

PATENT INELIGIBILITY: MAINTAINING A SCIENTIFIC PUBLIC DOMAIN

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I. THE THRESHOLD INQUIRY IN PATENT LAW

Patent eligibility is a doctrine which often surfaces when new technologies or scientific imperatives create the possibility of patenting novel forms of subject matter. Its relative dormancy should not be mistaken for obsolescence. The patentable subject matter inquiry defines the eligibility of a proposed invention for patent protection.¹ Patentable subject matter is statutorily defined as “any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof.”² A gatekeeping role for the patentable subject matter inquiry is legitimately inferred from its place in the numbering of statutory requirements for a patent as 35 U.S.C. § 101; however, the grant of a patent follows an examination of an invention and its patent application for compliance with all formal statutory requirements.³ The recognition of a hierarchy of statutory requirements in patent law has been stated explicitly: “The first door which must be opened on the difficult path to patentability is § 101,”⁴ and has been rephrased as “[w]hat *kind* of an invention or discovery is it?”⁵ In *Parker v. Flook*, the Supreme

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¹ See, e.g., 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.01 (2005) (treatise section devoted to 35 U.S.C. § 101).

² 35 U.S.C. § 101 (2000).

³ The relevant specific provisions of the patent statute are: 35 U.S.C. § 101 (2000) (patentable subject matter and utility), 35 U.S.C. § 102 (novelty), 35 U.S.C. § 103 (nonobviousness), and 35 U.S.C. § 112 (written description, enablement, best mode and definiteness).

⁴ *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979), *vacated sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980), *aff'd*, 447 U.S. 303 (1980).

⁵ *Id.* (emphasis in original).

Court stated: "The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious."⁶ Patentable subject matter within the bounds of 35 U.S.C. § 101 must be new, nonobvious, and useful, and each of these inquiries are legally distinct. In that sense, the term "patentable" subject matter is a term both narrowly and broadly used, but in its narrow formal interpretation, it represents an invention that meets the criteria of 35 U.S.C. § 101, as opposed to meeting all the other statutory requirements in order to be "patentable."⁷

The present vitality of the patentable subject matter inquiry bears some examination, in view of its relative invisibility within the schema of patent procurement and litigation.⁸ Its relative obscurity has several sources. Most clearly, many regard the signature battles over patentable subject matter to have ended. The emerging software and biotechnology industries of the 1970s and 1980s generated an intense period of legal scrutiny over the bounds of patentable subject matter for these technical fields, culminating in landmark decisions from the Supreme Court. *Diamond v. Chakrabarty*,⁹ issued in 1980, resolved the issue as to whether genetically engineered microorganisms were proper patentable subject matter. The court answered in the affirmative, approvingly quoting from the legislative history of the 1952 Patent Act to find a Congressional intent that patentable subject matter "include[s] anything under the sun that is made by man."¹⁰

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise,

⁶ *Parker v. Flook*, 437 U.S. 584, 593 (1978).

⁷ The term "statutory subject matter" is also used to define an invention that meets the criteria of 35 U.S.C. § 101.

⁸ See, e.g., John A. Allison & Mark R. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 208 (1998) (presenting data on the grounds for invalidity most frequently cited in their study of patent litigation). For further discussion, see *infra* Part II.

⁹ 447 U.S. 303 (1980).

¹⁰ *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.”¹¹

The Court next addressed software or computer-related inventions in *Diamond v. Diehr*,¹² which examined whether a computer program using the Arrhenius equation to determine the curing time for rubber was properly rejected for lack of patentable subject matter because it might preempt a mathematical formula. The Court decided that it did not, stating “we do not view respondents’ claims as an attempt to patent a mathematical formula, but rather to be drawn to an industrial process for the molding of rubber products.”¹³ Diehr’s invention employed an equation, but did not preempt the equation. It remained available for other technological uses. This decision was the last word from the Supreme Court on computer-related inventions as patentable subject matter, and it signaled an increasing accommodation of the patent system to the technological realities of the computer age.¹⁴

Both *Chakrabarty* and *Diehr* stood as portals to the inclusion of new technologies in biotechnology and software as patentable subject matter. However, as momentous as each decision was at the time, the decisions did not end the debates over patentable subject matter in these fields. For biotechnology, the debate continued as *Chakrabarty* was read to be limited to microorganisms, not addressing the patenting of higher life forms and not addressing the patentability of DNA.¹⁵ For software,

¹¹ *Id.* (citations omitted).

¹² 450 U.S. 175 (1981).

¹³ *Id.* at 192–93.

¹⁴ The decision also occurred a year after the finding of patentable subject matter in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

¹⁵ For further discussion of the patentable subject matter debates in biotechnology, see generally Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL’Y 65 (2002) (investigating the issues surrounding gene patents including scientific development, patient care, and international trade); Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2003) (exploring the ramifications of patent law’s moral utility doctrine on controversial biotechnology patents); Karl Bozicevic, *Distinguishing “Products of Nature” from Products Derived from Nature*, 69 J. PAT. & TRADEMARK OFF. SOC’Y 415 (1987) (noting that biochemical subject matter is no less entitled to patent protection than those inventions composed of mechanical or electrical engineering as both are derived from natural occurrences); John M. Cowley & Roberte Makowski, *Back to the*

patent applicants continued to spar with the U.S. Patent and Trademark Office (PTO) as *Diehr* was read to allow the patenting of an application of an equation to a specific technological end, but not to allow the patenting of algorithms in general.¹⁶ After

Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents, 85 J. PAT. & TRADEMARK OFF. SOC'Y 301 (2003) (Part I) [hereinafter Cowley & Makowski, *Back to the Future: Part I*] (arguing that while much biotechnology subject matter has been held to be patentable there exists distinct categories of patents that have been wrongly granted); John M. Cowley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 371 (2003) (Part II) [hereinafter Cowley & Makowski, *Back to the Future: Part II*] (same); Michael D. Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH. L.J. 293 (1995) (proposing a narrow scope of protection on patent claims for products of nature); Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303 (2002) (analyzing the grant of property rights over chemical and biological components of living organisms and its effect on scientific research and development); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987) (explaining how the disclosure mandates of patent law reinforce scientific norms by promoting the publication of scientific discoveries); Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707 (2004) (analyzing the patentability of genes with respect to judicially established exclusions from patentable subject matter); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827 (1999) (arguing that the CAFC's failure to understand new technologies in the realm of biotechnology has led to the misapplication of patent law doctrine to this field).

¹⁶ For further discussion of the patentable subject matter debates in computer-related inventions, see generally Vincent Chiapetta, *Patentability of Computer Software Invention as an "Article of Manufacture: Software as Such as the Right Stuff*, 17 J. MARSHALL J. COMPUTER & INFO. L. 89 (1998) (suggesting that software used as an instructional program for a computer constitutes patentable subject matter while software used in the linguistic sense does not); Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959 (1986) (contending that algorithms should be patentable matter if meeting the requirements of novelty and unobviousness as such protection would provide an incentive for innovations in software development); Julie E. Cohen, *Reverse Engineering and the Rise of Electronic Vigilantism: Intellectual Property Implications of "Lock-Out" Programs*, 68 S. CAL. L. REV. 1091 (1995) (analyzing the protection of computer programs under both patent and copyright law and proposing necessary adjustments); Richard S. Gruner, *Intangible Inventions: Patentable Subject Matter for an Information Age*, 35 LOY. L.A. L. REV. 355 (2002) (proposing new criteria on which to distinguish inventions having intangible content from unpatentable intellectual and scientific discoveries); Lee A. Hollaar, *Justice Douglas Was Right: The Need for Congressional Action on Software Patents*, 24 AIPLA Q.J. 283 (1996) (resuscitating the call to Congress to clarify the patentability of software-based inventions and suggesting amendments to the patent statute); Dennis S. Karjala, *Distinguishing Patent and Copyright Subject Matter*, 35 CONN. L. REV. 439 (2003) (advocating the inclusion of useful, non-physical processes as patentable subject matter as a means of maintaining a critical distinction from copyright subject matter); Robert A. Kreiss,

two more decades of conflict, the Federal Circuit decided that an algorithm is patentable subject matter in *AT & T Corp. v. Excel Communications, Inc.*¹⁷ In tandem with a steadily more permissive attitude toward patentable subject matter in biotechnology and computer-related inventions, judicially-created doctrines of subject matter exclusion that were previously thought to bar the issuance of patents have steadily been eliminated, such as the prohibitions against the patenting of business methods.¹⁸

The continuing vitality of the patentable subject matter doctrine has been addressed in legal scholarship. There is commentary to the effect that the issue of patentable subject matter may now be the least vital doctrine in the set of statutory requirements for patentability, particularly with respect to certain technical fields.¹⁹ However, in contrast, there is also recent commentary that urges employment of the patentable subject matter doctrine in order to set limits in the patenting of biotechnology²⁰ and computer-related inventions.²¹

Patent Protection for Computer Programs and Mathematical Algorithms: The Constitutional Limitations on Patentable Subject Matter, 29 N.M. L. REV. 31 (1999) (identifying constitutionally-based limits on eligibility from patent jurisprudence particularly relevant for determining whether computer programs and mathematical algorithms are patentable subject matter); Allen Newell, *Response: The Models are Broken, The Models are Broken!*, 47 U. PITT. L. REV. 1023 (1986) (responding to Professor Chisum's article in the same volume that the basic conceptual models for understanding the patentability of algorithms are severely inadequate); Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025 (1990) [hereinafter Samuelson, *Benson Revisited*] (elucidating *Benson* to analyze historical limitations in patent law that undermine the legitimacy of protection for software inventions); Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308 (1994) (advocating a sui generis approach to legal protection of computer programs that would guard valuable aspects of computer programs that are vulnerable to imitation).

¹⁷ 172 F.3d 1352 (Fed. Cir. 1999).

¹⁸ See *infra* Part III.

¹⁹ See Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 4 (2001) ("With some eighty thousand software patents already issued, the Federal Circuit endorsing patentability without qualification, and the Supreme Court assiduously avoiding the question, software patentability is a matter for the history books.").

²⁰ Recent scholarship has suggested reliance on the prohibitions against patenting "products of nature" or "laws of nature" in order to limit any harmful effects of DNA patents, or on the patentable subject matter doctrine more generally. See John H. Barton, *Patents, Genomics, Research and Diagnostics*, 77 ACAD. MED. 1339, 1343 (2002) (arguing for the relevance of the patentable subject matter doctrine in restricting the harmful effects of genomic patent); Cowley & Makowski,

There is an aspect of the patentable subject matter debate that is distinctive in the scheme of statutory requirements in patent law and worth attention. The doctrine is the locus for considering the commodification of scientific subject matter in general.²² Is it proper to regard scientific knowledge or research tools as the proper subjects of intellectual property? Should such knowledge be privately controlled? From the perspective of patent law, these questions are best answered at the level of patentable subject matter—deciding what sort of inventions may qualify for a patent. If one regards the patentable subject matter

Back to the Future: Part II, *supra* note 15, at 395 (arguing for revitalization of the product of nature doctrine, suggesting that it has been unevenly applied and should be tested against DNA patents); Demaine & Fellmeth, *supra* note 15, at 390 (arguing for a more rigorous “substantial transformation test” that would require a product of nature to be significantly altered from its natural state to qualify for patenting); Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?* 46 ARIZ. L. REV. 457, 468 (2004) (specifying that statutory exceptions for “fundamental principles of science and for products of nature” could be enacted, although noting the difficult line-drawing involved); Kane, *supra* note 15, at 753 (discussing the law of nature exclusion for the biological sciences, suggesting application of the prohibition against patenting laws of nature to preclude DNA patents which preempt the genetic code); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 299 (2003) (suggesting that the product of nature doctrine be “reinvigorate[d]” so as to test the patent eligibility of DNA and other molecules in biotechnology).

