

RULES AND STANDARDS ON THE FOREFRONT OF
PATENTABILITY

JOHN F. DUFFY*

TABLE OF CONTENTS

INTRODUCTION	610
I. CHALLENGES IN DEFINING THE LIMITS OF PATENTABILITY	616
II. THE HISTORY OF FAILED PATENTABILITY RULES	623
<i>A. The Unpatentability of Changes in Form and Proportions</i>	624
<i>B. The Unpatentability of Plants and Animals</i>	625
<i>C. The Unpatentability of New Uses</i>	632
<i>D. The Unpatentability of Methods of Medical Treatment</i>	634
III. THE MODEST SUCCESS OF PATENTABILITY STANDARDS	638
<i>A. The Unpatentability of Natural Principles and Phenomena</i>	639
<i>B. The Unpatentability of Abstract Ideas</i>	644
IV. THE FATE OF THE RULE FROM THE <i>BILSKI</i> EN BANC	647
CONCLUSION: THE FAILURE OF RULES AND THE VALUE OF FAILURE	651

* Oswald Symister Colclough Research Professor of Law, George Washington University Law School. The author thanks Erick Lee for his tireless research assistance in preparing this Article.

INTRODUCTION

Courts and legislatures face a fundamental dilemma in constructing the law of patents. Patents convey property rights, and a substantial degree of certainty is usually thought to be helpful, or even essential to well functioning property rights.¹ Yet patents also cover invention, and human inventiveness by its nature unsettles

1. See, e.g., Douglas Baird & Thomas Jackson, *Information, Uncertainty and the Transfer of Property*, 13 J. LEGAL STUD. 299, 320 (1984) (concluding that the “wisdom of [the] rules [governing the transfer of property] turns in large measure on how successfully they enable present and would-be property claimants to reduce the uncertainties that every assertion of ownership brings”); Clifford G. Holderness, *A Legal Foundation for Exchange*, 14 J. LEGAL STUD. 321, 322 (1985) (arguing that, as “[a] necessary foundation for exchange[,] ... the law assign all rights in any resource to a closed class of clearly identifiable persons, each of whom is able (both physically and mentally) to contract at any moment”); Troy A. Paredes, *A Systems Approach to Corporate Governance Reform: Why Importing U.S. Corporate Law Isn't the Answer*, 45 WM. & MARY L. REV. 1055, 1133-34 (2004) (assuming that “[l]egal certainty” is “part and parcel of well-defined property rights” and that it “is a valuable asset that facilitates business and investing”). In the courts, the need for certainty in property has long been a dominant theme and has been especially apparent in the doctrine of *stare decisis*. See, e.g., *Payne v. Tennessee*, 501 U.S. 808, 828 (1991) (noting that “[c]onsiderations in favor of *stare decisis* are at their acme in cases involving property and contract rights, where reliance interests are involved”); see also *Hodgson v. Ambrose*, (1780) 99 Eng. Rep. 216, 219 (K.B.) (stating that “[t]he great object, in questions of property, is certainty”). Though this is the traditional view, and courts continue to embrace this view, a growing modern literature has questioned the degree to which certainty is desirable in property rights systems. See, e.g., Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985, 1000-01 (1999) (arguing that uncertainty as to remedy may reduce the deadweight losses associated with patent rights); Ian Ayres & Eric Talley, *Solomonic Bargaining: Dividing a Legal Entitlement To Facilitate Coasean Trade*, 104 YALE L.J. 1027, 1034-35 (1995) (showing that, in certain circumstances, “[l]egal uncertainty or ambiguity about who owns property” might have the beneficial effects in encouraging parties “to act more cooperatively”); Jason Scott Johnston, *Bargaining Under Rules Versus Standards*, 11 J.L. ECON. & ORG. 256, 257 (1995) (concluding that, under certain circumstances, “bargaining may be more efficient under a blurry balancing test than under a certain rule”). Moreover, as another vein of literature emphasizes, supposedly muddled standards may sometimes provide more certainty than a hard-edged rule that does not comport with intuition. See, e.g., Carol M. Rose, *Crystals and Mud in Property Law*, 40 STAN. L. REV. 577, 609 (1988) (arguing that “in some instances, there is a great deal more clarity and certainty about a mud rule than a crystal one” and providing as an example the “commercial reasonableness” test of the Uniform Commercial Code). It is also true that, even excluding the uncertainties of patentable subject matter doctrine, patent rights are well-known to have a high degree of uncertainty both as to the validity and scope of rights. See, e.g., Mark Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. ECON. PERSPECTIVES 75 (2005) (detailing the numerous uncertainties associated with patent rights).

certainty, changes the status quo, and breaks through preexisting assumptions.

In legal doctrine, the conflict between certainty and creativity plays out within the familiar jurisprudential debate between rules and standards.² Clear rules can provide the certainty that encourages investment both in obtaining and developing the rights, but standards can provide the flexibility to accommodate the new and unpredictable wonders of human ingenuity. The stakes of this traditional debate are highest for the doctrine of patentable subject matter, which governs the fundamental boundaries of the patent law's domain.

