired.[114] The design may or may not have been inventive, but it undoubtedly qualified as patentable subject matter: "[w]hile a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."[115] The patented antenna was a structure, not a formula; it was an application of a natural principle, not the principle itself.

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[106] See Schering Corp. v. Gilbert, 153 F.2d 428, 432 (2d Cir. 1946) (if one could not patent a new molecule because "the inevitable result of the action of so-called laws of nature which are immutable by man and remain free for the use of all," then no processes or machines could be patented either, because forces such as gravity and friction always play role; "[o]bviously, such an advanced position cannot be maintained in the face of the patent statute and the multitude of authoritative decisions to the contrary").

[107] "All of the tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials. The 'matter' of which patentable new and useful compositions are composed necessarily includes naturally existing elements and materials." Merck & Co. v. Olin Mathieson Chemical Corp., 235 F.2d 156, 161-62 (4th Cir. 1958).

[108] *See In re* Bergy, 596 F.2d 952, 992 (CCPA 1979) (Baldwin, j., concurring) (Eibel Process Co., v. Minnesota & Ontario Paper Co., 261 U.S. 45 (1923), where the patentee improved a papermaking machine by elevating one end of the device to improve flow through the force of gravity, "is often cited approvingly as an example of the proper use of a natural phenomenon to produce a new and useful end result").

[109] *See* Dickey-John Corp. v. Int'l Tapetronics Corp., 710 F.2d 329, 348 n.9 ("all inventions that work can be explained in terms of basic truths").

[110] 306 U.S. 86 (1939).

[111] *See*, e.g., *Diehr*, 450 U.S. at 188; *Benson*, 409 U.S. at 67; *Funk*, 333 U.S. at 130.

[112] *See* MacKay, 306 U.S. at 92-93.

[113] Id. at 93.

[114] Id.

[115] Id. at 94.

C. Justifications for Denying Patents on Natural Laws and Natural Phenomena.

The rule against patenting nature denies monetary reward to some of the greatest discoveries of all. Einstein,[116] Newton,[117] Faraday,[118] Pythagoras[119] – even Prometheus[120] – could expect short treatment from the Patent Office, because their "[e]poch-making 'discoveries'"[121] fell on the wrong side of principle and application. If the reason for having patents is to encourage discoveries that benefit mankind, why would patents be denied to those who contribute the most to the increase of human knowledge? Why single out for reward "those lesser geniuses who put such discoveries to practical uses?"[122]

The rule can produce results that seem both unfair and at odds with the incentives rationale of patent law. In *Morton v. New York Eye Infirmary*[123] the patentee discovered that inhalation of sufficient quantities of ether would make patients insensible to pain while undergoing surgery. He discovered, in other words, the principle of anesthesia. The practical value of the discovery can hardly be overstated, as the surgeons who testified made plain: "They agreed in ranking it among the great discoveries of modern times; and one of them remarked that its value was too great to be estimated in dollars and cents. Its universal use, too, concurs to the same point. Its discoverer is entitled to be classed among the greatest benefactors of mankind."[124] But the court characterized this "benefactor's" discovery as one concerning the natural effects of a known substance on the human body.[125] That one could operate on a patient rendered insensible by drugs illustrated the utility of the natural effect, but it was no invention of the patentee.[126] He had not devised any new mechanism with which to apply his discovery,[127] so there was nothing he could patent.[128] A natural principle, such as the intoxicating effect of ether,

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[116] *See Chakrabarty*, 447 U.S. at 309 ("Einstein could not patent his celebrated law that $E=mc^2$").

[117] *See* id. ("nor could Newton have patented the law of gravity").

[118] *See* Katz v. Hornisignal Mfg. Corp., 145 F.2d 961, 961 (2d Cir. 1944) ("the great 'discoveries' of Newton or Faraday".

[119] *See Flook*, 437 U.S. at 590 ("the Pythagorean theorem would not have been patentable").

[120] *See* Schering Corp. v. Gilbert, 153 F.2d 428, 435 (2d Cir. 1946) (Frank, j., dissenting) ("No Prometheus is welcome in the Patent Office.").

[121] *Katz*, 145 F.2d at 961.

[122] Id.

[123] 17 F. Cas. 879 (S.D.N.Y. 1862).

[124] Id. at 883.

[125] Id. at 883.

[126] Id.

[127] "This new or additional effect is not produced by any new instrument by which the agent is administered, nor by any different application of it to the body of the patient. It is simply produced by increasing the quantity of the vapor inhaled. And even this quantity is to be regulated by the discretion of the operator, and may vary with the susceptibilities of the patient to its influence." Id.

[128] "It is only where the explorer has gone beyond the mere domain of discovery, and has laid hold of the new principle, force, or law, and connected it with some particular medium or mechanical contrivance by which, or through which, it acts on the material world, that he can secure the exclusive control of it under the patent laws. He then controls his discovery through the means by which he has brought it into practical action, or their equivalent, and only through them. . . . Sever the force or principle discovered from the means or mechanism through which he has brought it into the domain of invention, and it immediately falls out of that domain and eludes his grasp. It is then a naked discovery, and not an invention." Id. at 881.

could be the "soul" of an invention, but like a "disembodied spirit" it could not be subject to the patentee's exclusive control until made concrete in a novel and tangible means.[129] The momentous character of the discovery did not change the outcome, nor did it matter "what long, solitary vigils, or by what importunate efforts, the secret may have been wrung from the bosom of Nature."[130]

One would expect an incentives-based system to supply the greatest rewards to the greatest discoveries, particularly when "solitary vigils" and "importunate efforts" might otherwise go uncompensated. A system that rewards only the last step in practical application directs investments away from the place where, in the end, they may show the greatest return.[131] The *Morton* opinion supplies few explanations, asserting at one point that the unpatentability of such a discovery "needs neither argument nor authority to prove."[132]

1. Legislative Intent and Constitutional Authority.

One explanation might rest on the limits of Congressional power or the legislative intentions embodied in § 101 of the Patent Act. Although the patent clause of the Constitution refers to "discoveries," they are the discoveries of "inventors," which may imply that only a limited class of discoveries are patentable – discoveries that, through invention, introduce into the world something that did not exist before. Natural forces and phenomena already exist; only applications of those forces and phenomena are "invented." There is little contemporaneous evidence to go on, but this seems a plausible reading of the Constitutional language. Section 101 is potentially broader, in the first instance, by defining the class of potential patentees as "Whoever invents *or* discovers . . . ."[133] The list of patentable subject matter that follows includes some things, like processes and compositions of matter, that might be "discovered" existing in nature. In recent years, the courts have treated the terms of § 101 in a broadly literal sense.[134] On the other hand, part of their authority for doing so has been the statement in the Committee Reports that the patent laws should extend to "everything under the sun that is *made by man*."[135]

2. Altruistic Motives.

It would hardly be satisfying to draw a statutory line between nature and patentable inventions without a rationale to excuse the injustice to some of society's greatest benefactors or the paradoxical effect on the allocation of incentives. One

[129] Id. at 882.
[130] Id.
[131] *See* Donald F. Turner, "The Patent System and Competitive Policy," 44 N.Y.U.L. Rev. 450, 455 (1969) (arguing that the patent system "would appear to worsen . . . the allocation of research resources as between applied research on the one hand and basic research on the other").
[132] Id. at 882.
[133] 35 U.S.C. § 101 (emphasis added).
[134] *See, e.g., Chakrabarty*, 447 U.S. at 308, 315.
[135] *See supra* ____.

justification is that higher interests than monetary reward motivate the great theorists like Einstein and Faraday. A few courts have suggested this,[136] but the evidence is anecdotal at best. In any event, if scientists of Einstein's caliber were indifferent to financial gain, it would seem unnecessary to create rules that denied them patents they did not seek. Let us assume, therefore, that some of those great explorers of nature might desire, or need for covering expenses, the kind of financial returns that a patent could provide. On the other side of the balance, one could argue that the discovery of natural principles is not an activity valuable enough to society to warrant monopoly interests; only those lesser minds who apply natural principles to the "mundane problems of everyday existence"[137] actually enhance our material welfare. Clearly that has not been the reasoning of the courts, nor would it represent a broad view of how discovery benefits society, even in the most utilitarian respects. Moreover, it would be inconsistent to dismiss the value of a discovery at the same time one protests limits on its exploitation by anyone but the discoverer.

3. Natural Rights.

One could argue instead that exclusive rights to natural phenomena or principles in the abstract, even awarded to their discoverers, would impose too much upon the natural rights of others. In a copyright context, ideas expressed in nature have been called "the common heritage of humankind."[138] Similarly, the court in *Latimer* found that "nature has intended [its products] to be equally for the use of all men."[139] Even without personifying nature and giving it intentions, one can reasonably view nature, in its more abstract forms, as a resource held in common by all. On the other hand, Jefferson, in a famous passage, expressed similar views about ideas:

> If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea . . . . That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density in any point, and like the air in which we breathe, move, and have our physical being, incapable of confinement or exclusive appropriation.[140]

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[136] *See e.g., Katz,* 145 F.2d at 961 ("Interestingly enough, apparently many scientists like Faraday care little for monetary rewards; generally the motives of such outstanding geniuses are not pecuniary. Perhaps (although no one really knows) the same cannot be said of those lesser geniuses who put such discoveries to practical uses."); *Dickey-John*, 710 F.2d at 348 n.9 ("nor has it ever been considered that the lure of commercial reward provided by a patent was needed to encourage such contributions [as Einstein's]"). Universities, where much theoretical research takes place, may be less effected by the profit motive than other institutions. *See Turner*, *supra* note ___, at 452.

[137] *Dickey-John*, 710 F.2d at 348 n.9.

[138] Satava v. Lowry, 323 F.3d 805, 813 (9th Cir. 2003).

[139] 1889 Comm'n Dec. at 126.

[140] Graham v. John Deere Co., 383 U.S. 1, 9 n.2 (1966) (quoting VI Writings of Thomas Jefferson, at 180-81 (Washington ed.)).

Jefferson reasoned that ideas, and therefore inventions, "cannot, in nature, be a subject of property."[141] Nevertheless, Jefferson concluded that society, for its own benefit, might grant exclusive rights to the profits arising from inventions "as an encouragement to men to pursue ideas which may produce utility."[142] One could say the same of natural principles or phenomenon; they are held in common as a matter of right, but society for its convenience may award to the discoverers the profits derived from their useful exploitation. Why has it failed to do so?

4. Novelty.

Some courts supply the missing element by emphasizing novelty – always one of the most fundamental considerations in separating the patentable from the unpatentable. The benefit of the inventions that patents encourage must be weighed against the costs that patents impose on society. When a patent claims novel subject matter, the trade-off is generally positive; society can accept restrictions on the use of an invention that otherwise would not exist at all. However, if the patent claims something that is not new – something that society already possessed – the costs of the patent are unjustified. That is the reason that all patent claims must meet the standard of novelty, embodied in § 102 of the Patent Act.[143] In that provision, "[s]ociety, speaking through Congress and the courts, has said 'thou shalt not take it away.'"[144]

A phenomenon discovered in nature is not new, except in the sense that it was previously unknown. In 1928, the Third Circuit Court of Appeals held invalid a patent claiming a ductile form of tungsten, important because it could be drawn into thin wires for use in electric light bulbs.[145] Although the patentee, Coolidge, had been "first to uncover it and being it into view,"[146] and although he had converted it from the impure form in which it could be found in the earth, the property on which he relied was a characteristic of the metal.[147] "Naturally," wrote the court, "we inquire who created pure tungsten. Coolidge? No. It existed in nature and doubtless has existed there for centuries. The fact that no one before Coolidge found it there does not negate its origin or existence."[148] More recent cases extend the reasoning to scientific principles, like Newton's laws of gravitation, which also exist in nature before they are discovered. [149]

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[141] Id.