²¹ Recent scholarship questions the suitability of patents for computer-related inventions. See Jay Dratler, Jr., *Does Lord Darcy Yet Live? The Case Against Software and Business-Method Patents*, 43 SANTA CLARA L. REV. 823 (2003) (criticizing patents on computer programs, proposing a standard of “technological risk” to justify patent grants); Russell Moy, *A Case Against Software Patents*, 17 SANTA CLARA COMPUTER & HIGH TECH. L.J. 67, 96–99 (2000) (recommending that statutory subject matter exclude software patents, noting the availability of copyright protection); see also Samuelson, *Benson Revisited*, *supra* note 16, at 1029–36.

²² This observation has particular resonance in the biological sciences. For example, the commodification of biological materials further implicates such developments as organ banks, tissue repositories, gamete banks, and embryo transactions, and generates debate over the propriety of applying an economic calculus to the valuation of natural products. See, e.g., LORI B. ANDREWS & DOROTHY NELKIN, *THE BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE* (2001) (considering developments in medical science that allow the sale and transfer of biological materials); BRONWYN PARRY, *TRADING THE GENOME: INVESTIGATING THE COMMODIFICATION OF BIO-INFORMATION* (2004) (discussing the international controversies over the control of genetic resources); Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1936 (1987) (analyzing varying degrees of commodification that are commensurate with personhood).

doctrine as the patent law version of “standing,”²³ then its gate-keeping function is revealed, and the import of conflicts over the boundaries of patentable subject matter becomes clear.²⁴

The Article next considers how the limits of patentable subject matter are defined and tested, both procedurally and substantively. Part II traces some of the invisibility of the patentable subject matter doctrine to the difficulties with which some litigants and courts have handled the issue of patentable subject matter during patent litigation, noting recent judicial developments that have recognized patent eligibility conflicts. Part III examines the exclusions from patentable subject matter, with a focus on the Supreme Court’s mandate that “laws of nature, natural phenomena, and abstract ideas” are not patentable as a form of ineligibility that protects scientific knowledge from private control. Part IV specifically concentrates on the patent ineligibility of laws of nature as an important limit for the public domain in the biological sciences, considering its interpretation in patent jurisprudence and in scholarship from the philosophy of science. Part V concludes that the patentable subject matter doctrine is alive and well, as evidenced by recent developments in the Federal Circuit and the Supreme Court, and proposes that the patent ineligibilities be codified for the critical project of maintaining the scientific public domain, analogous to the statutory exclusions from copyright. The reductionist imperatives of modern scientific research suggest that conflicts over patentable subject matter will continue to shape the boundary between public and private knowledge.

II. CONFLICTS OVER PATENTABLE SUBJECT MATTER

There are several formal sources of conflict over patentable subject matter which present opportunities for understanding how the doctrine functions as the threshold standard for patentability. Collectively, these conflicts provide the raw material for doctrinal formation and illuminate the sparse language in the enabling statutory provision.²⁵

In the PTO, a patent applicant encounters the statutory requirement for patentable subject matter during patent

²³ See Kane, *supra* note 15, at 725.

²⁴ See Bagley, *supra* note 15, at 543 (discussing how the patentable subject matter doctrine could be used to limit “morally controversial” patents).

²⁵ 35 U.S.C. § 101 (2000).

prosecution. However, conflict is not to be expected in most patenting efforts, a conclusion which is reflected in the current PTO guidelines for patent examiners.²⁶ The document presents the simple statutory language of 35 U.S.C. § 101 and then proceeds with detailed instructions for the specific examination of biotechnology and computer-related inventions.²⁷

If a conflict with the PTO occurs through a rejection by the patent examiner for lack of patentable subject matter, a dissatisfied patent applicant can then appeal to the Board of Patent Appeals and Interferences.²⁸ Following a final rejection from the PTO for lack of patentable subject matter, an applicant can undertake a civil action in the District Court for the District of Columbia²⁹ or can take an appeal to the Court of Appeals for the Federal Circuit.³⁰ However, when the PTO (at the examiner or administrative appeal level) refuses to issue a patent for lack of patentable subject matter, the existence of such a conflict may be indicative of the PTO's wider resistance to the eligibility of subject matter in an entire technical field. The landmark

²⁶ U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (8th ed. 2001), available at <http://www.uspto.gov/web/offices/pac/mpep/index.htm>.

²⁷ *Id.* Chapter 2100, available at <http://www.uspto.gov/web/offices/pac/mpep/documents/2100.htm>. This section contains specific subsections for "Living Subject Matter" and "Computer-Related Inventions" as the only detailed guidelines for the determination of patentable subject matter. *Id.* Professor Kreiss has noted that the PTO Examination Guidelines for Computer-Related Inventions, 61 Fed. Reg. 7478 (Feb. 28, 1996), give short shrift to the issue of patentable subject matter. Kreiss, *supra* note 16, at 54 ("A closer reading, however, suggests that the PTO has deliberately adopted a view minimizing, if not quite eliminating, the subject matter inquiry."). However, recent developments have prompted a renewed focus from the PTO on patentable subject matter. The case of *Ex parte Lundgren*, Appeal No. 2003-2088 (B.P.A.I. 2004) (involving a patent on a method of manager compensation, an invention not necessarily in the technological arts), was followed by the issuance of U.S. PATENT & TRADEMARK OFFICE, INTERIM GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS FOR PATENT SUBJECT MATTER ELIGIBILITY, 1300 OFF. GAZ. PAT. OFFICE 142 (November 22, 2005). For further discussion of *Ex parte Lundgren*, see *infra* note 132.

²⁸ 35 U.S.C. § 134(a). It should be noted that the Board is charged with determining the patentability of any invention that is the subject of an interference. See 35 U.S.C. § 6(b) (2000) (stating "[t]he Board of Patent Appeals and Interferences shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents and shall determine priority and patentability of invention in interferences declared under section 135(a)").

²⁹ *Id.* § 145.

³⁰ *Id.* § 141. Prior to 1982, such appeals were taken to the Court of Customs and Patent Appeals (C.C.P.A.).

Supreme Court cases in biotechnology and software involved conflicts between applicants and the PTO over patentable subject matter in developing technologies.³¹

The federal district courts can encounter the patentable subject matter doctrine in civil actions for patent infringement.³² An accused infringer can allege invalidity of the claims of the patent in suit on the basis of a lack of patentable subject matter.³³ It is instructive to analyze some of these disputes at the trial court level to uncover ease or difficulty in the application of the doctrine. Formal emergence of the patentable subject matter issue in patent litigation means that one of the parties to the dispute is making such an allegation, or that the court has taken notice of the possible relevance of the issue to the litigation. However, there are cases where what can be labeled “informal” assertions are made that have overtones of a patentable subject matter controversy.³⁴

Modern empirical research on patent litigation has attempted to describe and quantify the nature of many patent disputes in order to discover what bases are asserted for invalidity. A study of litigated patent cases revealed that the assertion of a lack of patentable subject matter accounted for only 0.7% of the invalid patents in the study, in contrast to other more frequently asserted bases.³⁵

³¹ Computer-related inventions were presented to the Court in *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972), *Parker v. Flook*, 437 U.S. 584, 587 (1978), and *Diamond v. Diehr*, 450 U.S. 175, 181 (1981). Recombinant DNA technology was presented to the Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 305–06 (1980). Although the PTO continued to reject software-related patent applications after *Diehr*, and applicants prevailed at the C.C.P.A., the PTO did not appeal these later losses to the Supreme Court, a fact that also explains the absence of any Supreme Court cases on patentable subject matter between 1981, see *Diamond v. Diehr*, 450 U.S. 175 (1981), and 2001, see *J.E.M. Ag Supply, Inc., v. Pioneer Hi-Bred Intl., Inc.*, 534 U.S. 124 (2001). See ROBERT S. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY* 151 (3d ed. 2002) (noting shift in executive branch policies regarding PTO appeals to the Supreme Court).

³² 35 U.S.C. § 281.

³³ *Id.* § 282.

³⁴ Such cases cannot necessarily be identified by searching for all cases that mention 35 U.S.C. § 101, for many of these cases do not recognize or mention this statutory provision. Therefore, searches of the federal district court databases for cases discussing “patentable subject matter,” “natural phenomena,” “law of nature,” or “abstract ideas” have been undertaken to identify latent or informal assertions of lack of patentable subject matter.

³⁵ Allison & Lemley, *supra* note 8, at 208 tbl.1. Note that this statistic represents patents judged invalid in their study. The number stands in contrast to

The issue of patentable subject matter has several dimensions that distinguish it from the other possible doctrines that can be considered as bases for patent invalidity, and which might account for its relative invisibility during litigation.³⁶ First, the threshold nature of the patentable subject matter requirement might result in undue reliance on the PTO determination that patentable subject matter existed in granting the patent, a view that might influence the confidence of a litigant (or a court) considering raising the issue.³⁷ However, in addition to that source of hesitation, there appear to be some difficulties for litigants in identifying a lack of patentable subject matter as a distinct statutory basis for invalidity, even when a colorable assertion could be made. Several leading practitioner's handbooks offer cursory treatment of the doctrine of patentable subject matter, in comparison to fuller exploration of other statutory grounds available for assertions of invalidity and unenforceability.³⁸ In addition to the unfamiliarity with the patentable subject matter doctrine that can be evidenced by parties in litigation, there is another distinguishing characteristic of this issue. Many patent disputes are between similarly situated competitors, who may be in conflict over a particular patent, but in agreement regarding the general eligibility of subject matter in a particular field. The consequences of a determination that patentable subject matter

statutory grounds more routinely asserted such as obviousness (42.0%) or 35 U.S.C. § 102 non-prior art (31.1%). *Id.*

³⁶ The other statutory bases for alleging patent invalidity are utility (35 U.S.C. § 101), novelty (35 U.S.C. § 102), nonobviousness (35 U.S.C. § 103) and disclosure defects (35 U.S.C. § 112, first and second paragraphs).

³⁷ In view of the analysis by Professor Kreiss, there may be assumptions by a court about the rigor of the examination process that are not valid. *See* Kreiss, *supra* note 16, at 54–56. *See, e.g.,* Etak, Inc. v. Zexel USA Corp., No. C 94-4041 SC, 1995 WL 462240, at *2 (N.D. Cal. May 8, 1995) (“Without any contrary evidence, this court assumes that the PTO, in accordance with the Guidelines, considered the algorithm and the issue of patentability in issuing the patent.”).

³⁸ “Thus, a patent may be held invalid under § 101 for lack of patentable subject matter.” AM. BAR ASS'N SECTION OF INTELLECTUAL PROP. LAW, PATENT LITIGATION STRATEGIES HANDBOOK 471 (Barry L. Grossman & Gary M. Hoffman eds., 2000).

Another type of defense involves failure to satisfy the requirements of 35 U.S.C. § 101 which defines the subject matter that can be protected by a utility patent as ‘any new . . . thereof.’ Two different defenses may be asserted under this section—that the subject matter of the accused patent lies outside the statutory subject matter identified in section 101.