The latest controversy in the field of patentable subject matter provides a perfect example. In the en banc decision *In re Bilski*,³ rendered in the fall of 2008, the United States Court of Appeals for the Federal Circuit overruled its prior doctrinal test and established a new rule—not a flexible standard—for determining whether a process is patentable subject matter: “[A] claimed process is surely patent-eligible under § 101,” the *Bilski* majority confidently announced, “if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”⁴

The Federal Circuit identified that its overarching goal was to “clarify the standards applicable in determining whether a claimed method constitutes a statutory ‘process’ under § 101.”⁵ Because clarification was the goal, it is unsurprising that the Federal Circuit attempted to articulate a definite rule to govern this area of law, and the court plainly understood that it was choosing to attempt a more rule-based approach in this area of law. The court repeatedly referred to its new doctrine as “the machine-or-transformation test,”⁶

2. The literature has investigated and debated the merits and demerits of rules and standards. See, e.g., Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 YALE L.J. 65 (1983); Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. LEGAL STUD. 257 (1974); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557 (1992); Kathleen M. Sullivan, *The Supreme Court, 1991 Term—Foreword: The Justices of Rules and Standards*, 106 HARV. L. REV. 22 (1992); Cass R. Sunstein, *Problems with Rules*, 83 CAL. L. REV. 953 (1995).

3. 545 F.3d 943 (Fed. Cir. 2008) (en banc), cert. granted sub nom. *Bilski v. Doll*, 129 S. Ct. 2735 (2009).

4. *Id.* at 954 (emphasis added).

5. *Id.* at 949.

6. See, e.g., *id.* at 961, 963-64, 966 (emphasis added).

emphasized that its new test “is the only applicable test and must be applied ... when evaluating the patent-eligibility of process claims,”⁷ and warned that “[n]either the PTO nor the courts may pay short shrift to the machine-or-transformation test by using purported equivalents or shortcuts such as a ‘technological arts’ requirement.”⁸ Nothing in the en banc opinion suggested that the court envisioned that future three-judge panels or Patent and Trademark Office (PTO) examiners would have to weigh and balance a variety of competing policy considerations to apply the court’s new machine-or-transformation test.

In announcing its new test, the *Bilski* court expressly disavowed the analysis that had been set forth in its 1994 en banc decision *In re Alappat*,⁹ and had been applied in its 1998 and 1999 panel decisions, *State Street Bank & Trust Co. v. Signature Financial Group*¹⁰ and *AT&T Corp. v. Excel Communications, Inc.*¹¹ That line of cases had, in turn, disavowed an even earlier test, known as the *Freeman-Walter-Abele* test, which derived from three cases decided between 1978 and 1982.¹² Thus, the Federal Circuit and its predecessor court have changed the rules governing patentable subject matter no less than three times in thirty years.

While it is true that the en banc *Bilski* court was vigorously pursuing the goal of clarifying the law of patentable subject matter, that objective does not distinguish the present from the past. In the now disavowed *AT&T* decision, for example, the Federal Circuit had reassured the practicing bar that the “concern, that the rules [of patentable subject matter] are not sufficiently clear to enable

7. *See id.* at 964.

8. *See id.*

9. 33 F.3d 1526, 1543-44 (Fed. Cir. 1994) (en banc).

10. 149 F.3d 1368 (Fed. Cir. 1998).

11. 172 F.3d 1352 (Fed. Cir. 1999). For the *Bilski* court’s express disavowal of the analysis in this line of cases, see *Bilski*, 545 F.3d at 959-60 & n.19 (stating that the analysis in the *Alappat-State Street-AT&T* line of cases was “inadequate” and “should no longer be relied on”).

12. *See In re Freeman*, 573 F.2d 1237, 1245 (C.C.P.A. 1978), *modifying In re Walter*, 618 F.2d 758, 768 (C.C.P.A. 1980), and *In re Abele*, 684 F.2d 902, 907 (C.C.P.A. 1982). The progression toward disavowing the *Freeman-Walter-Abele* test is detailed in *AT&T Corp.*, when the court reviewed the prior history of the test, noted that *State Street* had questioned its continuing vitality, and concluded that “[w]hatever may be left of the earlier test, if anything, this type of physical limitations analysis [from the *Freeman-Walter-Abele* test] seems of little value.” *AT&T*, 172 F.3d at 1359.

reasonable prediction of outcomes, should be less of a concern today [1999] in light of the refocusing of the § 101 issue that *Alappat* and *State Street* have provided.”¹³ Not only did that reassurance fail to remain valid for the statutory life of a patent (approximately twenty years); it failed to remain good even for the time of prosecuting some patent applications. The very application at issue in *Bilski* had been already pending for two years when the *AT&T* court was touting the clarity that *Alappat* and *State Street* had brought to the law of patentable subject matter.

Since the announcement of the en banc court’s opinion, it has become evident that the Federal Circuit will not have the final word as to whether the machine-or-transformation test will be embraced as a means for clarifying the law of patentable subject matter. On June 1, 2009, the Supreme Court granted certiorari in the *Bilski* case.¹⁴ This development dramatically increases the importance of the case. In light of the Federal Circuit’s past failures to bring clarity to this area, the practicing patent bar—and more importantly their clients, the inventors of our society—might reasonably wonder whether the Supreme Court will also endorse the machine-or-transformation test or some other new rule in an attempt to bring clarity to the area. More importantly, the inventors and their attorneys will want to know (and indeed, to make investments, they may need to know) how durable any new test promulgated by the Supreme Court is likely to be.