[142] Id.

[143] 35 U.S.C. § 102.

[144] Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453-54 (Fed. Cir. 1984).

[145] General Electric Co. v. De Forest Radio Co., 28 F.2d 641 (3d Cir. 1928).

[146] Id. at 642.

[147] "What he discovered were natural qualities of pure tungsten. Manifestly he did not create pure tungsten, nor did he create its characteristics. These were created by nature . . . ." Id. at 643.

[148] Id. Note that today a court may well grant a patent on a purified form of a natural substance if that purified form does not occur in nature. In such cases, the subject matter of the claim is novel. *See* Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 1373, 1381 (Fed. Cir. 2003).

[149] *Flook,* 437 U.S. at 593 n.15; *see also* Arrhythmia Research Technology, Inc. v. Corazonix Corp., 958 F.2d 1053 1066 n.3 (Fed. Cir. 1992) (Rader, j., concurring) ("A law of nature, even if a process, is not 'new' within the meaning of § 101."); *In re* Meyer, 688 F.2d 789, 795 (CCPA 1982) ("The Supreme

Section 101 does specify "*new* and useful" processes, machines, manufactures and compositions of matter, which bolsters the argument that natural principles or phenomena are unpatentable subject matter. On the other hand, as discussed in Part II(C), in other contexts the courts have denied that novelty, generally the province of § 102, plays any part in determining what is patentable subject matter under § 101. Moreover, the issue of dispossessing the public arises primarily where the utility does not depend on understanding the phenomenon. In other words, it would be highly objectionable for the discoverer of oxygen to deprive mankind of the use of fire, but less objectionable for Coolidge to deprive mankind of the use of ductile tungsten. Fire had been used successfully for thousands of years; ductile tungsten had not been used at all because its existence had not been suspected until Coolidge discovered it. Coolidge's patent would not have "deprived [the public] of any rights that it theretofore freely enjoyed."

5. Overbreadth.

Another reason for excluding natural phenomena might be that claims to such phenomena are overly broad. Much of the value, and burden, of the patent monopoly depends on the breadth of the claims. Narrow claims may be easily avoided; broad claims may encompass large areas of economic activity, casting a forbidding shadow over future innovations and increasing our reluctance to recognize exclusive rights. The objection to Morse's claim 8 was primarily one of over-breadth. Covering *any* means for employing electromagnetism to transmit characters at a distance, even ones much different than Morse's own, it would have imposed too much on the "onward march of science."[150] *Benson* relies on the same theme. Because Benson claimed his invention in terms of mathematics, his patent would have covered a vast array of potential applications, including some not yet discovered.[151]

In comparison to an invention described as an application of a natural principle, an invention claimed as the principle itself is a step further removed from any specific utility. It is by nature more abstract and therefore broader in scope. On the other hand, the discovery of a natural principle might be considered a more significant discovery, deserving of more substantial rewards.[152] If Benson's mathematics could be employed in so many fields, perhaps his was a "broad discovery" meriting claims to match. Broad claims, generally speaking, are not disqualified as patentable subject matter, though they

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Court has recognized that scientific principles and laws of nature, even when for the first time discovered, have existed throughout time, define the relationship of man to his environment, and, as a consequence, ought not to be the subject of exclusive rights of any one person.").

[150] *O'Reilly*, 56 U.S. at 113.

[151] *See supra* note ____.

[152] With some sense of irony, courts often contrast ground-breaking, invaluable, but unpatentable discoveries in natural science with humble, incremental, but patentable advancements in technology. *See, e.g., Katz*, 145 F.2d at 961; *Morton,* 17 F. Cas at 884 (Patents can be granted to "very humble contrivances, of limited usefulness, the fruits of indifferent skill, and trifling ingenuity," but not to a discovery as imposing as that of anesthesia).

must pass muster under the enablement and written description requirements.[153] Some "pioneering inventions,"[154] those that open up vast new possibilities, receive broad claims without demur. In any event, the relatively brief duration of the patent term eliminates the startling prospect of Samuel Morse's claim 8 covering such advanced technologies as fax machines and cell phone text messaging. Even if some advancements occurred during the life of his patent, subsequent inventors would not be powerless. They could patent their own discoveries, after which anyone desiring to practice the advancement would need the permission of both Morse, the inventor of the basic principle, and the subsequent inventor who had improved upon it – perhaps an awkward situation, but not an impossible one.

6. Tools of Research.

Courts also warn against patenting the fundamental resources necessary for research. In *Funk*, the Supreme Court described as "the work of nature" the non-inhibiting qualities of the bacteria combined by the patentee,[155] and found that "[t]he qualities of these bacteria . . . are part of the storehouse of knowledge of all men." [156] In *Benson*, the court held natural phenomena unpatentable because "they are the basic tools of scientific and technological work."[157] If patents are intended to foster technological progress, perhaps it would be counterproductive to burden with legal restrictions the "basic tools" necessary for research.

The same concern arises in the context of the utility requirement.[158] In ***Brenner v. Manson***,[159] Manson developed a process to produce a steroid similar to one known to have tumor-inhibiting effects in mice. Manson's steroid had no demonstrated use, although it was a candidate for further research.[160] The Supreme Court held this insufficient to satisfy the utility requirement. An inability to patent the process might discourage its disclosure, but "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."[161] Like the monopolies feared in *Morse* and *Benson*, it could encumber a boundless territory of further research: "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,

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[153] *See supra* ____.

[154] *See* Sun Studs, Inc. v. ATA Equipment Leasing, Inc., 872 F.2d 978, 987 (Fed. Cir. 1989) ("[t]he concept of the 'pioneer' arises from an ancient jurisprudence, reflecting judicial appreciation that a broad breakthrough invention merits a broader scope of equivalents").

[155] 333 U.S. at 130.

[156] Id.

[157] 409 U.S. at 67; *see also* Nippon Elec. Glass Co. v. Sheldon, 539 F. Supp. 542, 545 (S.D.N.Y. 1982) (applying the "basic tools" language in a case where the patentee had discovered unsafe levels of radiation emitted by some television sets).

[158] Based on the language in 35 U.S.C. § 101 stating that a patentable invention must be "new and *useful*."

[159] 383 U.S. 519 (1966).

[160] Id. at 522.

[161] Id. at 534.

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."[162]

The "basic tools" argument is dubious. As Judge Rader recently pointed out in a dissenting opinion,[163] an improved microscope can be patented even though it is "tool of research." No one knows what studies might be conducted with an improved microscope or what practical discoveries it might facilitate; microscopes are valuable because they bring researchers "one step closer" to countless useful things.[164] If patents on microscopes were forbidden, one would expect fewer resources to be devoted to their development, and advancements in microscope technology might be kept secret by those who could patent only what the instrument revealed. The effect would be to *deny* researchers the tools needed for technological advancement – a situation inconsistent with the progress of the useful arts. Similarly, natural phenomena, though not reduced to practical utility, may bring researchers "one step closer." Disallowing patents to natural laws and phenomena might withhold necessary incentives at the very point where they are most needed, while failing to protect those willing to share their discoveries. These points, raised by Justice Harlan's dissenting opinion in *Brenner*,[165] failed to carry the day in the context of utility, and presumably would not persuade the courts in the context of patentable subject matter.

II. PROCESSES BASED ON OBSERVING NATURE.

The preceding discussion suggests that observations of nature turned to practical use – removed "from the laboratory of the philosopher, and ma[de] it the servant of man"[166] – are patentable subject matter. But when applying a principle of nature means observing and drawing conclusions, one must confront additional issues, including the meaning of "process" in § 101 and the status of "mental steps" as patentable subject matter.

A. The Meaning of "Process."

Section 100(b) of the Patent Act[167] states that "'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." Even when the Act referred to "arts" alone, the courts viewed processes as patentable subject matter.[168] The courts struggled at first with the incorporeal nature of processes as compared to physical materials. In *Tilghman v. Proctor*,[169] the Supreme Court drew the customary line between an unpatentable principle

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[162] Id.; *see also In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005) ("research tools" without a "real world" utility are unpatentable).

[163] *Fisher*, 421 F.2d at 1380-81.

[164] Id. at 1381.

[165] *See* 383 U.S. at 537-39.

[166] *O'Reilly*, 56 U.S. at 132 (Grier, J., dissenting).

[167] 35 U.S.C. § 100(b).

[168] *See, e.g.,* Tilghman v. Proctor, 102 U.S. 707, 722 (1881) ("That a patent can be granted for a process there can be no doubt. The patent law is not confined to new machine and new compositions of matter, but extends to any new and useful art or manufacture. A manufacturing process is clearly an art, within the meaning of the law.").

[169] 102 U.S. 707 (1881).

and a patentable application of that principle, contrasting Morse's claim 8 to Neilson's hot-blast furnace.[170] An inventor, it held, could not patent an effect, but only a specific "means" through which that effect might be produced.[171] The "means" might be a process rather than a machine.[172] Processes differ from machines in that a process is a fleeting series of events – not, like a machine, an enduring concrete object. Because a process does not depend on specific machinery, a process is something of an abstraction,[173] but still capable of serving as a patentable "means."[174]

A few years before in *Cochrane v. Deener,*[175] the court established the principle that new processes are patentable even if they can be performed with existing machinery.[176] The patentee's process involved the separation and re-grinding of "middlings" in order to produce a high-quality flour. The most famous language in the opinion is this description of a "process:"

> A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery.[177]

A process that "transform[s]" materials and "reduce[s]" them "to a different state or thing" – like the grinding process that transforms flour from coarse to fine – has a physicality comparable to that of an apparatus. It is not a theory, but a material transformation. Some courts have implied that *only* such processes are patentable subject matter.[178] Others have warned against misconstruing the language in *Cochrane*, first offered to support an expansive view of what a process can be, as a definition or limitation.[179] In today's environment of software and business method patents,[180] a clear definition of "process" is more important than ever. Contrary to the general trend toward

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[170] Id. at 724-27l.

[171] Id. at 728.

[172] Id. The opinion includes a number of statements that are difficult to fathom, including the observation that "[a] new process is usually the result of a discovery; a machine of invention." Id. at 722.

[173] *See In re* Yuan, 188 F.2d 377, 381 (CCPA 1951) (a process "'is so far abstract that it is capable of contemplation by the mind apart from any one of the specific instruments by which it is performed'" (citation omitted)).

[174] A patent claim describing a machine is also an abstraction – a description of a class of machines that satisfy the claim language. By contrasting the concrete nature of a machine as an *embodiment* and the abstract nature of a process as an *idea, Tilghman* understates the abstractness of the former.

[175] 94 U.S. 780 (1876).

[176] Id. at 787-88.

[177] Id. at 788.

[178] *See, e.g., Yuan*, 188 F.2d at 381 (a process "'consists in the application of physical force through physical agents to physical objects'" (citation omitted)); Halliburton Oil Well Cementing Co. v. Walker, 146 F.2d 817, 821 (9th Cir. 1944); *In re* Meinhardt, 1907 Comm'n Dec. 237, 238 (1907).

[179] *See, e.g., In re* Prater, 415 F.2d 1393, 1403 (CCPA 1969). In *Benson*, the Supreme Court added to the confusion. At one point, the court states that "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." 409 U.S at 70. Later, in response to the argument that a process claim, not linked to particular machines, *must* perform a transformation, the court employs this triple-negative: "[w]e do not hold that no process claim could ever qualify if it did not meet the requirements of our prior precedents." Id. at 71.