Roy E. Hafer & Tom Filarski, *Patent Defenses*, in PATENT LITIGATION, PRACTICING LAW INSTITUTE ch. 21 (Laurence H. Pretty ed., 2001).

does not exist might extend beyond the particular patent in suit, resulting in hesitation on the part of either party (or the courts) to raise the issue for fear of sector-wide consequences.³⁹

The following cases illustrate various scenarios in which the doctrine of patentable subject matter has surfaced in patent litigation, either implicitly or explicitly.⁴⁰ These cases, in contrast to those emanating from appeals of patent denials by the PTO, offer a window into how ably parties do, or do not, handle a possible patentable subject matter dispute. They also reveal how well the trial courts are able to discern the discrete statutory requirement for patentable subject matter, and adjudicate accordingly.

The potential appearance of an issue of patentable subject matter can be observed in *Kemin Foods, L.C. v. Pigmentos Vegetales del Centro S.A. DE*.⁴¹ The '714 and '564 patents were directed to purified lutein crystals, and methods for their production. The defendant had asserted several grounds for invalidity of the patents, including anticipation and obviousness. After a jury trial, the patent was judged valid and infringed. The court then considered post-trial motions filed by the parties. Specifically, the court discussed an assertion made by the defendant: "Further, PIVEG asserts that the scope of patentable subject matter does not include discoveries of natural phenomena because '[s]uch discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'"⁴² The court mentioned the defendant's contention "that the jury's decision was contrary to law to the extent it believed claim 1 of the '564 patent was valid because it was drawn to the scientific discovery of producing large crystals."⁴³ There is no indication by the court that such an assertion could have been interpreted as a claim of invalidity for lack of patentable subject matter, pursuant to the

³⁹ See Kane, *supra* note 15, at 726 (analogizing this cascade of consequence to that of class actions).

⁴⁰ These cases are illustrative, not exhaustive. For reasons that are clear from the examples, however, it is not possible to identify all of the cases in which a latent issue of patentable subject matter exists because of the linguistic imprecision that attaches to any such considerations from the parties and/or the courts.

⁴¹ 357 F. Supp. 2d 1105 (S.D. Iowa 2005).

⁴² *Id.* at 1135–36 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (alteration in original)).

⁴³ *Id.* at 1136.

distinct statutory ground afforded by 35 U.S.C. § 101. The plaintiff patent owner urged a denial of defendant's motion "as it [was] based on a newly asserted, post-verdict anticipation theory, a defense never raised at trial."⁴⁴ It does not appear that the defendant recognized the specific statutory basis of 35 U.S.C. § 101—albeit fatally late in the proceedings—and neither the plaintiff, nor, importantly, the court, appears to have countered with any such recognition. While it could be argued that the failure to specify the precise statutory provision that corresponds to a substantive argument is not required, its absence suggests a lack of appreciation for the patentable subject matter doctrine that caused it to be omitted as a formal ground for invalidity despite an inference, from the defendant, that the invention lacked patentable subject matter. To be sure, such a conclusion does not suggest that any such formal assertion might have been successful, only that the defendant's claim that "natural phenomena" might have been patented is striking, as it corresponds to one of the clear exclusions from patentable subject matter.⁴⁵

In *Monsanto Co. v. Good*,⁴⁶ a defendant accused of infringing a patent directed to DNA, a chimeric gene, appears to raise arguments regarding patentable subject matter, but does not offer 35 U.S.C. § 101 as a statutory ground for invalidity. Furthermore, the defendant erroneously posed such arguments, in its motion for summary judgment, as directed to the enforceability of the patent—an error that was noted by the court.⁴⁷ The defendant's claims that such a gene should not be patentable because "[g]enetic sequence data relating to plants and seeds is not patentable,"⁴⁸ and because "it attempts to patent a DNA construct that is not in its 'pure and isolated form,'"⁴⁹ were not raised with reference to 35 U.S.C. § 101, but, according

⁴⁴ *Id.*

⁴⁵ See *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) ("This Court has undoubtedly recognized limits to § 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas.").

⁴⁶ No. Civ.A.01-5678 FLW, 2004 WL 1664013 (D.N.J. July 23, 2004).

⁴⁷ *Id.* at *4 ("As an initial matter, the Court notes that [the defendant] inappropriately characterizes its challenge as an enforcement issue.").

⁴⁸ *Id.* (alteration in original).

⁴⁹ *Id.* (quoting Defendant's Notice of Cross-Motion for Partial Summary Judgment at 7, *Monsanto*, 2004 WL 1664013 (No. Civ.A.01-5678 FLW)).

to the court, relied on the case of *Amgen, Inc. v. Chugai Pharmaceutical Co.*,⁵⁰ in which the Federal Circuit addressed the patentability of “purified and isolated DNA.”⁵¹ The court stated that a “man-made gene” was at issue in the case, holding *Amgen* inapplicable, and then noted that 35 U.S.C. § 101 was implicated.⁵² The court then relied on *Diamond v. Chakrabarty*⁵³ for its conclusion that “genes altered by man” are patentable.⁵⁴ Despite the absence of the defendant’s assertion of 35 U.S.C. § 101, the court does locate the defendant’s arguments in that provision, and, indeed, compensates for the assertion of unenforceability by entertaining the arguments, and finding patentable subject matter.⁵⁵

The issue of patentable subject matter, however, is not always latent or overlooked by litigants at the district court level. There are cases, of course, where a question regarding patentable subject matter is identified early, and definitively—thus forming a basis for a claim of patent invalidity by an accused infringer during litigation. Not surprisingly, such lower court cases include those which have recently shaped the contours of patentable subject matter, including *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*,⁵⁶ a successful declaratory judgment action by a potential infringer alleging invalidity on this ground, *AT & T Corp. v. Excel Communications, Inc.*,⁵⁷ where the court granted the motion of an accused infringer for summary judgment of invalidity for lack of patentable subject matter, and

⁵⁰ 927 F.2d 1200 (Fed. Cir. 1991).

⁵¹ *Id.* at 1206.

⁵² *Monsanto*, 2004 WL 1664013, at *4–5.

⁵³ 447 U.S. 303 (1980). *Chakrabarty* did not address genes as patentable subject matter; it addressed a genetically engineered bacterium that had been altered by recombinant DNA techniques. *Id.* at 305.

⁵⁴ *Monsanto*, 2004 WL 1664013, at *5.

⁵⁵ *Id.* It can be further noted that the assertion of a “chimeric gene” in the patent, and its discussion by the court, is open to interpretation, as claim 1 of U.S. Patent No. 5,352,605 is directed to a chimeric construct which includes a viral promoter with any gene of interest. U.S. Patent No. 5,352,605 (filed Oct. 28, 1993). Such a construct may or may not be chimeric, but there is an argument that the gene is not, per se, chimeric, but rather unaltered, and arguments about the patentability of the gene itself are not obviated by the language of Claim 1.

⁵⁶ 927 F. Supp. 502 (D. Mass. 1996) (concerning the patentability of business methods).

⁵⁷ No. 96-434-SLR, 1998 U.S. Dist. LEXIS 5346 (D. Del. Mar. 27, 1998) (concerning the patentability of algorithms).

Pioneer Hi-Bred International, Inc. v. J.E.M. AG Supply, Inc.,⁵⁸ where the court denied summary judgment to a defendant alleging invalidity on the same basis.

If a litigant does not allege (or imply) invalidity for lack of patentable subject matter, despite a cognizable claim in a particular case, it is possible for a court to raise the issue *sua sponte*.⁵⁹ In the case of *Safe Flight Instrument Corp. v. Sundstrand Data Control, Inc.*,⁶⁰ the holder of patents to computer systems for monitoring wind shear in aircraft sued for infringement. The defendant asserted non-infringement of the patent, and moved for summary judgment. The patent claim to a method of producing a wind shear signal included the steps involved in the necessary calculations. The defendant did not advance any theory of invalidity for lack of patentable subject matter.⁶¹ The plaintiff patent owner opposed summary judgment, contending that an issue of material fact attended to whether the defendant's products actually produced a wind shear signal, which would then infringe its patent. Judge Roth characterized the plaintiff's allegation as asserting actual ownership of any means for producing a signal identifying the presence of wind shear. She then identified an issue of patentable subject matter necessitating adjudication *sua sponte*, noting that "Safe Flight cannot patent the concept of windshear."⁶² After reviewing the relevance of *Diamond v. Diehr*,⁶³ the judge noted that "Safe Flight describes its method for calculating windshear alternatively as an algorithm or an algebraic expression. Unlike the respondents in *Diehr*, the plaintiff here *does* seek to preempt use of the general windshear equation."⁶⁴ The judge distinguished the application of an equation from preemption of the same:

⁵⁸ No. C 98-4016-DEO, 1998 U.S. Dist. LEXIS 21782 (N.D. Iowa Aug. 19, 1998) (concerning the availability of utility patent protection for plants).

⁵⁹ "Sua sponte"—in Latin, meaning "of his or its own will"—refers here to a legal issue that originates by action of a court, in contrast to an issue raised by a party. BLACK'S LAW DICTIONARY 1424 (6th ed. 1990).

⁶⁰ 706 F. Supp. 1146 (D. Del. 1989).

⁶¹ *Id.* at 1147–48. This 1989 case occurred during the period of extensive litigation over the patentability of computer-related inventions. See Chiapetta, *supra* note 16, at 106–14.

⁶² *Safe Flight*, 706 F. Supp. at 1154.

⁶³ 450 U.S. 175 (1981).

⁶⁴ *Safe Flight*, 706 F. Supp. at 1155–56 (citation omitted).

Safe Flight can patent the use of the windshear signal in its airplane control system—+s once that signal has been produced, as long as it seeks protection for the use of the windshear equation in conjunction with all of the other steps in the system. It cannot, however, as it seeks to do here, prevent others from using the equation which simply describes a natural phenomenon.⁶⁵

Notably, the judge addressed the absence of any claim by the defendant that Safe Flight's patent was invalid for lack of patentable subject matter:

In so finding, we do not comment on the validity of the plaintiff's patents. The question of whether its patents cover more than the general windshear equation (and therefore whether its patents cover patentable subject matter) was not raised in this dispute and therefore is not addressed by the Court.⁶⁶

Judge Roth later commented on this patent case and the role of the court in safeguarding the availability of a natural phenomenon and the means for its use: "I felt that to adopt Safe Flight's [sic] argument would permit Safe Flight in effect to patent the wind shear equation, which it could not do."⁶⁷ The remedy was described: "I did not comment on the validity of the plaintiff's patents, I only refused to permit Safe Flight to preclude others from the use of the general wind shear equation."⁶⁸ This case illustrates the action of a court, *sua sponte*, recognizing that a patent might effectively foreclose others from being able to work with the natural phenomenon of wind shear if an equation for its description were privately controlled, and choosing to prevent that outcome by equitable means. The court recognized that such a result would have contravened the Supreme Court's dictate.⁶⁹ While the effect of this ruling preserved the availability of a natural phenomenon, the lack of an explicit finding regarding patentable subject

⁶⁵ *Id.* at 1156.

⁶⁶ *Id.* at 1156 n.9.

⁶⁷ Jane R. Roth, *A View From the Bench: Patent and Copyright Protection of Computers and Computer Programming in the Information Age*, 19 TEMP. ENVTL. L. & TECH. J. 11, 14 (2000). Judge Roth suggested that the Federal Circuit have jurisdiction over patent and copyright disputes in the computer field in order to achieve a coherent jurisprudence. *Id.* at 26.