That question is vitally important because subject matter doctrine governs the fundamental scope of the patent system. Changes to the doctrine have the potential to exclude from the system whole fields of endeavor, such as financial innovations, data processing methods, operations engineering, and diagnostic techniques. By contrast, changes to other patent doctrines such as obviousness law, enablement requirements, or the doctrine of equivalents might change the fate of *some* claims to invention or infringement. But at least in most instances, those claims would have been recognized as having marginal quality even under a somewhat different set of doctrinal rules.

13. *AT&T*, 172 F.2d at 1361.

14. *Bilski v. Doll*, 129 S. Ct. 2735 (June 1, 2009).

Moreover, clarity without durability has limited value for a system in which long term investment in tomorrow's innovations is supposed to be fostered through property rights lasting for two decades.¹⁵ For such a system, a clear but transient rule may be inferior to a standard that is less clear and less predictable in application, but more durable.

Evaluating the longer historical record, this Article makes two points about rules and standards in this field. First, for patentable subject matter, there is a clear winner in the long run. Eventually, rules always fail. This should surprise no one who studies innovation. The unruly process of creative destruction has the power to undermine today's legal rules every bit as much as it renders obsolete today's industrial products, processes, and institutions. Moreover, the long term failure of rules in defining patentability is also consistent with general models that predict standards to be more durable than rules when conditions are changing, and innovation presents a quintessential circumstance of change.¹⁶ Thus, patent lawyers and inventors need to take into account that any apparent clarity provided by a newly promulgated rule of patentable subject matter may not survive any longer than the rules provided by *Alappat*, *State Street*, *AT&T*, and their predecessors.

A second point, which should also be familiar to students of innovation policy, provides some consolation to the proponents of rules. Just as in innovation generally, failures have value. The short term certainty associated with rules may provide necessary, if temporary, safe harbors that allow property rights to thrive. And even in the long run, the repeated failures of patentable subject matter rules

15. 35 U.S.C. § 154(a)(2) (2006) (establishing twenty year term for patents).

16. See, e.g., Ehrlich & Posner, *supra* note 2, at 277 (noting that “[a]n important cost of legal regulation by means of rules is thus the cost of altering rules to keep pace with economic and technological change” and that “[o]bsolescence is not so serious a problem with regulation by standard”). The vulnerability of rules to obsolescence is also consistent with the view that rules fare better when they are applied to relatively homogeneous circumstances, for temporal change is merely one circumstance that can destroy homogeneity. See *id.* at 272 (predicting greater use of rules “where the relevant primary behavior is homogeneous”); Kaplow, *supra* note 2, at 563 (predicting that rules are more likely to be developed when they will be applied “frequently in settings with common characteristics”); Sunstein, *supra* note 2, at 993 (noting that “[r]ules are often shown to be perverse through new developments that make them anachronistic”).

provide crucial insights into the meaning and process of invention in our society.

This history of failures should not necessarily dissuade courts from ever attempting to create relatively clear rules of patentable subject matter, but the history provides some practical lessons into how courts should go about making and interpreting rules when they do decide to create them. Though knowing their rules will ultimately fail, courts might reasonably decide to fashion rules if the rules have a good chance at meaningful durability, but “durability” in the context of a patentable subject matter rule must, at the very least, exceed the statutory lifetime of a patent. A rule of patentability expected to endure for ten or fifteen years should not be considered a success. For such a short-lived rule, rational inventors would appropriately discount the apparent certainty of today’s rule and attempt, to the extent possible, to average today’s rule with the possible permutations of rules that might follow in future years. Of course, inventors may have very limited ability to forecast the precise contours of future new rules, but their limited ability to forecast the future simply makes the apparent certainty of today’s rule all the more useless.

The need for durability in patentability rules also has a corollary: during its lifetime, the rule must be such that judges of differing policy perspectives can agree to the rule and be willing to tolerate its inevitably formalistic boundaries. Such a rule does not need to approximate the policy preferences of the “median judge,” with an approximate balance between those judges who view the rule as excessively generous and those who view it as excessively restrictive. Indeed, attempts to craft such a “balanced” rule are likely to be counterproductive because such balances can shift fairly quickly as judicial personnel change. Rather, the rule needs to have some basis of certainty that is likely to command enough respect that a majority of future judges will be willing, without regard to their policy views about the rule’s over- or under-inclusiveness, to resist the temptation to recalibrate the rule repeatedly. If that sort of durability and stability cannot be achieved, a court should not strive to clarify the law with a crisp rule because any apparent clarity will be only a temporary illusion.