[180] *See infra* Part II(D).

the expansion of patentable subject matter into the realm of intangibles, in 2007 the Federal Circuit held that a process satisfies § 101 only if "it is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, i.e., a machine, manufacture, or composition of matter."[181] A process not tied in such a way to a physical phenomenon, said the court, is an "abstract" idea, unpatentable under *Benson*, even if it has a practical application.[182] *Benson* does not require a reading of "abstract" that would deny patents to incorporeal processes practically applied in the solution of specific problems; the algorithm rejected as unpatentable subject matter in *Benson* was not directed to any specific application, a point emphasized by the court in rejecting the patent.[183] Hence, the adoption by the Federal Circuit of this narrow definition of "process" is a surprising one, concurrent with a similar shift in its treatment of mental steps as potentially patentable subject matter.

B. The "Mental Steps Doctrine."

A further obstacle to patenting an invention based on observations of nature is the venerable "mental steps doctrine." A series of cases in the 1940s established that purely mental acts do not qualify as patentable subject matter. In *In re Heritage*[184] the invention consisted of testing the amount of coating that could be applied to fiber boards without impairing their noise-absorbing qualities. The user of the method applied progressively greater amounts of coating to samples of the board and selected the optimum coating based on the results.[185] The only novel aspect of the method was "the mental process of making a selection," which the court held to be unpatentable subject matter.[186] In *Halliburton Oil Well Cementing Co. v. Walker*,[187] the patentee devised an improved method for determining the distance to the fluid surface in an oil well using reflected sound. The claims used words such as "counting," "observing," "measuring," "comparing," and "computing."[188] The court found the invention, in essence, to be a series of mental steps, and unpatentable using the definition of "process" advanced in *Cochrane*. The observations, computations, and comparisons described did not transform any material substance into a different state or thing.[189] *In re Toth*,[190] involving another oil-field invention, confirmed that mental steps "can be given no patentable weight."[191]

While the rejection of *purely* mental acts as patentable subject matter seemed unequivocal,[192] at least two questions remained. One was whether a process that

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[181] In re Comiskey, 499 F.3d 1365, 1376 (Fed. Cir. 2007).
[182] Id.
[183] *Benson*, 409 U.S. at 64.
[184] *In re* Heritage, 150 F.2d 554 (CCPA 1945).
[185] Id. at 556.
[186] Id.
[187] 146 F.2d 817 (9th Cir. 1944).
[188] Id. at 821.
[189] Id.
[190] 63 U.S.P.Q. 131 (PTO Bd. App. & Int. 1944).
[191] Id. at 132.
[192] *See Yuan*, 188 at 380 (it has been "thoroughly established by decisions of various courts that purely mental steps do not form a process which falls within the scope of patentability as defined by statute").

combined mental and physical steps could be patented. A second was whether acts that could be carried out either in the mind or by a machine could be patented. In 1951, the CCPA addressed the first question in *In re Abrams*.[193] The applicant invented a process for identifying petroleum deposits by measuring the flow rate of certain gasses into a bore hole and comparing the results to a benchmark figure. The applicant proposed three "rules of law" to settle perceived confusion in the mental steps cases.[194] Rule 1 states that a process is unpatentable subject matter if all of the steps are "purely mental in character."[195] Rule 2 states that if a process includes *some* mental steps, and "the alleged novelty or advance over the art resides in one or more of [those] steps," then the process is unpatentable.[196] Rule 3 states that if some steps of the process are mental steps and others physical steps, but the novelty resides in the physical steps, then the combination is patentable subject matter.[197] The rules "appear[ed] to accord" with the case law, but the court found it unnecessary to decide anything further than the applicant's failure to qualify under proposed Rule 3.[198]

In the "first *Prater* opinion"[199] of 1968, Judge Smith of the CCPA challenged the conventional wisdom in several respects. First, he cast doubt on the origins of the mental steps doctrine, pointing out that in one of its earliest manifestations the claimed invention had failed the novelty test, rendering the subject matter question moot.[200] Second, he rejected the *Cochrane* definition of "process" – the surest ground for excluding mental steps from § 101. When *Cochrane* refers to a process as "an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing,"[201] the court's intention, said Judge Smith, was not to limit what a process could be but to expand it beyond the confines of specific machinery.[202] Third, Judge Smith dismissed the *Abrams* "rules" as propositions without judicial sanction. If the *Abrams* court embraced the rules at all, it was only for purposes of argument, to demonstrate that the applicant would fail even if the proposed rules were adopted.[203] Finally, Judge Smith distinguished *Abrams* on the ground that the invention in the earlier case included steps that could only be performed in the mind. In contrast, the applicant in *Prater* invented a method of choosing certain peaks in a spectrograph to achieve accurate measurements, and all of the steps could be performed by machinery the applicant disclosed.[204] As far as Judge Smith could determine, Congress had not denied patents to methods that might be performed, but did not *have* to be performed, in the human mind.[205] The sole caveat was

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[193] 188 F.2d 165 (CCPA 1951).
[194] Id. at 166.
[195] Id.
[196] Id.
[197] Id.
[198] Id. at 167.
[199] 415 F.2d 1378 (CCPA 1968).
[200] Id. at 1372 (referring to Don Lee, Inc. v. Walker, 61 F.2d 58 (9th Cir. 1932)).
[201] *Cochrane*, 94 U.S. at 788.
[202] 415 F.2d at 1372-73.
[203] Id. at 1371 (viewing the *Abrams* rules as adopted by the court is a "misreading" of the case that leads to "confusion").
[204] Id. at 1374.
[205] Id.

that the method must be "directed to an industrial technology – a 'useful art' within the intendment of the Constitution."[206]

Judge Smith's *Prater* opinion was important, but short-lived. The CCPA granted a petition for rehearing, and in 1969 issued the "second *Prater* opinion."[207] This time the court rejected the claims as indefinite. An application must include claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[208] Here the applicant regarded his invention as one limited to machines, but the claims failed to reflect his intentions.[209] The opinion duplicates portions of Judge Smith's earlier efforts, including the warning against treating *Cochrane's* process description as a limitation.[210] Again, the court distinguished *Abrams* as a case in which the claimed process could *only* be performed through mental steps.[211] Although the court declined to analyze the mental steps doctrine in detail,[212] and much of what it did say can be dismissed as *dicta*, the opinion marked a significant shift. Because *Abrams* and the earlier cases pre-dated the 1952 Patent Act, the court concluded that "[w]hether or not a sequence of purely mental steps comes within the bounds of 'process' . . . is . . . an issue which has never been squarely decided."[213]

The retreat continued the following year with *In re Musgrave*, where the applicant invented a method of analyzing seismograms.[214] The Patent Office rejected the claims, finding that mental steps were the only steps recited, or, in claims that also recited physical steps, the only source of novelty.[215] On appeal, the CCPA observed that nothing in the Patent Act specifically excludes, or includes, mental steps within the definition of a statutory process. [216] The case law it found "something of a morass," the term "mental step" having no clear meaning, nor any definite legal significance.[217] A physical process, the court held, is not unpatentable merely because the human operator must think, nor is a process to be performed by a machine disqualified because it might also be performed by a person.[218] As for the *Abrams* rules, the court found Rules 2 and 3 to be logically

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[206] Id. at 1375.

[207] 415 F.2d 1393 (CCPA 1969).

[208] 35 U.S.C. § 112.

[209] Id. at 1405. Today this seems an odd use of the definiteness requirement. A claim is indefinite under § 112 of the Patent Act if persons skilled in the art cannot understand its scope. *See* Intellectual Property Development Inc. v. UA-Columbia Cablevision of Westchester Inc., 336 F.3d 1308, 1319 (Fed. Cir. 2003). Here the court understood the claim perfectly well and found that it read on mental activity. *See* 415 F.2d at 1405. The claim might have failed the written description requirement if the applicant had not been in possession of such a broad invention when the application was filed. *See* Moba B.V. v. Diamond Automation, Inc. 325 F.3d 1306, 1320 (Fed. Cir. 2003). But the applicant in *Prater* seems to have known all along that, theoretically, the method could be performed mentally; it simply argued, unsuccessfully, that the claims were narrower than that. *See* 415 F.2d at 1404.

[210] Id. at 1403.

[211] Id. at 1401-02.

[212] Id. at 1403.

[213] Id. at 1402 n.23.

[214] 431 F.2d 882 (CCPA 1970).

[215] Id. at 888.

[216] Id. at 890.

[217] Id. at 890-91.

[218] Id. at 893.

unsound.[219] Whether a process qualifies as patentable subject matter cannot depend on where the novelty lies; otherwise, the subject-matter status of a process claim could change as the art advanced, ceasing to be statutory when the physical process steps ceased to be novel. "Logically," the court wrote, "the identical process cannot be first within and later without the categories of statutory subject matter, depending on such extraneous factors."[220]

If anything remained of the mental steps doctrine, it seemed limited to methods that could only be performed in the human mind, including judgments based on aesthetics, morals, politics, or other "peculiarly human" values.[221] Processes dependent on these judgments – a process for selecting the perfect drapes for the living room, for example – might exceed the scope of the useful arts. Rather than address these inventions through the muddied lens of the mental steps doctrine, the court devised a useful arts alternative like that proposed in the first *Prater* opinion: "All that is necessary, in our view, to make a sequence of operational steps a statutory 'process' within 35 U.S.C. 101 is that it be in the technological arts so as to be in consonance with the Constitutional purpose to promote the progress of 'useful arts.'"[222] This new test, Justice Stevens later observed, "effectively disposed of any vestiges of the mental-steps doctrine."[223] Judge Baldwin, concurring in *Musgrave*, argued that the new test was unnecessary because the "mental steps doctrine" had been so limited by the courts[224] that it was "no longer a serious problem."[225]

One factor marginalizing the mental steps "problem" was that computers soon handled many processes involving calculations or comparisons. Hence, after *Musgrave* attention shifted to the "mathematical algorithm" analysis. In *Benson* the court noted that, theoretically, one could perform the calculations with the aid of pencil and paper.[226] But because Benson's process was meant to be performed by a computer, the discussion turned to the abstract nature of the calculations even if performed by machines.[227]

Another reason for the decline of the mental steps doctrine may be that it was difficult to justify. In *Abrams* the court did not even try, declaring it "selfevident that thought is not patentable."[228] Leaving aside electrochemical processes in the brain, mental steps do not transform any physical substance into a different state or thing. Yet, as discussed in both *Prater* opinions, *Cochrane* probably intended no limitation on the meaning of "process," nor, in any case, would a *Cochrane* limitation help us understand the reason for the distinction. Some mental processes might fall outside the scope of the useful arts, but others, like those used in petroleum exploration, are unquestionably

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[219] Id. at 889.

[220] Id.

[221] *See* id. at 889 n.4.

[222] Id. at 893.

[223] *Diehr*, 450 U.S. at 200 (Stevens, J., dissenting).

[224] *See* id. at 894 ("there is now only a very narrow scope to this 'fearful' mental steps doctrine").

[225] Id. at 894-95.

[226] 409 U.S. at 67.

[227] In *dicta*, the *Benson* court did list "mental processes" as one of the exceptions to § 101, perhaps signaling that the mental steps doctrine had life in it still. Id. The similar list in *Diehr* includes only "laws of nature, natural phenomena, and abstract ideas." 450 U.S. at 185.