⁶⁸ *Id.* at 15.

⁶⁹ *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

matter and any effect on patent validity contributes to the underdevelopment of the doctrine by the courts.

A recent case from the Federal Circuit discussed the issue of patentable subject matter *sua sponte*. In *SmithKline Beecham Corp. v. Apotex Corp.*,⁷⁰ a patent dispute between a brand-name manufacturer and a generic competitor, the plaintiff patent holder asserted infringement of its patent to paroxetine hydrochloride hemihydrate, a crystalline form of the drug Paxil. The theory of infringement was based on the allegation that, although Apotex would be manufacturing a different (anhydrate) crystalline form of the drug, a trace amount of the patented compound would be organically produced during the synthetic process. The Federal Circuit decided that although the defendant's conduct did infringe the patent, the claim to the patented compound was invalid under 35 U.S.C. § 102(b) as anticipated by a prior patent.⁷¹ A concurring opinion by Judge Gajarsa raised the issue of whether the patent claim should be judged invalid for lack of patentable subject matter, first reviewing the authority for his decision to raise the issue. He noted: "The question of patentability under section 101 does not arise often, and a court's decision to raise it *sua sponte* is even less common. The centrality of patentable subject matter to the entire scope of the patent law suggests that there are times when such inquiries are critical."⁷² Citing the Supreme Court's decisions in *Slawson v. Grand Street Railroad Co.*⁷³ and *Richards v. Chase Elevator Co.*⁷⁴ for the proposition that a court may always consider the patentability of an invention in dispute in any legal proceeding, he stated: "These precedents remain good law, though the courts have relied on them infrequently. The policy that drove them, however, remains vibrant."⁷⁵ Judge Garjarsa considered whether a patent holder can claim infringement when the allegedly infringing product (paroxetine hemihydrate) only arises upon spontaneous chemical conversion of the non-infringing product into a crystalline polymorph. The question was not whether a synthetic chemical compound could

⁷⁰ 403 F.3d 1331 (Fed. Cir. 2005).

⁷¹ *Id.* at 1345.

⁷² *Id.* at 1352–53 (Gajarsa, J., concurring).

⁷³ 107 U.S. 649 (1882).

⁷⁴ 158 U.S. 299 (1895).

⁷⁵ *SmithKline*, 403 F.3d at 1353 (Gajarsa, J., concurring).

be patented per se, but rather whether “a natural physical process can convert a noninfringing product into an infringing one,”⁷⁶ and the patent claim would therefore be directed to subject matter both within and excluded from 35 U.S.C. § 101. The possibility that “unintentional infringement” can occur violates the principle of public notice, and Judge Gajarsa stated that this was a consequence of the lack of patentable subject matter under 35 U.S.C. § 101.⁷⁷ He viewed the plaintiff as claiming patent rights to a compound that solely arises from naturally occurring processes, noting that “[t]his distinction between the synthetic product and its natural ‘reproduction’ process is subtle, but critical.”⁷⁸ Judge Gajarsa reached a conclusion of invalidity of the patent claim under 35 U.S.C. § 101, a different basis than did the majority on the panel. The majority stated that “the concurrence confuses patent eligibility under § 101 with patentability under other provisions in the Patent Act”⁷⁹ and further commented that the scope of the claim could not be addressed by the patentable subject matter doctrine.⁸⁰

The contrast between the opinions of the majority and of the concurrence illustrate an important fact about the appearance of an issue of patentable subject matter during patent litigation, in contrast to patent prosecution. The patent claim in *SmithKline*⁸¹ may present as a standard claim to a composition of matter, an allowable category of invention under 35 U.S.C. § 101, and not trigger any concern from a patent examiner during patent prosecution. However, the assertion of the patent claim against an accused infringer revealed a theory of production of the patented compound that was arguably novel and unexpected, and, in the view of Judge Gajarsa, raised wholly new questions of patentable subject matter that had not surfaced in patent prosecution. It is possible that, during patent litigation, a particular theory of infringement or a specific claim construction might expose a legitimate issue regarding patentable subject

⁷⁶ *Id.* at 1359.

⁷⁷ *Id.* at 1359–60.

⁷⁸ *Id.* at 1360.

⁷⁹ *Id.* at 1342 (majority opinion).

⁸⁰ *Id.*

⁸¹ Claim 1 of the ‘723 patent read: “Crystalline paroxetine hydrochloride hemihydrate.” *Id.* at 1339.

matter, revealing a scenario that could not be foreseen at the time of patent prosecution.

The Supreme Court has recently identified an issue of patentable subject matter in a patent litigation which lacked any formal allegation of invalidity for lack of patentable subject matter. In *Laboratory Corporation of America Holdings (LabCorp) v. Metabolite Laboratories, Inc. et al.*,⁸² the holder of a patent to an assay for identifying a vitamin deficiency by determining the level of an amino acid asserted infringement of a method claim which involved measuring the level of homocysteine and correlating an elevated level with a deficiency of either cobalamin (Vitamin B12) or folate (folic acid).⁸³ Homocysteine metabolism requires a sufficient vitamin level; an inference of a possible vitamin deficiency can be drawn if the homocysteine level is elevated. The allegation of indirect infringement relied on the assertion that *LabCorp* intentionally induced infringement of Claim 13 of the patent by publishing knowledge of the biochemical correlation which promoted the use of a homocysteine assay by medical practitioners.⁸⁴ The claim construction endorsed by the Federal Circuit interpreted the term "correlating" in Claim 13 to occur whenever an individual made an association between homocysteine and vitamin deficiency, following the performance of any assay.⁸⁵ With that interpretation, the infringement theory relied on a determination that a doctor, for example, could directly infringe the claim by making the biochemical correlation. The Federal Circuit upheld the jury verdict that *LabCorp* had induced infringement.⁸⁶

The defendant had alleged the invalidity of the patent claim on several grounds during litigation, but did not advance any formal allegation for lack of patentable subject matter.⁸⁷ In the petition for certiorari filed by the petitioner *LabCorp* in the

⁸² 370 F. 3d 1354 (Fed. Cir. 2004), *cert. granted*, 126 S. Ct. 601 (2005) (No. 04-607).

⁸³ Claim 13 of U.S. Patent No. 4,940,658 is 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." *Id.* at 1358-59.

⁸⁴ *Id.* at 1365.

⁸⁵ *Id.* at 1362.

⁸⁶ *Id.*

⁸⁷ Other grounds for invalidity were advanced, however, including written description, enablement, obviousness, indefiniteness, and anticipation. *Id.* at 1365.

Supreme Court, the question of whether “a method patent . . . can validly claim a monopoly over a basic scientific relationship” was articulated.⁸⁸ The petitioners alleged disclosure defects in a patent claim to such a relationship, describing the correlation step as “indefinite, undescribed, and non-enabling.”⁸⁹ While there is no citation of 35 U.S.C. § 101, the petitioners stated in their petition that “scientific facts and laws of nature are outside the scope of patentable invention.”⁹⁰ This is a statement invoking the limits of patentable subject matter. While considering the petition, the Supreme Court invited the Solicitor General to file a brief in the case, limited to a newly posed question that directly invoked its trilogy of exclusions from patentable subject matter: “Is the patent invalid because one cannot patent ‘laws of nature, natural phenomena, and abstract ideas’? *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).”⁹¹ With that sentence, the Court directly signaled its interest in whether the limits of patentable subject matter had been exceeded by Claim 13, and explicitly shifted the discourse into the trilogy of exclusions from patentable subject matter that it has maintained. In response to the Court’s question, the Solicitor General stated that “Claim 13 appears to involve a natural phenomenon, because it asserts and relies on the existence of a naturally occurring correlation between elevated levels of total homocysteine and deficiencies in cobalamin or folate,”⁹² further analogizing the relationship to those observed in $E=mc^2$ or Newton’s law of gravitation.⁹³ However, the Solicitor General

⁸⁸ Question 3, Petition for Writ of Certiorari, *LabCorp v. Metabolite*, 370 F. 3d 1354 (Fed. Cir. 2004), *cert. granted*, 126 S. Ct. 601 (2005) (No. 04-607) at 2; *available at* http://patentlaw.typepad.com/patent/files/labcorp_petition_for_certiorari.pdf. (last visited November 7, 2005). Question 3 stated: “Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to “correlat[e]” test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.” *Id.*

⁸⁹ *Id.* These allegations invoke 35 U.S.C. § 112, first and second paragraphs. *Id.*

⁹⁰ *Id.* at 18.

⁹¹ Invitation to Solicitor General, *LabCorp v. Metabolite*, 543 U.S. 1185 (February 28, 2005).

⁹² Brief for United States as Amicus Curiae, *LabCorp v. Metabolite*, 370 F. 3d 1354 (Fed. Cir. 2004), *cert. granted*, 126 S. Ct. 601 (2005) (No. 04-607); *available at* <http://www.usdoj.gov/osg/briefs/2005/2pet/6invt/2004-0607.pet.ami.inv.html> (last visited November 7, 2005) at 5.

⁹³ *Id.* at 6. These analogies are important, because they support the recognition

argued against the petition for certiorari, noting that “petitioner did not argue below that claim 13 attempts to claim non-patentable subject matter and is therefore invalid under Section 101,” and further stating that such failure precluded any claim construction undertaken with this allegation at the fore, and eliminated the existence of a complete record on the issue of patentable subject matter.⁹⁴ The brief also noted the implication of any holding that Claim 13, or similar claims, lack patentable subject matter, revealing a quasi-class action effect: “A decision overturning PTO’s approach could call into question a substantial number of patent claims and undermine the settled expectations of numerous participants in technology-based industries.”⁹⁵ In its reply to the Solicitor General’s arguments, the petitioner *LabCorp* relied on arguments regarding the inherent jurisdiction of the Court over any issue of patentability, and further noted the latent assertions regarding patentable subject matter that did appear in the record, where the trial court judge had raised the possibility of patenting an “idea”⁹⁶ during claim construction and again at the Federal Circuit, where the petitioner had noted the possibility that the patent holder “would improperly gain a monopoly over a basic scientific fact.”⁹⁷ *LabCorp*’s reply brief began to adopt the language that the Court had used, characterizing the lower court’s rulings on the scientific relationship between homocysteine and folate as relating to a “law of nature” and noting that an allowance of Claim 13 resulted in preemption of a “natural principle.”⁹⁸ In response to the warning by the Solicitor General that settled expectations relating to PTO practice might change, *LabCorp*

of common cognitive structures between the physical and biological sciences that are labeled either natural phenomena or laws of nature, neither of which can be patented. *See infra* Part IV.

⁹⁴ *Id.* at 15. The Supreme Court had also granted certiorari against the recommendation of the Solicitor General over the patentable subject matter issue in *J.E.M. Ag Supply, Inc., v. Pioneer Hi-Bred Intl., Inc.*, 534 U.S. 124 (2001). *See* MERGES & DUFFY, *supra* note 31, at 119-120 (noting the unexpected grant of certiorari given the absence of lower court conflict and the Solicitor General opinion).

⁹⁵ *Id.* at 14. *See* Kane, *supra* note 15.

⁹⁶ Supplemental Brief for Petitioner in Response to Brief for the United States, *LabCorp v. Metabolite*, 370 F. 3d 1354 (Fed. Cir. 2004), *cert. granted*, 126 S. Ct. 601 (2005) (No. 04-607) at 7, *available at* http://docket.medill.northwestern.edu/archives/supplemental_brief.pdf.