I. CHALLENGES IN DEFINING THE LIMITS OF PATENTABILITY

The law of patentable subject matter has long been seen as an extremely difficult area of law. Thus, for example, Willard Phillips, one of the great early treatise writers of American patent law, introduced the section of his treatise on “what *kinds* of new inventions are patentable” with the warning that it was “a very difficult branch of the law patents.”¹⁷ So too, the most influential British commentator of the mid-nineteenth century, Thomas Webster, warned readers of the “difficulty” attendant with any attempt “to classify all the subject-matters of letters patent.”¹⁸ Similarly, George Curtis thought that “[l]anguage may be inadequate to express all the minute distinctions which present themselves, in considering what may, consistently with the purposes and objects of the Patent Law, be the subject of a patent.”¹⁹

That long recognized difficulty surely provides one reason that rules have not proven enduring in the area. But why has the field been considered so difficult? Before turning to the legacy of failed rules, we should consider possible answers to that question.

At least three overarching reasons explain why patentable subject matter has long been considered one of the most challenging doctrinal areas of patent law. First, as previously mentioned, changing conditions present well-known difficulties for rules, and the law of patentable subject matter inevitably operates on the ever-changing forefront of human knowledge and creativity. Settled expectations on these frontiers are not possible; forecasting and prognostication are perilous. The problem is especially hard for legal actors who are invariably trained to use precedent as a guide, for the very goal of the patent system is to foster departures from the past in new and unexpected ways. Patent law is designed to bring about the obsolescence of today’s technology; it should be no surprise that the form of lawmaking most susceptible to obsolescence—

17. WILLARD PHILLIPS, *THE LAW OF PATENTS FOR INVENTION* 73 (1837).

18. THOMAS WEBSTER, *THE LAW AND PRACTICE OF LETTERS PATENT FOR INVENTIONS* 8-9 (1841).

19. GEORGE TICKNOR CURTIS, *A TREATISE ON THE LAW OF PATENTS* § 69 (2d ed. 1873).

rules—would experience significant problems in defining the law of patentability.

The challenge of the field is perhaps best summarized by Thomas Webster, who perceptively noted over a century and a half ago that the difficulty in attempting “to classify all subject-matters of letters patent ... arises in great measure from the fact of the arts and manufactures of a country being in a continual state of progression, whereby objects of skill never before contemplated suddenly present themselves.”²⁰ For that reason, Webster preferred the simplicity of the English Statute of Monopolies, which extended patentability to “any manner of new manufactures within this realm” and thus had “comprehensive import” in “point[ing] out distinctly the class of inventions which it is the intention and policy of the legislature to protect.”²¹

The intractability of the ultimate policy issues provides a second cause for the failure of rules in this area. Though the case law of patentable subject matter sometimes frames the issue in semantic terms—for example, as a decision about whether a particular human achievement properly can be considered to be a patentable “invention,” not an unpatentable “discover[y of] a hitherto unknown phenomenon of nature”²²—the more careful judicial opinions recognize that any act, judicial or legislative, creating rules of patentable subject matter should be based on a policy judgment about the efficacy and desirability of patents in the area covered by the proposed rule. Justice Breyer, for example, candidly recognized in his dissenting opinion in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc. (LabCorp)*,²³ that the justification for prohibiting patents on natural laws “does not lie in any claim that ‘laws of nature’ are obvious, or that their discovery is easy, or that they are not useful.”²⁴ “Rather,” Justice Breyer noted, “the reason for the exclusion [from patentable subject matter] is that sometimes *too much* patent protection can impede rather than ‘promote the

20. WEBSTER, *supra* note 18, at 8-9.

21. *Id.* at 8.

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

23. 548 U.S. 124 (2006).

24. *Id.* at 126 (Breyer, J., dissenting).

Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection."²⁵

Justice Breyer's *LabCorp* opinion reveals a key reason for the instability of rules in the area, for the patentable subject matter doctrines are based not on a moral or ethical decision about the desirability of patents as an end in themselves, but on empirical estimation of the usefulness of patents in achieving other ends (progress). It is quite sensible that any exclusion to patentable subject matter should "reflect[] a *basic judgment* that protection in such cases, despite its *potentially positive incentive effects*, would *too often severely interfere with, or discourage*, development and the further spread of useful knowledge itself."²⁶ Unfortunately, no good data exist to make those empirical estimations, or at least no good data exist to make those empirical estimations in a way that could tailor distinct rules about patentability. Indeed, the ultimate policy judgment—the extent to which the potentially positive effects of patents are outweighed by their potential negative effects—has long been recognized as unknown given the current state of human knowledge.

As Fritz Machlup famously summarized society's inconclusive knowledge about the effects of the patent system:

If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.²⁷

Machlup made that statement in 1958, which was six years after Congress last amended the statutory sections on patentable subject matter.²⁸ Rigorous empirical knowledge was obviously more primitive in early times and might well be considered nonexistent in 1793, when the basic format of current § 101 was written into stat-

25. *Id.* at 126-27 (quoting U.S. CONST. art. I, § 8, cl. 8).

26. *Id.* at 127-28 (emphasis added).

27. STAFF OF SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 80 (Comm. Print 1958) (Patent Study of Fritz Machlup).

28. 35 U.S.C. § 101 (2006).

utory law as part of the second United States Patent Act. Thus, if courts look to statutory law, they will not find a satisfying answer to the empirical question that, as Justice Breyer notes, would be the best basis for the law.