[228] 188 F.2d at 168.

technological.[229] A thought process might be considered a natural process, and therefore excluded from § 101 like other natural phenomena.[230] But novel mental processes are not *found* in nature; like any other novel processes, they must be invented. While *Benson* includes mental processes, along with phenomena of nature and abstract intellectual concepts, among the "basic tools of scientific and technological work,"[231] the court does not explain why this is so. A process that requires only observation and reflection is not, necessarily, more fundamental to scientific inquiry than a process involving physical steps. Finally, one might argue that legal restrictions on thought process are inconsistent with basic freedoms, perhaps those guaranteed under the First Amendment.[232] This is an intriguing line of inquiry but by no means well developed in the mental steps cases.

Although the mental steps doctrine might have been considered defunct, it experienced an unexpected re-birth in 2007, through the Federal Circuit's decision in *In re Comiskey*.[233] The patent application at issue, rejected by the examiner on grounds of obviousness, concerned a method of conducting a mandatory arbitration involving legal documents. Relying on the unpatentability of "abstract" ideas, as recorded in *Benson*, the court held that purely mental processes, not tied to machinery or the physical transformation of matter, are unpatentable subject matter, even if they are usefully applied.[234] The court invoked the "basic tools" argument,[235] and, interestingly, argued that such purely mental processes exceed the scope of the "useful arts."[236] In other words, the "technological arts" consideration offered in *Musgrave* as a *substitute* for a discredited mental steps doctrine has now been used to justify its re-imposition. This development is certain to be controversial, both because the intentions of the framers are difficult to apply to the intangible technologies of today, and because mental processes applied to the solution of practical problems in technological fields actually might be considered technological processes, regardless of their incorporeal nature.

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[229] Some of the mental processes identified in Musgrave as "peculiarly human" might defy description, raising issues of definiteness. *See Musgrave*, 431 F.2d at 893 ("Of course, to obtain a valid patent the claim must also comply with all the other provisions of the statute, including definiteness under 35 USC 112. A step requiring the exercise of subjective judgment without restriction might be objectionable as rendering a claim indefinite, but this would provide no statutory basis for a rejection under 35 USC 101."). Many claims based on mental steps would pose no such difficulty.

[230] *See Prater I*, 415 F.2d at 1374 ("although appellant's novel calculations performed in the mind of a man might possibly considered to be in nature, performance of the process of these novel calculations on a computer is by 'a means which had never occurred in nature.'" (citation omitted)).

[231] 409 U.S. at 67.

[232] *See Prater II*, 415 F.2d at 1390 n.20 ("The solicitor . . . argues that 'the grant of a patent containing process claims of such breadth as to confer upon a patentee the right to exclude others from thinking in a certain manner' would run afoul of the First, Ninth, and Tenth Amendments to the Constitution. He urges that Article I, Section 8 must be construed in the light of the other constitutionally assured rights and that freedom of mind or thought may not be abridged by the patent laws.").

[233] 499 F.3d 1365 (Fed. Cir. 2007).

[234] Id. at 1377 ("mental processes – or processes of human thinking – standing alone are not patentable even if they have practical application").

[235] Id.

[236] *See* id. at 1378-79 ("the patent statute does not allow patents on particular systems that depend for their operation on human intelligence alone, a field of endeavor that both the framers and Congress intended to be beyond the reach of patentable subject matter").

C. The Relationship of Novelty and Patentable Subject Matter.

If "mental processes" are out of bounds, inventions based on observation of nature may still be patented if allied with physical steps preceding, or following, the observation. Because such steps are often necessary to enjoy the fruits of the discovery, adding them to the claim is unlikely to limit the economic value of the patent. As long as the physical steps in the expanded process are new, the mental component – observing and reflecting – should not affect the patentability of the claim; as the court said in *Musgrave*, a process is not unpatentable merely because the operator must think. The problem would arise if the physical steps were *not* new.

For many years there have been two starkly-contrasting views of the relationship between patentable subject matter and novelty. According to the first view, one must identify, in a claim comprising multiple elements, the particular elements that distinguish the claim from the prior art. Only those elements affect the status of the invention under § 101 of the Patent Act. This is the approach suggested by Rules 2 and 3 proposed in *Abrams*.[237] The other point of view holds that patentable subject matter and novelty are entirely separate requirements, making it inappropriate to consider which part of the claim is new, or if *any* part of the claim is new, when addressing § 101.

A patent claim is a combination of elements describing an apparatus, method, or composition of matter. A product or process that includes all of the elements of the claim infringes.[238] One could view the claimed combination *as a whole* as the patentee's invention; alternatively, one could view the invention as the advancement in the art – the "point of novelty" – most often recited in just a portion of the claim. Suppose, for example, that an inventor discovered an additive that would keep the graphite in a pencil from smudging. The claim might begin "A writing implement comprising . . . ," followed by a list of elements, many of them old (a shaft of wood, a metal band, a soft rubber eraser) and one of them new (a graphite rod with additive X). One could view the invention as the improved pencil or as the additive alone, and one could construct a patent system around either approach. Which system we have is a matter of debate.

Section 101 reserves patents to those who "invent" something new within the designated categories of patentable subject matter.[239] Section 112 requires that the claims "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention."[240] This suggests that the invention and the claim language are co-extensive, and often claims include both old elements and new. Section 103, requiring that a patented invention be not only new but nonobvious, [241] is the one provision to hint that some claim elements might embody the invention more than others. Section 103 focuses on the "differences" between the prior art and patented invention, differences that might reside in only a portion of the claim. However, the differences matter only if they render obvious "the subject matter [sought to be patented] as a whole,"[242] a phrase implying that the invention is more than just the differences. Hence, as far as one can

[237] *See supra* ____.
[238] *See* Techsearch L.L.C. v. Intel Corp., 286 F.3d 1360, 1371 (Fed. Cir. 2002).
[239] 35 U.S.C,§ 101.
[240] 35 U.S.C. § 112 ¶ 2.
[241] 35 U.S.C. § 103.
[242] 35 U.S.C. § 103.

determine from the statutory language, the applicant's invention is, for most purposes at least, the whole of the combination described in the claim.[243] The language is not as clear as it could be, and on other occasions courts have ignored the plain meaning of the statute – for example, by excluding certain processes from § 101.[244]

Parker v. Flook[245] best expresses the view that one must focus on the novel features in order to determine if the invention is patentable subject matter. The court assumed that Flook's mathematical formula was the only novel aspect of his method, something that Flook did not deny, and asked whether his discovery of the formula made eligible for a patent his "otherwise conventional method."[246] Because only useful applications of natural principles can be patented, "[t]he process itself, not merely the mathematical algorithm, must be new and useful."[247] The court rejected, as "exalting form over substance," the "notion that post-solution activity [i.e., physical steps], no matter how conventional or obvious in itself, can transform an unpatentable principle [such as Flook's algorithm] into a patentable process."[248] Viewed in this light, Flook's claim "as a whole" included no patentable invention.[249] *Flook* is a difficult opinion to interpret, in part because of its ambiguous use of terms such as "claim" and "invention."[250] Its clearest lesson is to test the *substance* of the invention under § 101, while ignoring any conventional process steps that might be added to the claim.

Judge Rich of the CCPA, and later of the Federal Circuit, expressed the opposing point of view[251] through his memorable "three doors" analogy:

> Achieving the ultimate goal of a patent . . . [requies] separate keys to open in succession the three doors of sections 101, 102, and 103. . . . If the invention, as the inventor defines it in his claims . . . falls into any one of the named categories [of § 101], he is allowed to pass through to the second door, which is § 102; "novelty and loss of right to patent" is the sign on it. Notwithstanding the words "new and useful" in § 101, the invention is not examined under that statute for novelty because that is not

[243] *See Flook*, 437 U.S. at 594 n.16 ("Section 103, by its own terms, requires that a determination of obviousness be made by considering 'the subject matter as a whole.' Although this does not necessarily require that analysis of what is patentable subject matter under § 101 proceed on the same basis, we agree that it should." (citation omitted)).

[244] *See supra* ____.

[245] 437 U.S. 584 (1978).

[246] Id. at 588.

[247] Id. at 592.

[248] Id. at 590.

[249] Id. at 594. The court found in its analysis no confusion of patentable subject matter and novelty. The court *assumed* that the algorithm was novel, but still rejected the claim for lack of a patentable invention. *See* id. at 593.

[250] *See, e.g.*, id. at 594 ("Here it is absolutely clear that respondent's application contains no claim of patentable invention.").

[251] Judge Rich found in *Flook* "an unfortunate and apparently unconscious . . . commingling of statutory provisions which are conceptually unrelated." *In re* Bergy, 596 F.2d 952, 959 (CCPA 1979).

> the statutory scheme of things or the long-established administrative practice.[252]

Without overruling *Flook*, the Supreme Court in *Diehr* adopted Judge Rich's analysis.[253] Which aspects of Diehr's process might be novel, if any, did not enter into the subject matter determination.[254] A claim, the court held, must not be "dissected" into old and new elements; it must be evaluated as a whole.[255] Diehr claimed his invention as a method of curing rubber – clearly, at that level, a "process" within the meaning of § 101.[256] Hence, whether or not Diehr's invention was new, it easily qualified as patentable subject matter.

In re Comiskey suggests a change of heart by the Federal Circuit. There the court held that "[t]he routine addition of modern electronics to an otherwise unpatentable invention" – unpatentable in this case because, as a purely mental process, it exceeded the scope of patentable subject matter – "typically creates a prima facie case of obviousness."[257] In other words, an invention barred at the door of patentable subject matter but not reviewed for obviousness cannot supply the non-obviousness element of a combination that is, as a whole, patentable subject matter. The *Diehr* court, one suspects, would call that confusing § 101 of the Patent Act with § 103. Nevertheless, any confusion in this case occurs at the § 103 "door." Because of this, and because D*iehr* was the Supreme Court's last word on the subject, one would still expect a process combining observation, thought, and physical action to pass scrutiny under § 101, even if the only *novel* aspects of the method were, considered independently, unpatentable.

D. Patentable Subject Matter in the Age of Intangibles.

Recent decades have witnessed a remarkable expansion in the subject matter one could expect to patent. One development responsible for this trend is an increased deference to the applicant's manner of characterizing the invention. Where the court in *Flook* looked behind the applicant's claim to discover its "substance," ignoring any physical process steps if they did not embody Flook's contribution to the art, in *Diehr* the court accepted the claim as written. On its surface, Diehr's claim described an industrial process for curing rubber – patentable subject matter even if one requires that a "process" transform physical materials into "a different state or thing."[258] After *Flook*, one would

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[252] Id. at 960; *but c.f., In re* Cruciferous Sprout Litigation, 301 F.3d 1343, 1351(Fed. Cir. 2002) (recognizing cancer-fighting properties inherent in cruciferous sprouts is not the invention of something *new*, as required by § 101).

[253] 450 U.S. at 190 ("The question of whether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject matter.'" (quoting *Bergy*, 596 F.2d at 961)).

[254] Id. at 188-89; *see also Musgrave*, 431 F.2d at 893 ("In considering the patentability of a process consisting of a plurality of steps we think it is immaterial to the question whether the combination is a statutory 'process' that individual steps are old. The whole process could be old and yet be statutory; a fortiori, it matters not that one or more steps are old.").

[255] Id. at 189.

[256] *See* id. at 184 ("[W]e think that a physical and chemical process for molding precision synthetic rubber products falls within the § 101 categories of possibly patentable subject matter . . . . Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws.").

[257] *Comiskey*, 499 at 1380.

[258] *See supra* ____.

have concluded that a mathematical algorithm cannot be patented, as a matter of principle, even if the algorithm were usefully employed in a specific industrial context. *Diehr* reduced the issue to one of claim drafting.