⁹⁷ *Id.* at 6.

⁹⁸ *Id.* at 3.

warned about a failure to review Claim 13: “The PTO’s approach, if allowed to stand, would in fact open the floodgates to monopolization of virtually any scientific correlation merely by drafting a vague “test plus correlate” claim.”⁹⁹

The Supreme Court did grant certiorari, limited to the original Question 3 in the petition, which had focused on the patenting of a “scientific fact.”¹⁰⁰ However, its question to the Solicitor General had clearly focused attention of the parties on the relationship of Claim 13 to the defined exclusions of laws of nature, natural phenomena and abstract ideas.¹⁰¹ *LabCorp*, then, illustrates the Court’s initiative in formulating a specific question that focused the parties on a possible defect related to patentable subject matter, and in the familiar language from *Diamond v. Diehr*.¹⁰² The possible patenting of a scientific relationship appeared, to the Court, to translate into the possibility a patent may have breached one of the core exclusions from patentable subject matter, despite the absence of attention to this issue at the lower court level. This is not surprising, as these exclusions originate with the Court and have surfaced to maintain fundamental scientific tools within the public domain.¹⁰³ Again, as *SmithKline* illustrated, a particular theory of infringement may expose an issue of patentable subject matter that was not visible in prosecution and was not fully appreciated or articulated during litigation. If the ability to raise a formal allegation related to the boundaries of patentable subject matter requires a litigant to possess an understanding of the “laws of nature, natural phenomena, and abstract ideas” exclusions, the omissions of this allegation that are observed in Part II, *supra*, may reflect the definitional confusion and underdeveloped rationales for these exclusions.¹⁰⁴ This ambiguity is observed in

⁹⁹ *Id.* at 9.

¹⁰⁰ *LabCorp v. Metabolite*, 126 S. Ct. 601 (November 2, 2005) (No. 04-607). As of this writing, the Court has not yet issued an opinion.

¹⁰¹ The law of nature exclusion and its relationship to Claim 13 is discussed in Part IV, *infra*.

¹⁰² 450 U.S. 175 (1981).

¹⁰³ In an analysis by Donald S. Chisum of the 24 “most relevant decisions” by the Supreme Court in the field of patent law, 4 addressed the issue of patentable subject matter. Donald S. Chisum, *The Supreme Court and Patent Law: Does Shallow Reasoning Lead to Thin Air?* 3 MARQ. INTELL. PROP. L. REV. 1, 23–24 (1999).

¹⁰⁴ These issues are further explored in Parts III and IV, *infra*.

conflicting descriptions of the scientific relationship in *LabCorp* as both a natural phenomenon and law of nature.¹⁰⁵

Although the absence of a formal allegation regarding patentable subject matter may deprive a particular litigant of a valuable defense in litigation, there is a broader consequence for patent law itself. The failure to raise a properly formulated allegation of invalidity will generally foreclose a formal appellate review, despite the recent instances where the issue was raised, *sua sponte*, at the Federal Circuit and the Supreme Court. In view of the existence of a specialized appellate court for patent appeals, the Federal Circuit, a goal of which is to aggregate doctrinal formulation in patent law, this lack is particularly unfortunate. The absence of otherwise credible debates over patentable subject matter during litigation may preclude a necessary review of PTO practices which cause patents to issue that unduly encroach subject matter belonging in the public domain. Some of the procedural difficulties in identifying the issue of patentable subject matter can be traced to the substantive difficulties in understanding the boundaries between the allowable categories of invention in 35 U.S.C. § 101 and the judicially-created exclusions of laws of nature, natural phenomena, and abstract ideas from patent protection. Part III further explores the identity and purpose of these judicially-created exclusions from 35 U.S.C. § 101.

III. THE EXCLUSIONS FROM ELIGIBILITY

Discussions about the border conflicts which place subject matter either inside or outside the intellectual property regimes can take place within two different baseline assumptions. One view regards the unprotectable as “exceptions” to a regime of intellectual property, while the other view regards the protectable as “exceptions” to a public domain. These conflicting views spur the question, which domain—public or private—is the default? The Supreme Court has stated that “free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception,”¹⁰⁶ and that “a patent is an exception to the general rule against monopolies.”¹⁰⁷ These views suggest the

¹⁰⁵ See *supra* notes 92–98 and accompanying discussion.

¹⁰⁶ *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989).

¹⁰⁷ *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945).

extraordinary nature of the patent grant; “the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure.”¹⁰⁸ If the public domain is therefore viewed as the default domain, then a discussion and analysis of the subject matter that it contains is essential.¹⁰⁹ Professor Merges notes: “The pervasiveness of IP rights has raised our awareness of the importance and strategic uses of the public domain.”¹¹⁰

Formal exclusions within intellectual property law are observed in several distinct areas. Within U.S. patent law, there are several statutory exclusions. No patents can issue for nuclear weapons or related inventions.¹¹¹ In addition, the enforceability of medical procedure patents against health care providers is limited.¹¹² The European Patent Convention (“EPC”) recognizes specific exclusions from patentability.¹¹³ The Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) treaty recognizes the ability of member states to exclude certain categories of invention.¹¹⁴ U.S. copyright law specifically recognizes a formal list of exclusions.¹¹⁵

¹⁰⁸ *Bonito Boats*, 489 U.S. at 151.

¹⁰⁹ See Tyler T. Ochoa, *Origins and Meanings of the Public Domain*, 28 U. DAYTON L. REV. 215, 267 (2002) (stating that the public domain is “conceived of as common property, owned by the public at large, which could not be alienated by the Government, except under the carefully limited provisions of the Patent and Copyright Clause”).

¹¹⁰ Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183, 184 (2004).

¹¹¹ See 42 U.S.C. § 2181 (2000).

¹¹² See 35 U.S.C. § 287(c) (2000).

¹¹³ See EUROPEAN PATENT CONVENTION art. 52 (2002), available at http://www.european-patent-office.org/epc/pdf_e.htm. Article 52(2) includes the exclusions of “(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; and (d) presentation of information . . . as such.” See *id.*

¹¹⁴ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Final Act of the 1986–1994 Uruguay Round of Trade Negotiations, Apr. 15, 1994, Annex 1C, art. 27, available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf. “Members may exclude from patentability inventions . . . to protect *ordre public* or morality, . . . [or] may also exclude . . . diagnostic, therapeutic, and surgical methods for the treatment of humans or animals; [and] plants and animals other than microorganisms . . .” See *id.* Professor Chisum notes that the above EPC exclusions are “[n]otably missing” from the TRIPS treaty. See 1 CHISUM, *supra* note 1, § 1.01, at 1–10 & n.28 (2005).

¹¹⁵ See 17 U.S.C. § 102(b) (2000). Comparisons to copyright law are apt in view of the common constitutional origin of the patent and copyright regimes. Both arise

In addition to the statutory exclusions, there is a long history of judicially created doctrines of exclusion in patent law.¹¹⁶ These additional sources of definition for patentable subject matter reveal that it is not possible to take the formal categories of invention in 35 U.S.C. § 101 at face value, and, as a result, they have been referred to as “terms of art.”¹¹⁷ Patent law jurisprudence reveals the rise and fall of a number of doctrines which, at one time, functioned as categorical exclusions to prevent the issuance of certain types of patents. The so-called mental steps doctrine, function of a machine, and business methods exceptions to patentable subject matter no longer exist as credible bases for rejecting potential subject matter.¹¹⁸ In a history of Judge Rich and the evolution of patentable subject matter through his years at the C.C.P.A. and the Federal Circuit, Professor Oddi summarized Judge Rich’s rationale for the gradual elimination of formal exclusions from patentable subject matter, including the business method at issue in *State Street*¹¹⁹: “Unless there was binding precedent adopting this exception, there was no rational basis for treating business methods differently from any other methods that produce a useful, concrete, and tangible result.”¹²⁰

from Article I, Section 8, Clause 8, of the Constitution, in which Congress is granted the power “To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” See U.S. CONST. art. I, § 8, cl. 8.

¹¹⁶ “[T]he following are not within the statutory categories of subject matter enumerated in § 101 and its predecessor statutes as interpreted through the years: principles, laws of nature, mental processes, intellectual concepts, ideas, natural phenomena, mathematical formulae, methods of calculation, fundamental truths, original causes [and] motives.” *In re Bergy*, 596 F.2d 952, 965 (C.C.P.A. 1979), *vacated sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980), *aff’d*, 447 U.S. 303 (1980).

¹¹⁷ See Kreiss, *supra* note 16, at 58 (“[T]he words ‘process,’ ‘machine,’ ‘manufacture,’ and ‘composition of matter’ are terms of art and neither the statutory language of § 101 nor the legislative history concerning that section can be relied upon to determine the scope of meaning of these words.”).

¹¹⁸ See *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1375–77 (Fed. Cir. 1998) (eliminating the business methods exception); *In re Musgrave*, 431 F.2d 882, 885–86, 890–93 (C.C.P.A. 1970) (eliminating the mental steps doctrine); *In re Tarczy-Hornoch*, 397 F.2d 856, 866–68 (C.C.P.A. 1968) (eliminating the function of a machine doctrine).

¹¹⁹ 149 F.3d 1368, 1375–77 (Fed. Cir. 1998). There is criticism, particularly, of the decisions to allow the patenting of computer programs and business methods. See, e.g., Dratler, *supra* note 21, at 879–82; Moy, *supra* note 21, at 86–90.

¹²⁰ A. Samuel Oddi, *Assault on the Citadel: Judge Rich and Computer-Related Inventions*, 39 HOUS. L. REV. 1033, 1096 (2002–2003). For a critique of the blurring

The judicially created exceptions to patentable subject matter which remain are those which have been reiterated by the Supreme Court as recently as 2005, namely, laws of nature, natural phenomena, and abstract ideas.¹²¹ There are several sources of confusion about the trilogy of exclusions, but the questions can be conceptually divided into two categories. What are the definitions of laws of nature, natural phenomena, and abstract ideas? Why are these categories excluded, particularly when an invention is claimed so as to fall into one of the formal classes of patentable subject matter?¹²² It is also possible to invert the concept of exclusions and ask a different question: what is protected for public use?

At the start, one could ask whether it matters whether these categories are ill-defined or under-reasoned. Definitional ambiguity appears in other areas of the law. However, patent law places a high value on clarity and linguistic precision, as illustrated by the strict disclosure requirements for the award of patent rights.¹²³ Both the specification and claims in a patent should exhibit, as much as possible, an exactitude which allows the public to understand what is patented and what it not. The patent statute should also provide notice regarding the limits of eligibility, which will be discussed in Part V, *infra*.

The trilogy of exclusions are not necessarily unrelated. In fact, it is possible to have instances where several of the exclusions apply to a particular subject matter sought to be patented. A natural phenomenon might be described in such abstract terms that it also becomes an “abstract idea.” For example, there is definitional heterogeneity in case law and in legal scholarship about the subject matter (electromagnetism) of the proposed invention in *O’Reilly v. Morse*,¹²⁴ which is variously described as a “natural phenomenon”¹²⁵ or as a “principle”¹²⁶ or

of the lines between the separate doctrines of patentable subject matter and utility in *State Street*, see John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139, 1160 (1999).

¹²¹ See *supra* note 91.

¹²² See 35 U.S.C. § 101 (2000).