Although the statutory law cannot hold the answer to the empirical question posed by Justice Breyer, case law is also an unpromising source of guidance. For example, Breyer's recent dissent in *LabCorp* cites *Neilson v. Harford*,²⁹ *Le Roy v. Tatham*,³⁰ *O'Reilly v. Morse*,³¹ *The Telephone Cases*,³² and *Funk Brothers Seed Co. v. Kalo Inoculant Co.*³³ Only the last of those was even decided in the twentieth century, and all of them were decided prior to Machlup's dismal assessment that mankind possesses hardly any rigorous empirical knowledge about the costs and benefits of the patent system. Furthermore, principles of *stare decisis* require that those earlier cases should provide the foundation for later cases such as *Gottschalk v. Benson*,³⁴ *Parker v. Flook*,³⁵ *Diamond v. Chakrabarty*,³⁶ and *Diamond v. Diehr*.³⁷ Thus, even if knowledge about the effects of the patent system were to have advanced in the half century since Fritz Machlup, the case law might still reflect the past.

The biggest impediment to developing stable patentable subject matter doctrine is not, however, the constraint of *stare decisis*; rather, it is the continuing inability to answer the question identified by Justice Breyer with any rigorous and convincing data. The social costs and benefits of the patent system as a whole remain the subject of fierce debate.³⁸ Given that overarching uncertainty—as to whether to have any patent system at all—it is hardly surprising that courts, legislatures, and other policymaking institutions have trouble answering the marginal question of where the periphery of

29. (1841) 151 Eng. Rep. 1266 (Exch.).

30. 55 U.S. 156 (1853).

31. 56 U.S. 62 (1854).

32. 126 U.S. 1 (1887).

33. 333 U.S. 127 (1948).

34. 409 U.S. 63 (1972); see *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, J., dissenting) (citing these cases).

35. 437 U.S. 584, 585 (1978).

36. 447 U.S. 303 (1980).

37. 450 U.S. 175 (1981).

38. See, e.g., JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE* 144-46 (2008) (collecting empirical data on the private costs and benefits of the patent system and purporting to demonstrate that the system “place[s] a drag on innovation”).

the system should be. Policymakers are thus left to fashion law with intuition, perhaps coupled with a willingness to tolerate some degree of experimentation.

A third reason for the doctrinal difficulties in this area is applicable specifically to the law fashioned by United States courts. For more than two centuries, United States statutory law has defined patentable subject matter in extremely broad terms. The current version of § 101, which was enacted in 1952, states quite simply that anyone who “invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore.”³⁹ Section 101 is also supplemented by § 100(b), which defines the statutory word process as “mean[ing] process, art, or method, and includ[ing] a new use of a known process, machine, manufacture, composition of matter, or material.”⁴⁰ That broad and seemingly unqualified statutory language had only two statutory predecessors—enacted in 1790 and 1793—both of which were also remarkable for their breadth.⁴¹ Thus, the statutory language has consistently pointed toward an expansive approach to patentable subject matter, but the courts have vacillated between quite different approaches to interpreting the statute.

When they have viewed the issue as a matter of statutory interpretation, the courts have generally sustained broad patent eligibility. Thus, in the past three patentable subject matter cases it has decided, the Supreme Court has been guided by textualist instincts. In its 1980 *Chakrabarty* opinion, the Court reasoned that “[i]n choosing such expansive terms as ‘manufacture’ and ‘composition of matter’ [in § 101], modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”⁴² The following year, the Court repeated in *Diamond v. Diehr* its long-standing admonition that “courts ‘should not read into the patent laws limitations and conditions which the legislature has

39. 35 U.S.C. § 101 (2006).

40. 35 U.S.C. § 100(b) (2006).

41. The first U.S. Patent Act in 1790 defined as patentable subject matter “any useful art, manufacture, engine, machine, or device, or any improvement therein.” Act of Apr. 10, 1790, 1 Stat. 109, 110. In 1793, Congress modified the definition of patentable subject matter to be “any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement [thereof].” Act of Feb. 21, 1793, 1 Stat. 318, 319.

42. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

not expressed.”⁴³ Finally, in *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, the Court described the language of § 101 as “extremely broad.”⁴⁴ Not surprisingly, the Court sustained the patentability of the claimed inventions in each of those cases.⁴⁵ These textualist decisions avoid the intractable empirical questions of whether, on average, patents in particular classes advance or retard progress, for the judges adhering to a textualist approach can lay responsibility at Congress’s doorstep.

Contrasting with this textualist approach to the issue, an entirely different methodology for deciding patentable subject matter questions has treated the area as one of federal common law. That approach starts with the judicially recognized exceptions to patentability and tailors the scope of those exceptions either through case law reasoning, or, as Justice Breyer aspired to do in his *LabCorp* dissent, with estimations of the answers to ultimate policy questions such as whether the costs of patent protection outweigh the benefits in any particular area.⁴⁶

It is an understatement to say that there is an obvious and significant tension between the statutory and common law approaches to the patentable subject matter issue. Thus, while the statutory method forbids courts from “read[ing] into the patent laws limitations and conditions which the legislature has not expressed,”⁴⁷ the cases decided under the common law approach “foreclose[] a purely literal reading of § 101”⁴⁸ and make inventions unpatentable even though they fall within “the ordinary sense of the word[s]” of § 101.⁴⁹ When it has felt unencumbered by a literal reading of the statute and the ordinary sense of the statute’s words, the Court has in fact been reading into the statute a set of unexpressed conditions and limitations, and those rules, however transitory they may be, have defined the restrictions imposed on the statute’s text.