A similar shift occurred in even more abstract areas of computing, beginning with *In re Alappat*.[259] Alappat invented a method of producing smooth lines on a display, such as an oscilloscope display, by shading the pixels according to a mathematical algorithm.[260] Alappat's algorithm, like Benson's, involved the manipulation of numbers. But unlike Benson, Alappat claimed his invention as *a machine* – an improved display (or "rasterizer").[261] The claims described the machine as a collection of "means" for executing the steps of the algorithm – each "means" consisting of conventional computer hardware.[262] The Federal Circuit, en banc, determined that a re-programmed general-purpose computer qualifies as a patentable apparatus, even if mechanically unchanged.[263] Although the court fell short of holding that every algorithm claimed as an apparatus qualifies under § 101,[264] the form of the claim occupied much of the court's attention.[265] Subsequent cases followed suit. In *State Street Bank & Trust Co. v. Signature Financial Gp.*,[266] the patentee claimed a "data processing system" for managing a mutual fund portfolio, providing centralized resources and tax advantages. The patentee invented no new hardware, but because the claim used the "means" format, and the patent specification included general references to computers, the claim literally described a machine. "A 'machine,'" the court observed, "is proper statutory subject matter under § 101."[267]

Another striking trend has been the Federal Circuit's emphasis on utility, rather than physicality, as the key to patentable subject matter. One could treat utility and patentable subject matter as entirely separate "doors," to use Judge Rich's analogy, even though § 101 is the source of both requirements.[268] A novel compound, for example,

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[259] 33 F.3d 1526 (Fed. Cir. 1994) (*en banc*).

[260] Id. at 1537-38.

[261] Id. at 1538-39.

[262] Paragraph 6 of 35 U.S.C. § 112 provides that "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

[263] 33 F.3d at 1545.

[264] *See* id. at 1545 ("a computer operating pursuant to software *may* represent patentable subject matter" (emphasis in original)).

[265] In its concluding sentence, the court observes that "a computer, like a rasterizer, is apparatus not mathematics." Id. Judge Archer, dissenting, deplored the majority's "simplistic" and deferential approach, which overlooked the actual invention in favor of the superficial aspects of the claim Id. at 1554. Every § 101 analysis, he wrote, "must begin with this question: What, if anything, is it that the applicant for a patent 'invented or discovered?'" Id. at 1557. By that Judge Archer meant something more than "What does the applicant's claim say?" Judge Archer's opinion in *In re* Grams, 688 F.2d 789 (CCPA 1982) similarly resists the idea that the claim alone determines the nature of the invention. *See id.* at 839 ("]I]n answering this inquiry [what did the applicant invent?] 'each invention must be evaluated as claimed: yet semantogenic considerations preclude a determination based solely on words appearing in the claims.'" (quoting *In re* Abele, 684 F.2d 902, 907 (CCPA 1982)).

[266] 149 F.3d 1368 (Fed. Cir. 1998).

[267] Id. at 1372.

[268] Just as § 112 ¶ 1 spawned the separate requirements of enablement, best mode and written description.

might qualify as a "composition of matter," but fail the utility requirement because its inventor had discovered no practical use for it.[269] But in a number of cases, beginning with *Alappat,*[270] the Federal Circuit relied on a "*useful*, concrete, and tangible result" to establish that an invention is patentable subject matter, rather than an abstract principle.

In *State Street,* the court applied the phrase to the calculation of mutual fund share prices.[271] "Useful" the result certainly was; anyone can appreciate the advantage of saving money through economies of scale and tax avoidance. "Concrete" is more debatable; the numbers were "concrete" only in the sense that the computer calculated them to the last penny. "Tangible" is a puzzle. The numbers had a definite meaning, but if anything is *in*tangible, in the usual sense of non-physical, it is data representing dollar amounts – symbols corresponding to an abstract medium of exchange. A contemporaneous case, *AT&T Corp. v. Exel Communications, Inc.*,[272] also speaks of a "useful, concrete, and tangible result," this time in the context of obtaining telephone billing information through Boolean logic.[273] Here the court explains that physicality is just one way to demonstrate that the invention is more than an abstract idea.[274] Although the Federal Circuit used the word "tangible," utility seemed to be the key consideration under § 101. As in so many other respects, *Comiskey* marks a reversal. In that case, the Federal Circuit held that mental processes are not patentable subject matter even if they are usefully applied.[275] It remains to be seen whether this signals a more restrictive application of the "useful, concrete, and tangible" limitation than *Alappat* or *AT&T* would suggest.

The last important trend responsible for the expansion of patentable subject matter has been the reluctance of both the Supreme Court and the Federal Circuit to limit § 101 without specific instructions from Congress. This has led to the demise of some limitations that used to represent the conventional wisdom. In *Chakrabarty*, the Supreme Court announced that, absent a definite signal from Congress, living things would be considered patentable subject matter.[276] *Diehr* applied the same approach to computer software.[277] In *State Street*, the Federal Circuit held that, whatever the treatises might say, methods of doing business are not disqualified as patentable processes.[278] The Patent Office has found that the Patent Act does not limit patentable subject matter even

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[269] *See Brenner*, 383 U.S. at 434-35.

[270] 33 F.3d at 1544.

[271] "Today, we hold that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces 'a useful, concrete and tangible result' – a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades." [Cite]

[272] 172 F.3d 1352 (Fed. Cir. 1999).

[273] Id. at 1358.

[274] Id. ("The notion of 'physical transformation' . . . is not an invariable requirement, but merely one example of how a mathematical algorithm may bring about a *useful* application." (emphasis added)).

[275] 499 F.3d at 1379 ("the application of human intelligence to the solution of practical problems is not in and of itself patentable").

[276] *See* 447 U.S. at 314-317.

[277] *See* 450 U.S at 182.

[278] 149 F.3d at 1375 ("We take this opportunity to lay this ill-conceived exception to rest. . . . Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.").

to the technological arts – the "useful arts" referenced in the Constitution.[279] On the last point at least, it appears that the Federal Circuit is pushing back. In *Comiskey,* the court held that processes having no physical component, such as mental processes, are beyond the scope of the "useful arts" intended by Congress, and the framers, to be the subject matter of patent law.[280]

Against this background, a technique combining observation of nature and useful physical action seems a plausible candidate for a patent. Such an invention is not one of philosophical inquiry, or a natural principle in the abstract; it is a principle applied to practical ends. Because the claim will be viewed as a whole for purposes of the § 101 analysis, it should not matter whether the physical steps are old or new. Although *Comiskey* raises doubts on that score,[281] the Supreme Court's approach in *Diehr* should trump them. With proper claim drafting, the discoverer of any natural relationship usefully applied might expect to patent the discovery – until recently. In his *Lab. Corp.* opinion, Justice Breyer cast doubt on the patentability of inventions based on useful observations of nature.

F. The *Lab. Corp.* Opinion and its Predecessors.

Gathering information about the things around us can be a matter of purely academic interest. Astrophysicists seldom change things for the better. But in other contexts information is a highly practical commodity. Without it, one could not drill for oil or treat a patient. That information is useful does not overcome the § 101 problem if one tries to patent the information itself. Some information – the location of a petroleum deposit, or the condition of a patient – exists in nature, so to reveal that information is not to *invent* it. On the other hand, one might invent processes or machines that take advantage of the information in a new way. These should be patentable as natural phenomena usefully applied.

Many of the cases discussing patentable subject matter deal with observations of natural phenomena. In *Diehr*, for example, the rubber-curing process depended on observing temperatures inside the mold and understanding the natural relationship between those temperatures and the condition of the rubber.[282] One difficulty in such cases lies in separating the phenomenon itself from the machine or process sought to be patented. When computers process the data obtained through observation, *Benson's* mathematical algorithm exception adds an additional layer of complexity.

Several cases on observing and analyzing natural phenomena involve patient diagnosis. The results are mixed. *In re Meyer*[283] concerned a process and apparatus, described in abstract terms, for testing the elements of a complex system and correlating the results to identify elements that might be malfunctioning.[284] An intended use was as a computer-based diagnostic aid for a neurologist running a battery of tests on a patient –

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[279] *See In re* Lundgren, Appeal No. 2003-2088 (Bd. Pat. App. & Int. 2005).
[280] *See* 499 F.3d at 1378-79.
[281] *See supra* ____.
[282] *See supra* ____.
[283] 688 F.2d 789 (CCPA 1982).
[284] Id. at 790.

an aid supplementing the neurologist's own memory and processes of deduction.[285] The court determined that the invention was a mathematical algorithm representing a mental process, divorced from any physical elements or process steps.[286] Without reference to *Musgrave*, which had seemingly dispensed with the mental steps doctrine,[287] the court held the invention beyond the scope of § 101.[288] *In re Grams*[289] also involved a method for testing the elements of a complex system and analyzing the results to identify abnormalities. The claims limited the invention to the diagnosis of abnormalities in human patients based on the results of laboratory tests.[290] Again the court found that the analysis constituted nothing more than an unpatentable mathematical algorithm,[291] even when combined with steps for gathering data.[292] In contrast, the court in *Arrhythmia Research Technology, Inc. Corazonix Corp.*[293] held patentable a method of analyzing electrocardiographs to identify a patient's susceptibility to ventricular tachycardia. Here the invention was not too abstract for § 101. The inputs were "not abstractions; they [were] related to the patient's heart function."[294] The output also was "not an abstract number, but . . . a signal related to the patient's heart activity."[295] Indeed, the method was one of physical process steps because it "transformed one physical, electrical signal into another,"[296] potentially an argument for bringing any computer-implemented calculation into the realm of a physical process.

The *Lab. Corp.* situation is in some respects much simpler because it does not involve a mathematical algorithm, nor an invention described in vacuously abstract terms. The patentee claimed a process for diagnosing a vitamin deficiency by observing in a patient's blood an elevated level of the amino acid homocysteine. Claim 13 read as follows:

> A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> assaying a body fluid for an elevated level of total homocysteine; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.[297]

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[285] Id. at 793, 795.
[286] Id. at 796.
[287] *See supra* ____.
[288] 688 F.2d at 796.
[289] 888 F.2d 835 (Fed. Cir. 1989).
[290] Id. at 836.
[291] Id. at 841.
[292] "'Given that the method of solving a mathematical equation may not be the subject of patent protection, it follows that the addition of the old and necessary antecedent steps of establishing values for the variables in the equation cannot convert the unpatentable method to patentable subject matter.'" Id. at 839 (quoting *In re Christensen*, 478 F.2d 1392, 1394 (CCPA 1973)).
[293] 958 F.2d 1053
[294] Id. at 1059.
[295] Id.
[296] Id. at 1059
[297] Id. at 2924.

The district court, affirmed by the Federal Circuit, held the defendant liable for inducing infringement by encouraging doctors to order the necessary tests.[298] The Supreme Court granted certiorari to determine whether the patent "claim[ed] a monopoly over a basic scientific relationship" – the relationship between homocysteine and the vitamin deficiency.[299] Later the court dismissed the writ as improvidently granted.[300] Justice Breyer, joined by Justices Stevens and Souter, dissented.