¹²³ The disclosure requirements include those of written description, enablement, best mode, and definiteness. 35 U.S.C § 112, first and second paragraphs.

¹²⁴ 56 U.S. (15 How.) 62 (1853).

¹²⁵ *In re Bergy*, 596 F.2d 952, 990 (C.C.P.A. 1979) (Baldwin, J., concurring), *vacated sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980), *aff’d*, 447 U.S. 303 (1980).

“abstract idea”¹²⁷ or “law[] of nature.”¹²⁸ Further analysis of *Morse* occurred in *In re Bergy*: “Although the Court did not use the words ‘phenomenon of nature,’ it is apparent that claim 8 was held improper because by disclaiming all apparatus limitations, Morse was attempting to define the limits of his invention in terms of the natural phenomenon of electromagnetism and would, therefore, preempt the use of this phenomenon.”¹²⁹ Thus, *Morse* certainly stands as a paradigmatic case for the exclusion of natural phenomena, and aids an understanding of what the courts might recognize as such. However, one can distinguish between an invention which could be described as a “natural phenomenon” and the actual claiming of the same invention, which could be written so broadly as to make it also an “abstract idea.” Both prohibitions might be applicable.

A general distinction could be drawn between the prohibition on patenting natural phenomena and laws of nature versus the patenting of abstract ideas. The prohibition on patenting abstract ideas was particularly prominent in the disputes over the patenting of computer-related inventions, as the mathematical algorithms which were at the heart of these inventions were sometimes described as abstract ideas.¹³⁰ At times, an algorithm was also described as a “law of nature.”¹³¹ However, the lingering prominence of the abstract idea exclusion has led to suggestions that this is the only credible exclusion from patentable subject matter at the present time.¹³² The

¹²⁶ *Parker v. Flook*, 437 U.S. 584, 592 (1978).

¹²⁷ Kreiss, *supra* note 16, at 69 (characterizing the *Morse* decision as a prohibition on the patenting of an abstract idea and on a claim of excessive scope).

¹²⁸ 1 ERNEST BAINBRIDGE LIPSCOMB III, WALKER ON PATENTS 157 (3d ed. 1984) (describing Claim 8 as directed to a law of nature).

¹²⁹ *Bergy*, 596 F.2d at 990.

¹³⁰ See Kreiss, *supra* note 16, at 68 (“Purely mathematical algorithms provide one illustration of the theory that abstract ideas are not patentable.”).

¹³¹ *Parker v. Flook*, 437 U.S. 584, 589 (1978) (“Reasoning that an algorithm, or mathematical formula, is like a law of nature, *Benson* applied the established rule that a law of nature cannot be the subject of a patent.”).

¹³² See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1642 (2003) (“[T]he most significant remaining exception is the rule against the patenting of abstract ideas. The rule originated in the case of *O’Reilly v. Morse*, which involved Samuel Morse’s patent on the telegraph.”). The authors describe this prohibition as a meaningful policy lever in patent law, serving as a limitation on patents of undue scope and preventing the patenting of “abstract ideas and natural rules”—including $E=mc^2$. *Id.* at 1643. The abstract idea exclusion is likely to surface again with respect to the recent decision by the Board of Patent Appeals and Interferences in *Ex parte Lundgren*, Appeal No. 2003-2088 (B.P.A.I.

concurrent existence of disclosure defects that can accompany a claim to an abstract idea might account for its greater visibility.

Rationales for the exclusion of the laws of nature, natural phenomena and abstract ideas cannot be described with precision.¹³³ However, the Court did comment in *Gottschalk v. Benson*: “Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”¹³⁴ The absence of extensive justifications by the Court may speak for itself.¹³⁵

If the eligibility of computer-related inventions was particularly shaped by the prohibition against the patenting of abstract ideas, inventions in the biological sciences have been particularly shaped by the prohibitions on natural phenomena and products of nature.¹³⁶ The natural phenomena which have been presented to the patent system have a logical relationship to the category of “laws of nature.” If laws of nature are understood to provide a mechanistic underpinning for observed phenomena, then they are implicitly referenced when actual phenomena are presented, and can illustrate the relationships between such phenomena.¹³⁷ Yet, the prohibition on patenting laws of nature can result in an absurd kind of legal reductionism if a distinction is not made between the embodiments of physical

2004) (involving a patent on a method of manager compensation not requiring any software-related implementation).

¹³³ See MERGES & DUFFY, *supra* note 31, at 77 (“Despite the imprecision in its formulation, the rule is the primary doctrinal tool by which the courts limit the category of patentable subject matter.”).

¹³⁴ 409 U.S. 63, 67 (1972).

¹³⁵ With respect to the trilogy of exclusions, Professor Samuelson described the Court’s view in *Diehr* as “that such discoveries are merely recognizing what was already in existence, rather than creating something new.” Samuelson, *Benson Revisited*, *supra* note 16, at 1097.

¹³⁶ For example, the prohibition on the patenting of natural phenomena was raised in *Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. De C.V.*, 357 F. Supp. 2d 1105 (S.D. Iowa 2005), and *Monsanto Co. v. Good*, 2004 WL 1664013 (D. N.J. July 23, 2004), discussed *supra* Part II. For discussions of the product of nature doctrine, see *supra* note 20. Both prohibitions were articulated late in the petition phase of *LabCorp v. Metabolite*, see *supra* notes 92–98.

¹³⁷ “There is also a rhythm and a pattern between the phenomena of nature which is not apparent to the eye, but only to the eye of analysis; and it is these rhythms and patterns which we call Physical Laws.” RICHARD FEYNMAN, *THE CHARACTER OF PHYSICAL LAW* 13 (1965).

laws and the laws themselves, such that all entities are judged to be the unpatentable expression of underlying natural laws.¹³⁸

If one tries to calibrate the harms which can result from the patenting of a law of nature, natural phenomenon, or an abstract idea, how are they to be understood? In other words, what is the cost? There is consensus that the protection of these entities is maintained so that they remain in the public domain for use by all. If one were to phrase a cause of action against the patenting of, for example, a law of nature, it would be that such patenting results in “preemption” of the law of nature—that which should be public is now privately controlled. It could be argued that there are shadow doctrines behind each exclusion from patentable subject matter which amplify why they cannot be patented. The patenting of natural phenomena and laws of nature most directly implicates issues of novelty, while the patenting of abstract ideas would be most immediately objected to on disclosure grounds.¹³⁹ This is not to suggest that these exclusions are redundant to existing doctrines—the Supreme Court certainly adheres to the categorical exclusions from patentable subject matter as the meaningful components of a public domain.

Limits on patentable subject matter in the biological sciences have most often encountered the prohibition on the patenting of natural phenomena,¹⁴⁰ but increasing reductionism in the life sciences will likely reveal underlying mechanisms of biological function that could make the law of nature exclusion more relevant.¹⁴¹ Because of the doctrinal underdevelopment of the

¹³⁸ These warnings are explicit in *Diamond v. Diehr*, 450 U.S. 175, 189 n.12 (1981), where the Court stated that the acceptance of such an analysis would, “if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious.”

¹³⁹ The implication of novelty as a rationale for the bar against patenting products of nature and laws of nature can also be approached by invoking the doctrine of inherency, in cases where the prior art implicitly disclosed or provided the public the benefit of the product or law of nature. See Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 408 (2005).

¹⁴⁰ See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (“He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.”).

¹⁴¹ Reductionism underlies the modern research imperative to investigate biological phenomena at its most fundamental level in order to understand structure

law of nature exclusion and its potential for protecting scientific knowledge in modern biological science, this Article next considers how patentable subject matter may be limited when laws of nature remain in the public domain.

IV. THE PATENT INELIGIBILITY OF LAWS OF NATURE

A deeper understanding of the concept of a law of nature and its intersection with patent law can contribute to the project of defining the contours of the public domain with respect to both the physical and the biological sciences. This investigation into the laws of nature as protected entities within the patent scheme can be informed by patent jurisprudence¹⁴² and the philosophy of science.¹⁴³ The identity and function of a law of nature has been a recurring analytic problem for the philosophy of science. As a field that investigates the structure and foundation of scientific knowledge, it studies the essential tasks of the scientific enterprise: “The study and discovery of the laws of nature are, after all, two of the major tasks of science.”¹⁴⁴

Historically, science itself, as a distinct field of knowledge, originates from the general field of philosophy, such that science came to be formulated as “natural philosophy.”¹⁴⁵ This origin is reflected in early patent cases, such as *O’Reilly v. Morse*.¹⁴⁶ “[T]he discovery of a principle in natural philosophy or physical science, is not patentable.”¹⁴⁷ In *Whittemore v. Cutter*,¹⁴⁸ the “original elementary principles of motion, which philosophy and science have discovered”¹⁴⁹ were not considered to be principles for which an inventor could be granted a patent. The

and function.

¹⁴² For a historical treatment of the laws of nature in patent jurisprudence, see Kane, *supra* note 15, at 745–756.

¹⁴³ The philosophy of science is a branch of philosophy. “In its broadest terms, the philosophy of science is the investigation of philosophical questions that arise from reflecting on science. What makes these questions philosophical is their generality, their fundamental character, and their resistance to solution by empirical disciplines such as history, sociology, and psychology.” MARTIN CURD & J.M. COVER, *PHILOSOPHY OF SCIENCE: THE CENTRAL ISSUES* xvii (1998).

¹⁴⁴ STEPHEN MUMFORD, *LAWS IN NATURE* 4 (2004).

¹⁴⁵ PETER GODFREY-SMITH, *THEORY AND REALITY* 4 (2003).

¹⁴⁶ *O’Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853).

¹⁴⁷ *Id.* at 116.

¹⁴⁸ 29 F. Cas. 1123 (C.C.D. Mass. 1813) (No. 17,601).

¹⁴⁹ *Id.* at 1124.

intertwining of science and philosophy shapes commentary in 19th Century patent jurisprudence.

Philosophers of science strongly disagree as to the existence of laws of nature, although it is possible to identify consensus attributes which have emerged in discussions of the concept.¹⁵⁰ Views range from those who defend the concept of laws of nature as necessary—independent of human enterprise—to those who simply view laws of nature as regularities which are observed and noted by human actors.¹⁵¹ In contrast, a third point of view holds that there are no laws of nature, because many so-called laws of nature have exceptions or require special conditions for their uniform character to emerge.¹⁵²

Although patent law jurisprudence has not provided any clear definition of a law of nature, there are signature examples offered by the Supreme Court, and these are explicitly described as laws. Here is a clear example, offered in *Diamond v. Chakrabarty*: “Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’”¹⁵³

If we take the two explicit mentions of “laws” from this excerpt, we have the Court offering two exemplars for laws of nature that cannot be the subject of a patent grant. Are these examples helpful for identifying other instances when the patent system is confronted with a law of nature? In addition to its mention by the Court, $E=mc^2$ is an equation with a wide following in the scientific community as a paradigmatic law of nature.¹⁵⁴ Newton’s law of universal gravitation also enjoys wide

¹⁵⁰ See RONALD N. GIERE, SCIENCE WITHOUT LAWS 86 (1999) (identifying the characteristics of laws of nature identified by modern philosophers of science as true statements of universal form, possessed of both contingency and necessity, and as objective, meaning that they exist apart from human cognitive structures).

¹⁵¹ See CURD & COVER, *supra* note 143, at 805–07.