43. 450 U.S. 175, 182 (1981) (quoting *Chakrabarty*, 447 U.S. at 308).

44. 534 U.S. 124, 130 (2001).

45. *Id.* at 145-46; *Diehr*, 450 U.S. at 192-93; *Chakrabarty*, 447 U.S. at 347-48.

46. See *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 138-39 (2006) (Breyer, J., dissenting).

47. *United States v. Dubliner Condenser Corp.*, 289 U.S. 178, 199 (1933).

48. *Parker v. Flook*, 437 U.S. 584, 589 (1978).

49. *Id.* at 588.

None of this is to judge whether a statutory or common law approach is more meritorious to the area of patentable subject matter. Rather, the point here is merely that the Court has not consistently adhered to one or the other methodology. The changes in approach perhaps have tracked jurisdictional battles between the Justices. Vacillation between the two approaches has occurred and is at least partly responsible for the instability in the area.

In addition to these general factors making patentable subject matter a difficult area (and an especially difficult area for articulating stable rules), two other factors have tended to operate against patentable subject matter rules in particular contexts. First, the promulgation of rules is generally assumed to require greater amounts of information than does the articulation of standards.⁵⁰ If so, institutions having greater access to information are likely to be more inclined to create rules than are institutions with lesser access.⁵¹ Since repeated experience with a subject is one way to gain information, institutions with greater day-to-day experience with deciding patentability issues should be more willing to attempt to formulate rules. Thus, within the patent system, the PTO should be most inclined to create rules governing patentability, and the Supreme Court should be the least inclined.

Second, an important asymmetry exists in the costs of a rule *restricting* patentable subject matter as compared to the costs of a rule *expanding* patentable subject matter. If an empirical approach similar to Justice Breyer's in *LabCorp* is embraced as the touchstone by which to judge rules of patentable subject matter, the costs associated with rules authorizing a broad approach to patentable subject matter—the costs arising from the possibility that the patent “would *too often severely interfere with, or discourage*, development and the further spread of useful knowledge itself”⁵²—can be mitigated by other patent law doctrines that limit the availability and scope of patents.

50. See, e.g., Kaplow, *supra* note 2, at 585 (“When the government promulgates a rule, it gathers information before individuals act and announces its findings.”).

51. Sunstein, *supra* note 2, at 1003 (predicting that rules will likely be avoided “when the lawmaker lacks information and expertise, so that the information costs are too high to produce rules”).

52. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127-28 (2006) (Breyer, J., dissenting) (emphasis added).

For example, the statutory obviousness doctrine provides courts with a means to restrict the patent system to “those inventions which would not be disclosed or devised but for the inducement of a patent.”⁵³ Indeed, the Supreme Court recently reemphasized that the nonobviousness requirement is designed to eliminate patents that “might stifle, rather than promote, the progress of useful arts.”⁵⁴ Thus, given the nonobviousness doctrine as articulated in *Graham* and *KSR*, it should be a rare situation in which an entire class of patents complies with the nonobviousness requirement and yet still somehow discourages or impedes the development and spread of useful knowledge. Moreover, if such a class of patents can be identified, there are alternatives to restricting patentable subject matter rules, including imposing a more demanding nonobviousness requirement or restricting patent scope through the enablement doctrine or via restrictive claim interpretation. By contrast, patent law itself has no way to remedy the costs of a rule restricting patentable subject matter, which include the loss of the “*potentially positive incentive effects*” associated with granting patents that comply with the nonobviousness requirement and other patent doctrines. As a result, we should expect to observe fewer, and perhaps less durable, rules excluding inventions from patentable subject matter.

The confluence of these factors has produced a clear effect: the law defining limits of patentability has generally been hostile to rule-based approaches, and that hostility has been especially apparent for rules of exclusion at the Supreme Court.

II. THE HISTORY OF FAILED PATENTABILITY RULES

It is tempting to think that the recent instability in the law of patentable subject matter—three different approaches articulated by the Court of Appeals in three decades, with each new one disavowing its predecessor—bespeaks a rather extraordinary time in the history of patentable subject matter. But it is not so. Below is at least a partial list detailing the march of failures in the area.

53. *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966).

54. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 427 (2007).