A successful patent policy, wrote Justice Breyer, requires judicious balancing. Against the monetary incentives to inventors one must weigh the costs imposed on others; "sometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts.'"[301] By raising costs and interposing complex legal issues, patents can discourage research and the free exchange of information.[302] One of the ways in which patent law maneuvers between the "opposing and risky shoals" of over-protection and under-protection is through the rules of patentable subject matter.[303] The exclusion of scientific truths and natural phenomena preserves from monopoly the "'basic tools of scientific and technological work'" – a part of the "'storehouse of knowledge' . . . 'free to all men.'" [304] Because they are so fundamental, patents on natural principles and phenomena, like copyrights on ideas, would create vast opportunities for rent seeking and enormous transaction costs.[305] The law withholds patent protection even though discoveries about the natural world may be difficult, expensive, time-consuming, dependent on monetary incentives, and a "great benefit to the human race."[306]

Justice Breyer admitted that the line drawing can be challenging.[307] Many patentable inventions begin with an understanding of the natural world.[308] But this case, he found, was not difficult.[309] The relationship between elevated homocysteine levels and vitamin deficiencies is a natural phenomenon, and it remains so even when "packag[ed]," by the claim language, in the form of a process.[310] The process does not "transform" the blood of the patient subject to the test; the process simply requires the physician to "(1) obtain test results and (2) think about them."[311] Moreover, even if diagnosing a vitamin deficiency could be considered a "useful, concrete and tangible result," Justice Breyer warned that this language had never been endorsed by the Supreme Court, nor, if taken literally, would it be consistent with *Morse*, *Benson* or

[298] Id. at 2921.
[299] Id. at 2922.
[300] Id. at 2921.
[301] Id. at 2922 (emphasis in original).
[302] Id.
[303] Id.
[304] Id. at 2923 (citations omitted).
[305] Id. at 2922-23.
[306] Id. at 2922.
[307] Id. at 2926.
[308] Id.
[309] Id. at 2927 (this invention was "not at the boundary").
[310] Id.
[311] Id.

Flook.[312] The patentee's attempt to restate a natural law in the language of a process produced only "an instruction to read some numbers in light of medical knowledge."[313] Justice Breyer called the correlation between homocysteine and vitamin deficiency a "natural phenomenon" and found "nothing in [the] claim that adds anything more of significance."[314]

With all respect to Justice Breyer, the situation was more complicated than he admitted, for three reasons. First, the step of "assaying" implies a physical process. Even if the process is not new or patentable, *Diehr* suggests that it cannot be ignored; rather, the claim must be viewed "as a whole," and the inclusion of some steps that might, by themselves, be nonstatutory, does not change the character of the overall process under § 101.[315] Second, the claim does not describe the natural relationship between homocysteine and vitamins *per se*, but a way of *applying* the natural relationship to diagnose the condition of a patient. It is overlooking a great deal to say simply that claim 13 "amount[s] to a simple natural correlation."[316]

Finally, the justifications that Justice Breyer provides for the exclusion of patents on natural principles have little force as applied to claim 13. A patent that claimed the law of gravity would be of enormous scope because gravity is operative in so many contexts. Even a patent on the natural relationship between homocysteine and certain vitamins could cover a "basic tool of research," if we imagine that the relationship might be employed in medical treatments, improved vitamin supplements, or tests for related conditions. Indeed, one could generalize so far as to say that any natural principle or phenomenon is a "basic tool of research." But here the claim applies the relationship to a specific purpose – diagnosing a vitamin deficiency. Diagnosis might be important to research; obviously it is important to patient care. The patent might raise the costs of healthcare, limit the use of an important technique, encourage rent-seeking, encumber physicians with legal problems and transaction costs, and all the rest. However, compare claim 13 to a hypothetical patent on a medical imaging device, like an MRI scanner. Scanners have at least the same potential as tools of research, if not more, and they make enormous contributions to healthcare. A patent on the scanner would carry the same kinds of penalties as a patent on the method of diagnosis. Yet there is no question that a scanner would qualify as patentable subject matter under § 101, and it is unlikely that Justice Breyer would find a patent on a scanner objectionable as a matter of policy. In short, the generalizing that seems plausible, if unproven, when comparing natural laws in the abstract to machinery and other applications of natural laws – the first "basic tools of research" and the latter patentable inventions – no longer holds once the natural law is

[312] Id. at 2928. If one took "tangible" *literally*, the standard would be consistent with *Benson* and *Flook*. In each case the result of the process was a number – an intangible thing – and the patent was denied. In *Morse*, the description of the invention in the broadest, vaguest claim was less than "concrete." The cases where a literal reading of "useful, concrete and tangible" actually seems inconsistent with the result are some of the very cases relying on the phrase – e.g., *State Street* and *AT&T*.

[313] Id. at 2928.

[314] Id.

[315] *See supra* ____.

[316] 126 S. Ct. at 2928.

applied in a form that yields useful information and a specific beneficial result.[317] There is no reason to suppose that the usual weighing of incentives against costs produces here a result uncharacteristically adverse to the progress of the useful arts.[318]

III. DANGEROUS KNOWLEDGE AND ITS ECONOMIC EFFECTS.

One thing *does* distinguish claim 13 from most patent claims, and that is the role that knowledge plays in carrying out the process. Once a physician learns of the natural relationship between elevated levels of homocysteine and vitamin deficiencies, that physician, on reviewing a lab report, cannot help but "correlate" the result and the likely condition of the patient. In a process having only two steps, step one is unpatentable and step two would "occur automatically in the mind of any competent physician."[319] This is a serious problem, having little to do with whether the process of diagnosis is a phenomenon of nature or a basic tool of research. Usually potential infringers, no matter how tempted they may be to adopt the advancements discovered by the patentee, can choose to avoid them. Rather than suffer the costs of a patent license or the risk of litigation, they can elect to practice techniques in the public domain – perhaps those revealed in expired patents, or those of inventors who forfeited the right to obtain a patent. But physicians who choose to avoid claim 13 may have no such choice, beyond abandoning blood tests altogether – a harsh alternative indeed.

None of the cases on patentable subject matter, even those dealing with "mental steps," pose this issue of the unwilling infringer paralyzed by the burden of knowledge. But the situation is comparable to one that arises in trade secret law, known as "inevitable disclosure."

A. Inevitable Disclosure.

Trade secret law is a branch of intellectual property governed, in civil cases, by state and common law.[320] It protects information that is valuable to a business because it is not generally known.[321] One can "misappropriate" a trade secret by using or disclosing confidential information contrary to a legal duty.[322] Employees generally have a duty toward their employers, even after they leave employment, to refrain from using trade

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[317] *See* N. Scott Pierce, "A New Day Yesterday: Benefit as the Foundation and Limit of Exclusive Rights in Patent Law," 6 J. Marshall Rev. Intell. Prop. L. 373, 450-51 (2007) (diagnosis based on elevated levels of homocysteine is not a natural phenomenon but a novel technique with a specific benefit).

[318] Collins agrees that an isolated fact or "statistical syllogism" may not qualify as "an exceptionally basic tool or a particularly fundamental input into ongoing progress;" he regards thought in general, however, as a "possible ur-tool." *Collins*, *supra* note ___, at ___.

[319] *Lab. Corp.*, 126 S. Ct. at 2924; *see also Collins*, *supra note* ___, at ___ (arguing that claims to statistical syllogisms are "unconstitutionally overbroad" because they may be infringed without intention by persons practicing the prior art).

[320] Most states have adopted a version of the Uniform Trade Secrets Act (hereinafter UTSA).

[321] *See* UTSA § 1(4). The subject matter of trade secret law overlaps with the subject matter of patent law; a product formula, for example, might be protected as a trade secret or as a patented invention. It cannot be both, however, because one of the obligations of a patentee is to disclose the invention in detail through the patent specification, after which the information loses its status as a secret.

[322] *See* UTSA § 1(2).

secret information. The deliberate use of the trade secrets of a first employer for the benefit of a second is, therefore, a clear instance of misappropriation. The most difficult cases arise when the very nature of the employment makes avoiding use of the first employer's trade secrets impossible. *PepsiCo v. Redmond*[323] supplies the best-known example of the "inevitable disclosure" phenomenon. Redmond, a high-level executive of PepsiCo, resigned to take employment at Quaker Oats Co., which at the time was a PepsiCo rival in the markets for sports drinks and "new age" beverages. While employed by PepsiCo, Redmond had been exposed to detailed marketing plans and competitive strategy. The court enjoined Redmond not only from disclosing PepsiCo's trade secrets but also from immediately assuming his new position. Even though Redmond had signed a confidentiality agreement with PepsiCo and no breach of that agreement had yet taken place, PepsiCo "[found] itself in the position of a coach, one of whose players has left, playbook in hand, to join the opposing team before the big game."[324] Even with good intentions, it would have been impossible for Redmond to ignore the things he knew about PepsiCo's strategy while performing similar duties for Quaker.

PepsiCo is a controversial decision. A leading treatise on trade secret law denounces the "mischief"[325] said to have been created by that "profoundly flawed"[326] decision. Some courts have expressly rejected *PepsiCo's* concept of inevitable disclosure.[327] The source of the controversy lies in the conflicting interests of trade secret protection and employee mobility. Employers have a legitimate interest in protecting their trade secrets – an interest that society must recognize if businesses are to invest in developing proprietary information.[328] Employees, on the other hand, should not be "shackled"[329] to an employer because they have been exposed to trade secrets, nor should they be prevented from assuming elsewhere the positions for which they are best suited and trained. Inevitable disclosure theories limit individual freedom, weaken employee bargaining power, and harm society through diminished competition.[330] In some states, concerns over employee mobility have led to severe restrictions on contractual covenants that limit post-employment opportunities.[331] At least those covenants are the subject of bargaining at the outset; some regard an inevitable disclosure restraint as equivalent to a restrictive covenant imposed after the employment has ended, without consent, and

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[323] 54 F.3d 1262 (7th Cir. 1995).

[324] Id. at 1270.

[325] Roger M. Milgrim, Milgrim on Trade Secrets § 5.02[3][d] at 5-46 n. 38 (2007) ("The mischief engendered by *PepsiCo* is hard to exaggerate.").

[326] Id. at 5-63.

[327] *See, e.g.,* Whyte v. Schlage Lock Co., 101 Cal. App. 4th 1443, 1447 (4th Dist. 2002).

[328] *See* Wexler v. Greenberg, 160 A.2d 430, 434-35 (S. Ct. Penn. 1960) ("Society as a whole greatly benefits from technological improvements. Without some means of post-employment protection to assure that valuable developments or improvements are exclusively those of the employer, the businessman could not afford to subsidize research or improve current methods.").

[329] Id. at 435.

[330] Id.

[331] *See* Earthweb, Inc. v. Schlack, 71 F. Supp.2d 299, 313 (SDNY 1999) ("'Once the term of an employment agreement has expired, the general public policy favoring robust and uninhibited competition should not give way merely because a particular employer wishes to insulate himself from competition.' . . . 'Important, too, are the "powerful considerations of public policy which militate against sanctioning the loss of a man's livelihood."'" (citations omitted)).

without compensation to the employee.[332] Accordingly, even courts that do not reject the principle of inevitable disclosure outright may apply it "only in the rarest of cases."[333]

At a broad level, the concerns that animate resistance to inevitable disclosure in trade secret law are relevant to a patent that a knowledgeable person, carrying out otherwise legitimate activity, cannot help but infringe. Physicians aware of the relationship between homocysteine and vitamin deficiencies would face the same difficulty as Redmond. No matter how they tried to compartmentalize their thoughts, inevitably they would remember what an elevated homocysteine level implied when they observed it on a lab report. In fact, their dilemma would be worse than Redmond's. He could try to act as he would have acted without knowledge of PepsiCo's strategic plans. The physicians would not have even that opportunity; once they had observed the correlation, the infringement would be complete.

Employee mobility and bargaining power would not be threatened, but freedom and competition would be. The only choice of a physician who wished to avoid patent liability might be to forego the relevant blood tests. If these tests had important uses other than diagnosing vitamin deficiencies through homocysteine measurements, the choice to abandon the tests might make the practice of medicine impossible, or at least limit what the a physician could offer the public in competition with patent licensees.