¹⁵² See NANCY CARTWRIGHT, HOW THE LAWS OF PHYSICS LIE 54 (1983) (“For the fundamental laws of physics do not describe true facts about reality. Rendered as descriptions of facts, they are false; amended to be true, they lose their fundamental, explanatory force.”).

¹⁵³ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

¹⁵⁴ See MICHAEL GUILLEN, FIVE EQUATIONS THAT CHANGED THE WORLD 5 (1995) (a book focused on “the small number of mathematical equations that have influenced our existence in such profound and intimate ways,” including $E=mc^2$ as one of its examples); Kenneth Chang, *What Makes An Equation Beautiful*, N.Y. TIMES, Oct. 24, 2004, § 4, at 12 (describing a survey of readers of *Physics World*

acclaim, even from those who are skeptical of the actual existence of laws of nature.¹⁵⁵ However, several inferences might be drawn from these judicially-cited examples that inadvertently contribute to narrow, context-specific conclusions and an under-appreciation for the inherent expansiveness of the concept of laws of nature. First, both of these examples are drawn from the field of physics, with the possible consequence that other fields of science are either not considered to have their own versions of laws of nature, or that their versions must conform to existing models.¹⁵⁶ Second, both of these laws of nature have a mathematical character which furthers explanatory power, but which may not be a necessary attribute for a law of nature.¹⁵⁷ Third, both laws are also identified by the names of their discoverers, i.e., Einstein and Newton, with the possible consequence that all laws of nature are thought to arise from the work of a single, well-known genius, accompanied by an attendant mystique and celebrity.¹⁵⁸ Such an assumption would contravene the reality of much modern scientific work, which is

magazine, asking “Which equations are the greatest?” in which $E=mc^2$ was one of the top entries).

¹⁵⁵ See D. M. ARMSTRONG, WHAT IS A LAW OF NATURE? 7 (1983).

We now know that Newton’s Law of Universal Gravitation is not really a law. Yet we also know that Newton’s formula approximates to the truth for at least a wide range of phenomena. Its predictive power would be inexplicable otherwise. So it makes a very good stand-in for a paradigm of a law of nature.

Id.

¹⁵⁶ See CARTWRIGHT, *supra* note 152, at 54 (challenging reliance on physics as the dominant scientific paradigm, and stating: “It is customary to take the fundamental explanatory laws of physics as the ideal. Maxwell’s equations, or Schroedinger’s, or the equations of general relativity, are paradigms, paradigms upon which all other laws—laws of chemistry, biology, thermodynamics, or particle physics—are to be modelled [sic].”).

¹⁵⁷ See GIERE, *supra* note 150, at 88 (discussing the origin of the concept of law of nature in the philosophy of science and stating: “Would the concept of laws of nature have gained such currency in the absence of simple mathematical relationships which could be taken [to] express such laws? And do not the qualities of universality and necessity also attach to mathematical relationships? These questions are as difficult as they are relevant.”). This physics-dominated view of the laws of nature also appears in legal scholarship. See Burk & Lemley, *supra* note 132, at 408 (stating that it “is the language of mathematics in which such laws are expressed”).

¹⁵⁸ See CURD & COVER, *supra* note 143, at 805 (“Undoubtedly, much scientific activity is devoted to discovering laws, and one of the most cherished forms of scientific immortality is to join the ranks of Boyle, Newton, and Maxwell by having a law (equation or functional relation) linked with one’s name.”). The paradigmatic laws of nature exclusively cite male scientists.

collaborative and group-driven. Fourth, these laws were cited by the Court at a time when their significance was well-established,¹⁵⁹ with the possible consequence that a law of nature is understood only in hindsight, and most assuredly at a time when any possible patenting would additionally fail for lack of novelty. Such a rearview mirror image of a law of nature would render the patent law exclusion meaningless, as it could not be used to shape any vital, contemporaneous public domain.

Patent jurisprudence provides other examples of scientific relationships which cannot be patented such as the Pythagorean theorem defining geometric relationships ($a^2=b^2+c^2$),¹⁶⁰ the formula for determining the circumference of a circle ($C=2\pi r$),¹⁶¹ the Arrhenius equation,¹⁶² or the multiplication tables.¹⁶³ A common attribute of these exclusions is the existence of an equation or formula that defines a fixed relationship.

Does the concept of a law of nature map onto the biological sciences? Clearly, patent law to date has conceived of such laws using examples drawn from physics. In parallel, the philosophy of science has struggled with whether laws of nature appear in the biological sciences.¹⁶⁴ Why was this question necessary? One reason is that assumptions about the unity of science have influenced the intellectual development of each developing field of science, such that the modern age of biological science may be viewed through cognitive structures developed in physics, resulting in theoretical assumptions regarding similarities between disciplines which do not appear in practice. There is an argument that the "disunity of science" is a more accurate statement of scientific endeavor, and that biological science

¹⁵⁹ Newton's law of gravity was published in *Principia* in 1687. See PETER J. BOWLER & IWAN RHYS MORUS, MAKING MODERN SCIENCE 47 (2005). Einstein published his equation in 1905. See DAVID BODANIS, E = MC²: A BIOGRAPHY OF THE WORLD'S MOST FAMOUS EQUATION 7 (2000).

¹⁶⁰ See *In re Bergy*, 596 F.2d 952, 965 (C.C.P.A. 1979), *vacated sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028 (1980), *aff'd*, 447 U.S. 303 (1980).

¹⁶¹ See *Parker v. Flook*, 437 U.S. 584, 595 (1978).

¹⁶² See *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

¹⁶³ See *Flook*, 437 U.S. at 598 (Stewart, J., dissenting).

¹⁶⁴ See GODFREY-SMITH, *supra* note 145, at 201 ("Over many years, philosophers searched fields like biology for statements of laws of nature.").

presents unique analytic difficulties.¹⁶⁵ The intellectual concepts that shape its public domain may need to reflect this complexity.

It appears that “law of nature” in patent law can be called a term of art, in that the examples provided by the courts relate to scientific relationships which might be contested by some as true laws of nature.¹⁶⁶ For example, Newton’s law of Universal Gravitation did not survive as an exception-less law, and there is commentary noting that Einstein’s formula is not generally described as a law at all.¹⁶⁷ This conceptual fluidity can be advantageous: a dynamic view of laws of nature recognizes that such intellectual creations have an instrumental role which may change over time.

A scientific law, even one exclusively about what we can observe, goes beyond the data available, because it makes a claim which if true is true everywhere and always, not just in the experience of the scientist who formulates the scientific law. This of course makes science fallible: the scientific law, our current best-estimate hypothesis, may turn out to be, in fact usually does turn out to be, wrong. But it is by experiment that we discover this, and by experiment that we improve on it, presumably getting closer to the natural law we seek to discover.¹⁶⁸

It is interesting to compare this theme of adaptability in the philosophy of science with the Constitutional mandate to “promote the Progress of Science and the useful Arts.”¹⁶⁹ The evolution of a science requires knowledge tools which advance the field, and the patent law concept of “laws of nature” can represent the protection of intellectual tools which are used to

¹⁶⁵ See ALEXANDER ROSENBERG, INSTRUMENTAL BIOLOGY OR THE DISUNITY OF SCIENCE 6 (1994) (noting the high degree of complexity posed by biological systems, and stating: “If we were very much smarter, biological theory would be very different, but physical and chemical theory would not be.”).

¹⁶⁶ See Kreiss, *supra* note 117, observing that the named categories of patentable subject matter in 35 U.S.C. § 101 may also be terms of art.

¹⁶⁷ See MUMFORD, *supra* note 144, at 137. In another context, Professor Samuelson observed that the debate over the patenting of mathematical formulae encountered the philosophical dilemma as to whether such tools are invented or discovered and noted: “It quite obviously makes no sense to make the patentability of mathematical formulae turn on whether they are ‘invented’ or ‘discovered,’ for it is impossible to know for certain which is the case.” Samuelson, Benson *Revisited*, *supra* note 16, at 1097 n.274.

¹⁶⁸ ALEXANDER ROSENBERG, PHILOSOPHY OF SCIENCE: A CONTEMPORARY INTRODUCTION 112 (2000).

¹⁶⁹ U.S. CONST. art. I, § 8, cl. 8.

conceptualize uncovered knowledge in order to advance understanding. Does biology have laws of nature? Modern biological research offers some examples. A law of nature underlies the central dogma in molecular biology, namely, the genetic code that defines the relationship between DNA and protein, and preemption of this law of nature undermines the legitimacy of DNA gene patents.¹⁷⁰ Other molecular relationships in biology can be defined similarly. The inverse quantitative relationship between homocysteine and folate or between homocysteine and cobalamin in the patent at issue in *LabCorp* is a paradigmatic example of many binary metabolic relationships which can qualify as laws of nature.¹⁷¹ The validity of any such patent, therefore, must be assessed in view of its possible preemption of the law of nature—does the scientific relationship itself become captured by the patent? Has the scientific community lost meaningful access to the use of this law of nature?

Laws of nature in biology must be understood in context. Any requirement that a law in biology have absolutely universal application cannot be sustained in view of taxonomic diversity, but species-specific knowledge tools are no less essential for scientific work, and may properly be called laws of nature as they become the working truths that describe biological phenomena. Moreover, notions of permanent knowledge structures in the biological sciences must also contend with evolutionary development and change, a reality that can be addressed with a dynamic conception of laws of nature.

If laws of nature are so defined, increasing reductionism in the biological sciences may actually revive and make relevant the seemingly obscure law of nature prohibition, as modern biochemical investigation identifies specific molecular actors and their relationships, leading to patents which attempt to capture these subcellular activities.¹⁷² Developments in nanotechnology

¹⁷⁰ Kane, *supra* note 15, at 752.

¹⁷¹ 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted*, 126 S. Ct. 601 (2005) (No. 04-607). Professor Kreiss notes: "The existence of statistical correlations between a particular biological test and a particular genetic or biological condition is another example of a law of nature." Kreiss, *supra* note 16, at 67 n.251.

¹⁷² Modern biological research is concerned with the identification of new molecules, such as genes and proteins, and with deciphering relationships between such molecules. Many binary relationships, such as inverse or direct quantitative correlations in metabolic cycles, or relay molecular sequences in a signal

could also pose similar dilemmas at the level of atomic or subatomic structure.¹⁷³ It is important that the laws of nature be acknowledged contemporaneously with their characterization, in order that the progress that they facilitate does not await the expiration of a patent term. A vigilance over the encroachment of patenting on fundamental scientific relationships is required in order that the prohibition against private appropriation of the laws of nature is meaningfully observed.

V. THE RELEVANCE OF PATENT ELIGIBILITY

Patent eligibility is a doctrine which often reappears when new technologies or scientific imperatives create the possibility of patenting novel forms of subject matter. It may lie dormant, but it is not obsolete. The doctrine frequently appears to be invisible in the scheme of statutory requirements for patenting, yet it has a distinct gatekeeping function. Because the patentable subject matter doctrine has the delicate role of safeguarding the scientific public domain, it is essential that all stakeholders in the patent system appreciate the availability of the doctrine and its potential. At the level of patent prosecution, PTO review for compliance should take note of the inclusions and the exclusions from patentable subject matter.¹⁷⁴ Patent examiners have few

transduction pathway, could be described in claim terms that might result in private capture of such relationships, which could be described as laws of nature.