A. *The Unpatentability of Changes in Form and Proportions*

While most of the rules for finding patentable subject matter have been judicially created, we begin with an example of a legislative rule that was also short-lived. Enacted in 1793, the second patent act in the United States included not only the general statutory formulation of patentable subject matter, but also a very specific rule stating that “simply changing the form or the proportions of any machine, or composition of matter, in any degree, shall not be deemed a discovery.”⁵⁵ Though today we may correctly view that rule as having a distant kinship to modern obviousness doctrine, at the time, the rule was properly characterized as a restriction on patentable subject matter.⁵⁶

How did this early rule fare? Not so well. Almost as soon as courts began to apply it, they began to modify it.⁵⁷ As Chief Justice Marshall summarized the doctrine in 1822:

It is not every change of form and proportion which is declared to be no discovery, but that which is simply a change of form or proportion, and nothing more. If, by changing the form and proportion, a new effect is produced, there is not simply a change of form and proportion, but a change of principle also.⁵⁸

As this passage indicates, the statutory “form and proportions” rule quickly morphed into a more flexible, judicially-created doctrine under which patentability turned less on whether there had been a change in form and proportions and more on whether the innovator’s work had brought forth a “change of principle.” The statutory

55. Patent Act of Feb. 21, 1793, ch. 11, § 2, 1 Stat. 318, 321. The “form or proportions” language was nearly a verbatim translation of an identical provision in the 1791 French Patent Law. See John F. Duffy, *Inventing Invention*, 86 TEX. L. REV. 1, 36 (2007).

56. The 1793 Act’s statutory prohibition on patenting changes in “form or proportions” was drafted as a basic limitation on what could be considered a patentable “discovery.” Patent Act of Feb. 21, 1793, ch. 11, § 2. Commentators of the time included this provision within general discussions of patentable subject matter. See, e.g., PHILLIPS, *supra* note 17, at 126-35 (discussing the “changes in form” doctrine in the chapter on “The Subjects of Patents” and grouping the doctrine at the end of a list of doctrines defining what types of innovations could be patentable).

57. See Duffy, *supra* note 55, at 37.

58. *Davis v. Palmer*, 7 F. Cas. 154, 159 (Va. Cir. Ct. 1827) (No. 3,645) (Marshall, C.J., sitting as Circuit Justice).

“form or proportions” restriction was repealed in 1836,⁵⁹ and though treatises continued to mention the rule throughout the nineteenth century, its importance continued to wane until it was utterly forgotten.⁶⁰ The more flexible “change of principle” concept became dominant, though that too eventually evolved into the modern concept of obviousness.⁶¹

Thus, the history of the doctrine governing “changes in form or proportions” can be seen as a very clear example in which a more flexible standard triumphed in the long run over a *per se* rule. The original legislatively created rule was based on a valid policy concern—that patents should not be granted for minor and insignificant changes. The legislature did not, however, choose merely to announce a general standard prohibiting patents on trivial or easily made inventions. The legislature tried to craft a rule. As is always the case, the rule had some degree of over- and under-inclusiveness. Yet the sharp edges of the rule did not survive long. The court immediately interpreted it in a way that blurred the sharp lines that the legislature had tried to draw, and the legislature itself abandoned the rule within a half century. What was left of the rule—or rather what took the place of the rule—was the “invention” or “nonobviousness” standard, which has now survived more than a century and a half and has come to be adopted throughout the world.

B. The Unpatentability of Plants and Animals

Ever since the Supreme Court’s *Diamond v. Chakrabarty* decision in 1980, it is tempting to think that plants, animals, and other living creations are clearly patentable if the living matter “is the result of human ingenuity and research” rather than a “product of nature[.]”⁶² While that is the law after *Chakrabarty*, it is fairly clear that the rule of practice had previously been the opposite.

59. Compare Patent Act of 1793, ch. 11, § 2, 1 Stat. 318, 321 (repealed 1836) (current version at 35 U.S.C. § 112 (2006)) (providing that “simply changing the form or the proportions of any machine, or composition of matter, in any degree, shall not be deemed a discovery”), with Patent Act of 1836, ch. 357, § 6, 5 Stat. 119 (failing to include the “form or proportions” language).

60. See Duffy, *supra* note 55, at 37-38.

61. See *id.* at 37-41 (tracing that development).

62. *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980).

As mentioned in *Chakrabarty* itself, the Secretary of Agriculture opined to Congress in 1930, when Congress was considering the enactment of the Plant Patent Act, that “the patent laws ... at the present time are understood to cover only inventions or discoveries in the field of inanimate nature.”⁶³ The Supreme Court majority dismissed this assessment by noting that the Secretary of Agriculture lacked “competence” in patent law and by claiming that “there [was] language in the House and Senate Committee Reports suggesting that to the extent Congress considered the matter it found the Secretary’s dichotomy unpersuasive.”⁶⁴

There are huge problems with the Supreme Court’s history here. First, the language in the congressional Committee Reports cited by the Court merely noted that “[t]here [was] a clear and logical distinction *between the discovery of a new variety of plant and of certain inanimate things*.”⁶⁵ As noted by the Court, the Committee Reports explained that a newly discovered inanimate object, such as a new mineral, “is created wholly by nature unassisted by man,” while a newly discovered plant “resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man.”⁶⁶ Yet if anything, the language from the Committee Reports supports the Secretary of Agriculture’s view. For despite the “clear and logical distinction” noted in the Committee Reports—and despite the necessity of human intervention to bring forth and maintain the new cultivated plant—the Reports still make clear that such plants were *not* within the patent system as it then existed.⁶⁷

Second, the Secretary of Agriculture, while not in charge of the patent system, was supposed to be an expert on matters of farming, agriculture, and the plants and animals used in those pursuits.⁶⁸ If he did not have expertise in patent law, it was only because patent

63. *Id.* at 312 (quoting S. REP. NO. 71-315 app. A (1930) and H.R. REP. NO. 71-1129 app. A (1930)).