When trade secret rights are based on duties arising in the course of a relationship, the parties to the relationship have an opportunity to negotiate an arrangement of mutual benefit. Today, in jurisdictions that recognize the inevitable disclosure principle, sophisticated employees might realize, at the outset of employment, that a confidentiality agreement could later restrict their mobility. Understanding that, they could seek to negotiate terms, including appropriate compensation. Patent rights are not based on relationships and are not the fruits of bargaining with potential infringers. A physician who learned of the homocysteine/vitamin correlation might have no prior opportunity to negotiate, and any negotiating that occurred after the fact might be in the form of "an offer one cannot refuse." In short, the policy arguments against "inevitable infringement" seem at least as compelling as those against inevitable disclosure.

B. Inevitable Infringement.

The problem of the unwilling patent infringer can arise in other contexts. In *Smithkline Beecham Corp. v. Apotex Corp,*[334] the patent concerned the substance paroxetine hydrochloride (PHC) used as an antidepressant. Originally produced in anhydrous crystals (without bound water molecules), the patentee discovered a hemihydrous form (with one bound water molecule for every two PCH molecules). In

[332] *See Whyte*, 101 Cal. App. 4th at 1463 ("As a result of the inevitable disclosure doctrine, the employer obtains the benefit of a contractual provision it did not pay for, while the employee is bound by a court-imposed contract provision with no opportunity to negotiate terms or consideration.").

[333] *Earthweb*, 71 F. Supp. 2d at 310 ("[T]he inevitable disclosure doctrine treads an exceedingly narrow path through judicially disfavored territory. Absent evidence of actual misappropriation by an employee, the doctrine should be applied in only the rarest of cases.").

[334] 403 F.3d 1331.

the new form it was more stable, making it easier to package and preserve.[335] Patent owner SmithKline argued that the defendant, even though still using techniques previously used to produce anhydrous crystals, now inevitably produced at least trace amounts of infringing hemihydrous PCH. Why? Because the newly-introduced form of PCH "seeded" the environment, introducing trace amounts of the more stable crystals into every production facility. Fabrication of pure anhydrous PCH had become virtually impossible, even using prior techniques, because no production facility could escape contamination.[336] The district court ruled for the defendant, fashioning an equitable defense based on the role played by the patentee in causing the infringement.[337] On appeal, the Federal Circuit declined to endorse the equitable defense, finding instead that the original production techniques, disclosed in an earlier patent, inherently produced hemihydrous PCH, thereby anticipating claims to the compound.[338]

In a concurring opinion, Judge Gajarsa focused on the dilemma of the unwitting infringer. In his view, the "unusual tendency [of hemihydrous PCH] to 'appear' even where it is unwanted," contradicted the public notice function of the patent.[339] A patent should clearly define the scope of the grant so that it can be *avoided*, and this SmithKline's patent failed to do.[340] Even with every effort to manufacture only unpatented anhydrous PCH, Apotex could not avoid infringing.[341] Judge Gajarsa found the solution to the problem in § 101. Hemihydrous PCH, as a synthetic material, was a patentable composition of matter when first created; however, it "reproduces" itself by natural chemical processes once released into an environment where production of anhydrous PCH takes place.[342] He compared the situation to the release of a patented organism let loose in the wild and spreading uncontrollably.[343]

Section 101, Judge Gajarsa maintained, invalidates any "patent claim[] drawn broadly enough to encompass products that spread, appear, and 'reproduce' through natural processes."[344] Had his analysis had been adopted by the majority, it would have been interesting to consider whether it applied not only to spontaneously-reproducing crystals or organisms but to *ideas.*

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[335] Id. at 1334.

[336] *See* id. at 1335-36. Even if Apotex moved production to Antarctica, a single employee who brought a Paxil tablet to work might forever destroy the ability of the plant to make pure anhydrous PCH. *See* id. at 1358.

[337] Id. at 1342.

[338] Id. at 1344.

[339] Id. at 1358.

[340] Even though the *meaning* of the claim was perfectly clear. It included only four words, each having a definite significance to chemists: "1. Crystalline paroxetine hydrochloride hemihydrate."

[341] "A [PCH] anhydrate manufacturer, such as Apotex, could exert reasonable efforts to manufacture only products already in the public domain, could direct its entire production process toward developing only products that scrupulously respected all patent rights, and could nevertheless infringe because a natural physical process acting upon its legitimate anhydrous product 'made' new hemihydrous crystals that Apotex then 'sold' to the public." Id. at 1359.

[342] Id. at 1360.

[343] Id. at 1361. For an extended analysis of the problem of pollen drift in creating unwitting infringers, *see* Paul J. Heald & James Charles Smith, "The Problem of Social Cost in a Genetically Modified Age," 58 Hastings L.J. 87 (2006).

[344] Id. at 1361.

Publishing the discovery that elevated homocysteine levels indicate a vitamin deficiency, even through the teachings of the patent itself, might be considered "seeding the environment" – after which knowledgeable persons, even those intending to practice the prior art, could not help but infringe. Thomas Jefferson once remarked on the tendency of ideas to spread uncontrollably, like a life-form released into the wild: "'the moment [an idea] is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it.'"[345] Certainly the negative consequences that Judge Gajarsa feared could occur, including "a widespread in terrorem effect crippling entire industries whose artisans learn that even their best efforts to respect patent rights may not save them from liability as inadvertent, inevitable infringers."[346] The notice function of the patent might be, in Judge Gajarsa's sense, "meaningless."[347] On the other hand, while Judge Gajarsa identified notice as the critical issue, he relied on the "natural" character of the crystal reproduction to find the patent invalid under § 101. Is the spread of an idea a "natural process?" It might be in the sense that it occurs spontaneously, but it is not "natural" in the sense that distinguishes non-human from human activity. Hence, Judge Gajarsa's conclusion that "patent law does not sanction the concept of inevitable infringement"[348] might require other support in the case of the infringing physician.

C. The Social Costs of Thought Infringement.

As Justice Breyer observed, patents impose costs on licensees, potential infringers and society. They can discourage technological developments, distract researchers with complex legal issues, and, by offering monopolistic returns, divert resources into rent seeking.[349] As long as the benefits outweigh these costs, patents, generally speaking, fulfill the Constitutional mandate to promote the progress of the useful arts. The benefits to be expected from patents involving thought processes or observations of nature are the same as for any other type of patent. The grant of exclusive rights encourages research, and the disclosures mandated by patent law contribute to the art when the patent has expired. The costs, however, might be significantly greater.

One of the perennial concerns of patent law is to confine a patentee's market power within its proper limits.[350] A patent only creates market power if products or processes covered by the patent have such advantages in comparison to potential substitutes that they can command a premium price.[351] Inventions that have such advantages generate a greater than competitive return, which rewards the patentee for advancing the art. However, patentees violate the law by extending their market power beyond the intended scope of the patent grant.[352] One example is an unlawful tying

[345] Graham v. John Deere Co., 383 U.S. 1, 9 n.2 (1966) (quoting VI Writings of Thomas Jefferson, at 180-81 (Washington ed.)).

[346] 403 F.3d at 1364.

[347] Id.

[348] Id.

[349] *See Lab. Corp.*, 126 S. Ct. at 2922-23.

[350] *See* 6 Donald S. Chisum, Chisum on Patents § 19.04.

[351] *See* Illinois Tool Works, Inc. v. Independent Ink, Inc., 547 U.S. 28, 44 (2006).

[352] *See* Atari Games Corp. v. Nintendo of America, Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990) ("a patent owner may not take the property right granted by a patent and use it to extend his power in the marketplace improperly, i.e., beyond the limits of what Congress intended to give in the patent laws").

arrangement, which conditions the availability of a product where the seller has market power (e.g., a uniquely desirable and patented television set) on the additional purchase of a separate product where the seller has no market power (e.g., an unpatented microwave oven). The principle fear is that power in the market for the tying product, perhaps lawfully obtained, will translate into market power in a different market.[353] Power in the market for television sets, for example, might be used to suppress competition, eliminate competitors, and raise prices in the market for microwave ovens, contrary to the intentions of Congress in allowing the television set to be patented.

In some cases, a patent infringed by observing a natural correlation would have similar effects. Assume for the moment that the tests discussed in *Lab. Corp.* could be used for other purposes than diagnosing a vitamin deficiency. According to Justice Breyer, "growing recognition that elevated homocysteine levels might predict risk of heart disease led to increased testing demand."[354] To the extent that homocysteine tests to predict heart disease are unrelated to the vitamin deficiency, they are a service that physicians should be permitted to offer their patients. Yet the well-informed physician could not help observing the vitamin deficiency "correlation" when observing elevated homocysteine levels on a lab report. Simply performing the tests would lead to infringement liability, without further voluntary action. Consequently, the patentee could, at least theoretically, eliminate competition in the market for blood tests unrelated to the patented invention.

The high costs of avoidance could be manifested in other ways. Physicians who did not wish to give up homocysteine tests altogether might investigate "clean room" techniques. Clean rooms have been used in other contexts where demonstrating ignorance is advantageous.[355] For example, a company using a computer program based on unlawfully-obtained trade secret information might organize a clean room, staffed by programmers isolated from the misappropriated original, to create a functionally-identical but legally blameless substitute.[356] Similarly, a physician who prescribed homocysteine tests for heart disease might turn over care of the patient to other professionals who had never learned of the homocysteine/vitamin correlation. Just describing such a process, however, suggests its absurdity. For one thing, because the correlation is publicly-available information, it would be difficult to find a test administrator guaranteed to possess the necessary level of ignorance. If such a person were found, the qualifications of that person to provide medical care would be in serious doubt. If the test administrator simply returned the patient to the original physician with a recommendation to treat the patient for heart disease, the physician, inferring that the tests indicated elevated levels of homocysteine, could not avoid "correlating" that result with a possible vitamin deficiency.

Even if it were possible to avoid the patent by cultivating ignorance, the result would be starkly contrary to one of the overriding policy goals of patent law – to

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[353] *See Illinois Tool Works,* 547 U.S. at 34-35.
[354] Lab. Corp., 126 S. Ct. at 2923.
[355] *See* Sega Enterprises Ltd. v. Accolade, Inc., 977 F.2d 1510, 1526 (9th Cir. 1992).
[356] *See* Computer Associates Int'l, Inc. v. Altai , Inc., 982 F.2d 693, 700 (2d Cir. 1992).

encourage the spread of knowledge.[357] Some of the conditions attached to the issuance of a patent require the disclosure of information. The patentee must set forth a detailed disclosure sufficient to allow any person skilled in the art to make and use the invention without undue experimentation.[358] In addition, the specification must disclose the best mode of practicing the invention known to the patentee when the application was filed.[359] Such disclosures may be described as a part of the "bargain" that the patentee makes with society – the disclosure of useful information in exchange for a period of exclusive rights.[360] It would be strange indeed if patent law encouraged ignorance of the very disclosures that patent law demands.

Importantly, these problems would occur only if homocysteine tests had substantial noninfringing uses. If checking for a vitamin deficiency were the *only* purpose for conducting the test, infringement would no longer be involuntary and no independent market would be threatened. It might still seem odd that physicians could be barred from conducting an unpatented test, but this is not a phenomenon unknown in patent law. Through the principle of contributory infringement, a patent owner can prohibit others from selling an unpatented component of a claimed combination, if the component has no substantial noninfringing uses.[361] Even something previously known can come under the control of a patentee – for example, a known substance having no use except in connection with the patentee's discovery.