¹⁷³ Research in nanotechnology identifies atomic-level materials and structures which exhibit physical properties that diverge from those observed at the larger molecular level. Nanoscience is, at its simplest, the study of the fundamental principles of molecules and structures with at least one dimension roughly between 1 and 100 nanometers." MARK RATNER & DANIEL RATNER, NANOTECHNOLOGY; A GENTLE INTRODUCTION TO THE NEXT BIG IDEA 7 (2003). It is not yet clear if discrete doctrinal difficulties attach to patenting in this field. *See generally* Mark Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601 (2005) (discussing the likelihood of future patent conflicts in the field). With respect to patentable subject matter, the exclusions for natural phenomena and laws of nature might find application for claimed inventions that describe naturally-existing material structures or for claims that attempt to capture the properties observed by such entities or their mechanism of action. Lemley observes that to date, the prohibition on patenting abstract ideas would not have precluded any of the basic patents he identifies in nanotechnology, although the product of nature doctrine might have prevented the patenting of buckminsterfullerenes (carbon-60). *Id.* at 607 n.25 , 614 n.63; *see also* Burk & Lemley, *supra* note 132.

¹⁷⁴ Several recent cases illustrate this vigilance. *In re Bowman*, 61 U.S.P.Q.2d 1669 (B.A.P.I. 2001), involved a PTO rejection for an invention characterized as "nothing more than an abstract idea which is not tied to any technological art, environment, or machine." *Id.* at 1671. *In re Bonczyk*, 10 F. App'x. 908 (Fed. Cir.

explicit prohibitions left when they examine for patentable subject matter, but those that remain are a product of the Supreme Court's insistence on limits which preserve a public domain.

If it is possible to assume that the possession of patentable subject matter is considered during patent prosecution, that assumption does not apply to patent litigation. The likelihood that a lack of patentable subject matter will be raised in litigation is less than the other available statutory grounds for invalidity. Although the issue may not be relevant in many patent disputes, the discussion in Part II described instances where the issue only surfaced in a latent or indirect manner. There are several consequences from the relative invisibility of the patentable subject matter doctrine in litigation. First, a litigant may lose an opportunity for a legitimate challenge to a patent containing questionable subject matter. Second, the nature of *inter partes* litigation offers an advantage for doctrinal development that is lacking in patent prosecution.¹⁷⁵ While there is always a possibility that a trial court will act sua sponte where needed, such reliance is not realistic in view of Professor Rai's observation of "the reality that patent law is suffused with complicated findings of scientific fact"¹⁷⁶ and resulting suggestions that the creation of a specialized trial court for patent law might be necessary.¹⁷⁷ In view of the specialized

2001), the Federal Circuit upheld a PTO rejection for an invention it characterized as an "attempt to claim a form of energy," noting that "[e]nergy . . . is a natural phenomenon that does not qualify as patentable subject matter." *Id.* at 911.

¹⁷⁵ Donald S. Chisum notes that *ex parte* Patent Office adjudication in the absence of persons with active adverse interests results in decisions based on a record which is only the product of the applicant. If an appeal by such an applicant can be taken to the Supreme Court, for example, public input is possible through the filing of amicus curiae briefs by third parties interested in the policy implications of the decision. Professor Chisum further notes that an advantage of a fully litigated, *inter partes* infringement suit is that fact-finding relevant to the impact of the patentable subject matter resolution can occur, with the potential for more specific consideration of the impact of granting a specific patent. Donald S. Chisum, *supra* note 16, n.44 (specifically referring to public interest in the outcome of *Gottschalk v. Benson*, 409 U.S. 63 (1972), noting that the decision in that case would affect a whole category of inventions relating to computer software).

¹⁷⁶ Arti K. Rai, *Patent System Reform: Specialized Trial Courts: Concentrating Expertise on Fact*, 17 BERKELEY TECH. L.J. 877, 897 (2002).

¹⁷⁷ *Id.*; see also Rochelle Cooper Dreyfuss, *The Federal Circuit: A Continuing Experiment in Specialization*, 54 CASE. W. RES. L. REV. 769, 798 (2004); Kimberly A. Moore, *Are District Court Judges Equipped to Resolve Patent Cases?*, 15 HARV. J.L. & TECH. 1 (2001) (reviewing the difficulties faced by district court judges in claim

expertise of the Federal Circuit, the absence of opportunities to review serious allegations regarding the absence of patentable subject matter is unfortunate. Although there are criticisms of excessive forays into fact-finding on the part of the Federal Circuit,¹⁷⁸ the issue of patentable subject matter might benefit from a slightly more activist stance. Following the recent initiative of the Supreme Court with respect to patentable subject matter in *LabCorp*,¹⁷⁹ judicial vigilance during patent disputes may result in further instance of the issue being raised by the courts *sua sponte*.¹⁸⁰ Certainly, the Court's recent reminder of its protection of laws of nature, natural phenomena, and abstract ideas from private appropriation signals an intention to maintain vigilance over the boundaries of patentable subject matter.

There is no statutory recognition of the judicially created exclusions from patentability. This omission could contribute to their invisibility, and to a societal impression that patent law has no limits. A positive legislative enactment, stating that "the following are not eligible for patenting: laws of nature, natural phenomena, and abstract ideas" could more effectively place this protected subject matter within public view.¹⁸¹ Such an enactment would act as legislative bolstering of the constitutional mandate, "[t]o promote the Progress of Science and the useful Arts,"¹⁸² because it would signal the express protection of "the basic tools of scientific and technological work"¹⁸³ that facilitate the progress of scientific research. There is precedent for codification of judicially created doctrines in intellectual property law with special importance for the public domain, such as the idea-expression dichotomy¹⁸⁴ and the fair use defense in

construction).

¹⁷⁸ See Dreyfuss, *supra* note 177, at 798; Rai, *supra* note 176, at 877; William C. Rooklidge & Matthew F. Weil, *Judicial Hyperactivity: The Federal Circuit's Discomfort with its Appellate Role*, 15 BERKELEY TECH. L.J. 725 (2000) (describing Federal Circuit practice of factual inquiry at an appellate level of review).

¹⁷⁹ 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted*, 126 S. Ct. 601 (2005) (No. 04-607).

¹⁸⁰ See *supra* Part II.

¹⁸¹ Such a proposed revision could be codified as 35 U.S.C. § 101(b).

¹⁸² U.S. CONST. art. I, § 8, cl. 8.

¹⁸³ *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

¹⁸⁴ 17 U.S.C. § 102(b) (2000). The doctrine was created in *Baker v. Selden*, 101 U.S. 99 (1879), and generally allows protection of the expression of an idea, but not of the idea itself. The legislative record suggests that its incorporation in the 1976

copyright law.¹⁸⁵ This Article proposes that the patent law exclusions be expressly codified, in order to provide the possibility for a legislative record and to provide public notice, in particular, to the scientific community. Although codification would not guarantee clarity regarding the definition of laws of nature, natural phenomena and abstract ideas, an express recognition in the statute would incorporate the acknowledgement of a public domain that must coexist with private patent rights. Formal notice of this public/private boundary would facilitate the recruitment of scientists to the analytic project of defining the scientific public domain, which is essential in view of the complexity of modern science.

Further reductionism in the research programs of twenty-first century science (such as genomic, proteomics, bioinformatics, and nanotechnology) suggests that patenting efforts at the margins of the unpatentable may be more likely. For example, it is possible to imagine that patenting efforts in nanotechnology, the science of atomic structure and performance, might generate conflicts which further test the limits of the

Copyright was an attempt to make the copyright statute comprehensive. The House Report stated: "Section 102(b) in no way enlarges or contracts the scope of copyright protection under the present law. Its purpose is to restate, in the context of the new single Federal system of copyright, that the basic dichotomy between expression and idea remains unchanged." H.R. REP. No. 94-1476, at 57 (1976), *as reprinted in* 1976 U.S.C.C.A.N., 5659, 5670.

¹⁸⁵ Fair use is a defense in copyright law codified at 17 U.S.C. § 107 in the 1976 Copyright Act. This codification per se did not create clarity about the doctrine and its application. The House Report stated:

Although the courts have considered and ruled upon the fair use doctrine over and over again, no real definition of the concept has ever emerged. Indeed, since the doctrine is an equitable rule of reason, no generally applicable definition is possible, and each case raising the question must be decided on its own facts.

H.R. Rep. No. 94-1476, at 65 (1976), *as reprinted in* 1976 U.S.C.C.A.N., 5659, 5679. Professor Litman reported the limits and benefits of codification:

Each of these general limitations originated in judicial opinions of the nineteenth century. Each appeared in the 1976 Act in response to particular concerns. The codification process introduced its own distortions. The useful articles doctrine, for example, ceased to be a general limitation and became instead a peculiarity of copyright in pictorial, graphic, and sculptural works. The fair use doctrine became encumbered with the idiosyncratic needs of educational users. These doctrines are, however, the most flexible limitations the statute offers in order to balance its expansive rights and broad subject matter.

Jessica Litman, *Copyright Legislation and Technological Change*, 68 OR. L. REV. 275, 341-42 (1989).

exclusions of natural phenomena and laws of nature.¹⁸⁶ The investigations into cellular and subcellular functions in genomics and proteomics could generate patenting efforts which intersect with the product of nature doctrine and/or the prohibition on patenting laws and phenomena of nature.¹⁸⁷ Drawing on insights from the philosophy of science, this Article has articulated a dynamic conception of laws of nature which is contemporaneously useful and which comports with the mandate of the patent system to “promote progress” in the relevant disciplines. Laws of nature in the life sciences must be regarded as working truths for a particular field, reflecting the evolutionary developments and taxonomic diversity that distinguish biology from physics.

Several trends suggest that conflicts over patentable subject matter could emerge more, not less, frequently in the future. The future development of a formal opposition procedure in U.S. patent law could offer the first opportunity for diverse stakeholders to challenge patents for lack of patentable subject matter, as this will likely be one of the available formal grounds for such oppositions.¹⁸⁸ Such an opposition procedure would necessarily facilitate wider public participation in “the care and feeding of the public domain.”¹⁸⁹ The likelihood that challenges for lack of patentable subject matter do not surface in patent litigation because of the shared bias of similarly situated parties suggests a role for dispassionate observers. In tandem with new procedural opportunities, the increased involvement of a vigorous public interest sector in intellectual property policy will likely result in renewed vigilance at the borders of patentable subject matter.¹⁹⁰

¹⁸⁶ See, e.g., Albert P. Halluin & Lorelei P. Westin, *Nanotechnology: The Importance of Intellectual Property Rights in an Emerging Technology*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 220 (2004) (describing initial encounters of nanotechnology with the patent system).

¹⁸⁷ See Kane, *supra* note 15, at 712–13.

¹⁸⁸ See Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 324 (2005). “The issues of invalidity that may be considered during the opposition proceeding are double patenting and any of the requirements for patentability set forth in sections 101, 102, 103, 112 and 251(d).”

¹⁸⁹ See Merges, *supra* note 104, at 184.

¹⁹⁰ For example, the Public Patent Foundation (“PubPat”) is a public interest organization formed in 2003 which “represents the public’s interests against the harms caused by the patent system, particularly the harms caused by wrongly issued patents and unsound patent policy.” Pub. Patent Found., <http://www.pubpat>.

Although conflicts over patentable subject matter are infrequent, they are not trivial. Access to the “basic tools of scientific and technological work”¹⁹¹ must be preserved. The prohibitions on patenting laws of nature, natural phenomena, and abstract ideas can be interpreted broadly or narrowly, with consequences for the integrity of the patent system and the progress of the scientific enterprise. The goals of each, theoretically, are not in conflict.