The latter is what occurred in *Dawson Chemical Co. v. Rohm & Haas Co.*[362] The patentee discovered that the unpatented compound propanil could be used as a selective herbicide in rice paddies. Propanil had no other known use. Farmers who purchased propanil from the patentee received an implied license to use it on their crops. Because rice farmers who purchased propanil elsewhere had no such license, other sellers of propanil became contributory infringers. Even though enforcing the patent meant barring sales of unpatented propanil, the Supreme Court held that the patentee's refusal to license was not an unlawful extension of the patent monopoly. The Patent Act, wrote the court, "effectively confer[s] upon the patentee, as a lawful adjunct of his patent rights, a limited power to exclude others from competition in nonstaple goods. A patentee may sell a nonstaple article himself while enjoining others from marketing that same good without his authorization. By doing so, he is able to eliminate competitors and thereby to control

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[357] *See Brenner*, 383 U.S. at 533("one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions").

[358] 35 U.S.C. § 112 ¶ 1; Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371 (Fed. Cir. 1999) (experimentation must not be "undue"); National Recovery Technologies, Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195-96 (Fed. Cir. 1999) ("The enablement requirement ensures that public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.").

[359] 35 U.S.C. § 112 ¶ 1.

[360] *See* Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 63 (1998) ("the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time"); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1209-10 (Fed. Cir. 1991) (disclosure is a *quid pro quo* for the right to exclude others).

[361] 35 U.S.C. § 271(c).

[362] 448 U.S. 176 (1980).

the market for that product."[363] That control was no more than the patentee's due because the market was entirely dependent on the patentee's discovery. Without it, no one would buy propanil at all. Whether the patentee chose to license farmers who used propanil or set itself up as the only seller of propanil was a matter of indifference. Similarly, no meaningful extension of the patent grant would occur if the *Lab. Corp.* patentee controlled homocysteine tests having no use other than to detect a vitamin deficiency.

D. Setting Limits.

The dangerous patents based on natural relationships or "correlations" are those one can only avoid (1) by ignorance, or (2) by foregoing activity that should *not* be controlled by the patentee. The challenge lies in identifying those patents, and in finding legal tools to deal with them.

The obvious place to begin is with patentable subject matter under § 101, but methods of observing and correlating are always "processes," in a literal sense. They are not principles of nature in the abstract; they are, potentially, ways to apply nature for specific, useful purposes. And they are not, necessarily, "basic tools of research" in a way that distinguishes them from other patentable inventions. One could require that a statutory process transform a physical substance, but this would be undesirable as a matter of policy if it prevented, for example, patents on useful (and technological) software inventions. A more limited solution may lie in the revival of the until-recently moribund "mental steps doctrine."[364] The weakness with that solution, as with a more physical concept of "process," is that one might avoid the issue by adding physical steps.

Observing nature often requires physical process steps, like "assaying" the blood of a patient to measure homocysteine. Once such steps are added to the claim, the process *as a whole* becomes a physical process. One cannot ignore the physical steps because they are not new; to do so would be to confuse novelty with patentable subject matter.[365] But adding these steps does not cure the basic problem. A potential infringer might avoid liability by foregoing tests or assays, but possibly at the cost of using the results of such tests for legitimate purposes – an overextension of the patentee's monopoly. Courts might ignore "data gathering steps," as they have sometimes done when judging the subject matter status of mathematical algorithms.[366] However, even if this were consistent with the holistic approach adopted after *Diehr,*[367] it would affect *all* "correlation" patents, including those that do not threaten undesirable spill-over effects. What distinguishes a "good" patent from a "bad" patent is not whether the physical process steps are merely data-gathering, but whether the data gathering has any purpose other than the one discovered by the patentee.

One also has to consider the effect of physical process steps *subsequent* to the correlation – like administering vitamin supplements to a patient. *Diehr* dismissed

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[363] Id. at 201.
[364] *See supra* ____.
[365] *See supra* ___.
[366] *See, e.g., Grams*, 888 F.2d at 839.
[367] *See supra* ____.

"token post solution activity" in the context of mathematical calculations.[368] Treating a patient hardly seems a "token" activity, particularly if improved by observation and correlation. Indeed, one could speak in a general sense of an improved process of treating a patient, just as *Diehr* spoke of an improved process of curing rubber. If the physical process steps occurred after the mental steps, one could avoid infringement by ignoring what one had learned – by taking no action to correct the vitamin deficiency. Aside from the ethical problem of deliberately withholding medical care, attempts to ignore what one knows may prove futile. A doctor might, like Redmond, find it impossible to continue at all.[369] Neither § 101 nor the complex heritage of the mental steps doctrine provide tools to address this distinction.

Creative minds might look beyond § 101 for solutions. One could argue that infringement cannot occur without volition.[370] It *can* occur without *intent*,[371] including infringement by persons who are unaware of the patent, but even the unintentional infringer generally undertakes some action voluntarily – such as choosing to make and sell an apparatus that might prove, however unexpectedly, to infringe the rights of a patentee. A patent that could be infringed simply by thinking permits not even that degree of volition. On the other hand, choosing to conduct homocysteine tests having both infringing and noninfringing uses would be a deliberate act. The physician conducting the test and aware of the patent would know that, inevitably, observing an elevated level of homocysteine would lead to the infringing "correlation." The infringement would not be free of all volition, but the physician should nevertheless be protected for the sake of preserving the alternative use of the test.

Another possibility is an equitable defense based on the patentee's role in causing the infringement. The District Court in *SmithKline* crafted such a defense based on the patentee's responsibility for "seeding the environment," causing unavoidable infringement by those seeking only to practice the prior art.[372] Similarly, a patentee who "seeded the environment" with knowledge might be denied an opportunity to enforce the patent.[373] The difficulty with equitable defenses is that they are usually, by nature, flexible remedies dependent on the circumstances of each case. An equitable defense could not be used, like an invalidity defense, to strike down patents that should not be enforced against anyone. Also, an equitable defense would provide uncertain protection to potential infringers unless the circumstances for invoking the defense could be clearly defined. If they could be so defined, and if they related to the nature of the patent rather than the circumstances of each infringement, then an invalidity defense is a more attractive solution. Unfortunately, no existing invalidity defense exactly fits the bill.

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[368] 450 U.S. at 192 n.14.

[369] *See supra* ____

[370] *See Heald & Smith*, *supra* note ___, at 141-42.

[371] *See* Florida Prepaid Postsecondary Education Expense Bd. V. College Savings Bank, 527 U.S. 627, 645 (1999) ("Actions predicated on direct patent infringement . . . do not require any showing of intent to infringe."); *Heald & Smith*, *supra* note ___, at 89 ("Patent law . . . is based on the concept of strict liability.").

[372] *See SmithKline*, 403 F.3d at 1336.

[373] *See Heald & Smith*, *Supra* note ___, at 142-146 (considering in the case of pollen drift both *volenti non fit injuria* and unclean hands defenses).

The best answer may lie in the adoption of the following principle: no patent claim may be enforced if infringement can be avoided only by foregoing or modifying activity not reserved exclusively to the patent owner. Activity reserved exclusively to the patent owner includes both that which is claimed, and that which has no substantial noninfringing use. This principle might apply in some situations having nothing to do with mental processes – as in the case of genetically-modified corn invading other cornfields.[374] If the patented strain intruded on the land on an innocent farmer left with no option but to abandon the field, the patent could not be enforced. In the context of a method claim applying observations of nature to modify a physical process (e.g., applying test results to modify a course of treatment), the territory reserved to the patent owner would include the process in its entirety, and portions of the process having no substantial noninfringing use. If tests had no object except to perform the patented process, such tests would be forbidden, just as the sale of a part useful only in a patented combination is forbidden. But if the tests had other uses they could not be enjoined, even if the person who performed them would inevitably apply the results in the manner claimed – not by choice, but by force of logic.

Although this proposition does not fit neatly into any existing category of patent invalidity, it is consistent with the policy of confining a patentee's market power to the intended channels.[375] The discoverers of important technological advancements would be suitably rewarded, ensuring that such discoveries continue. At the same time, patentees would not have power over activities unrelated to their advancements. Of course controversy might arise over the existence of a noninfringing use for any process of analysis. Scientific inquiry alone might be offered as a substantial use, or one might worry that limiting tests in the absence of a noninfringing use would forestall the discovery of such uses. These are legitimate concerns, but the same concerns do not prevent patentees from controlling unpatented physical substances, such as propanil, that have no known noninfringing uses.

Another issue would be whether a potential infringer can avoid completing the patented method. If the method includes not just the step of drawing a conclusion but *physical* process steps governed by observation, avoiding those physical steps will often be possible, even if one is reluctant to do one thing when one knows there is a superior alternative. Patents often, however, present potential infringers with this very dilemma. An engineer who has read a new patent disclosing a superior apparatus may be sorely tempted to build one, but knows that the only choice is to adopt an unpatented alternative or secure a license. What sets apart processes with a mental component is the problem of compartmentalization, familiar from the trade secret cases. If one is already treating a patient, and has obtained test results for legitimate reasons, how can one avoid the

[374] *See Smithkline*, 403 F.3d at 1361. For an extended analysis of the problem of pollen drift in creating unwitting infringers, *see* Paul J. Heald & James Charles Smith, "The Problem of Social Cost in a Genetically Modified Age," 58 Hastings L.J. 87 (2006).

[375] An extension of a patent beyond its intended scope may be the basis of a defense of patent misuse. Some have suggested that suing farmers who, because of pollen drift, cannot avoid growing some patented crops would constitute patent misuse. *See Heald & Smith*, *supra* note ___, at 147. It would, however, seem odd to base a defense of patent "misuse" solely on making the disclosures required by the patent statutes and suing those who infringe. In the case of pollen drift, some potential infringers might be innocent and others opportunists. In the case of "knowledge drift," it would be hard to differentiate.

influence of a patented insight? With the proper context provided through expert testimony, courts should have little difficulty in identifying the hopeless case and striking down the patent that creates it.

Some predicted that Justice Breyer's *Lab. Corp.* opinion heralded a dramatic reassessment of the bounds of patentable subject matter.[376] *Comiskey* has vindicated such predictions already. If continued reassessment comes from the courts, or from a Congress now deeply engaged in the possibility of patent reform, recognition of the principle set forth above could establish, more effectively than vague prohibitions against patenting "tools of research" or "principles of nature," a system that rewards discovery, encourages the spread of knowledge, *and* confines the market power of patents within appropriate limits.

CONCLUSION

Although the language of § 101 suggests a simple inquiry, the analytical complexity of patentable subject matter seems inexhaustible. For more than a century, courts have struggled to distinguish between patentable inventions and unpatentable principles, producing an intricate and perplexing set of rules, some still embraced and others apparently abandoned. Yet even today fundamental questions cannot be answered with certainty. The *Lab Corp.* opinion poses one such question – whether one can patent a useful method that consists in observing and drawing conclusions, based on a newly-discovered natural relationship. Justice Breyer addressed the question principally through the principle/application dichotomy, which has long stood as a bastion against denying others the "basic tools of research." In fact, the danger of the *Lab. Corp.* patent has little to do with research, and the principle/application distinction suggests that the invention should be patentable. The greater threat posed by the *Lab. Corp.* patent and others of its kind hinges on the role that knowledge plays in infringement. Even well-intentioned competitors of the patent owner may find infringement unavoidable, except by cultivating ignorance or abandoning legitimate activity. This could supply the patent owner with unintended and undesirable market power. Unfortunately there are no simple tools at hand to deal with this issue, demonstrating that even after many decades of wrestling with patentable subject matter there is still urgent work to be done.

[376] *See* Cynthia M. Ho, "Lessons from *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*," 23 Santa Clara Computer & High Tech. L.J. 463, 464 (2007) ("rumblings" ahead of what might be a "seismic shift").