64. *Id.* at 313.

65. *Id.*

66. *Id.*

67. *Id.*

68. See Act of May 13, 1862, ch. 2, § 1, 12 Stat. 387 (establishing the Department of Agriculture, to be headed by a Commissioner of Agriculture to “diffuse among the people ... useful information on subjects connected with agriculture in the most general and comprehensive sense of the word”).

law had never been construed to permit the patenting of the plant and animal breeds that were important to agriculture. Moreover, when proposals had been made to cover living things with a patent-type system of regulation, the Department of Agriculture was considered one of the most logical government agencies to lead the change.⁶⁹ Indeed, when Congress later enacted the Plant Variety Protection Act in 1970 (which creates exclusive rights for new varieties of plants even if not asexually reproduced), Congress lodged supervisory power over the new Act in the Department of Agriculture.⁷⁰

Third, despite many successful efforts to develop new plant types for agricultural purposes prior to the enactment of the Plant Patent Act, “no instance of anyone attempting to patent a plant under that statute—successfully or unsuccessfully—seems to have been reported,” and “none of the patent law commentators of the day took issue with the generally accepted premise that plants were categorically ineligible for patent protection.”⁷¹ That unbroken and unchallenged practice explains why the enactment of the Plant Patent Act in 1930 was widely viewed as “radically enlarg[ing] the field of patentable inventions.”⁷² Similarly, Thomas Edison praised the new law as “giv[ing] the plant breeder the same status as the mechanical and chemical inventors now have through the patent law.”⁷³ Both of these quotations suggest that the new Plant Patent Act was significant, not because Congress was merely relaxing the written description requirement as applied to plants (which was the *Chakrabarty* Court’s view of what the Plant Patent Act had done), but because Congress was extending the patent system to a wholly new area.

Fourth, both before and after the enactment of the Plant Patent Act, commentators had interpreted the general patent system as

69. See Harold C. Thorne, *Relation of Patent Law to Natural Products*, 6 J. PAT. OFF. SOC’Y 23, 27 (1923) (suggesting that “[t]he Department of Agriculture might be able to have laws enacted on behalf of the plant propagators for compensating them for their valuable discoveries and services in a similar manner”).

70. See 7 U.S.C. §§ 2321-2372 (2006) (establishing the Plant Variety Protection Office in the Department of Agriculture and conferring on the Secretary of Agriculture supervisory powers over the office).

71. John W. Behringer, *Microorganism Patents*, 63 J. PAT. OFF. SOC’Y 128, 130-31 (1981).

72. Joseph Rossman, *Plant Patents*, 13 J. PAT. OFF. SOC’Y 7, 8 (1931).

73. *Id.* (quoting Edison).

inapplicable to living things. Thus, for example, one commentator writing in 1923 opined that “plants and animal organisms, even though very valuable uses may be discovered for them, or they may have been obtained by the aid of scientific management in their propagation, grow as natural products, and as such they are not discoveries which are subject to patentable protection.”⁷⁴ The basic belief thus seemed to be that breeds of plants and animals should be considered “natural” and therefore unpatentable even when the new plant was obtained by human intervention.

Similarly, writing in 1937, seven years after the Plant Patent Act, P. J. Federico opined that one of Louis Pasteur’s claims—directed to “[y]east, free from organic germs of disease, as an article of manufacture”—was “unique in patents in respect of its subject matter.”⁷⁵ At the time of Federico’s article, it was well known that patents could claim purified natural products (that is, products “free from” various other substances).⁷⁶ The “unique”-ness of Pasteur’s claim must have been that it was claiming a living organism—yeast. Such a claim, Federico wrote, “would now probably be refused by the examiner, since it may be doubted that the subject-matter is capable of being patented.”⁷⁷

In 1953, another commentator—one who sought to have a patent-like system extended to all plants (legislatively)—nonetheless recognized:

The protection of biological specimens and products does not fall within the pattern of thinking of those who have regarded the question of patentable classes of inventions and discoveries as confined entirely to things capable of being manufactured. Even the plants covered by the U.S. Patent Plant Act partake of the nature of manufacture, since excluded by the Act are tubers and plants which are sexually reproduced.⁷⁸

74. Thorne, *supra* note 69, at 25. Thorne considered, but rejected, any extension of the patents to living matter, arguing that to have a patent “system in which plant and animal life is involved would be the granting of patents for the use of natural powers and would undoubtedly be of little or no help in promoting progress along those lines.” *Id.* at 28.

75. P. J. Federico, Commentaria, *Louis Pasteur’s Patent*, 19 J. PAT. OFF. SOC’Y. 966, 967 (1937).

76. See *Parke-Davis & Co. v. H.K. Mulford & Co.*, 189 F. 95, 99, 103 (S.D.N.Y. 1911) (L. Hand, J.), *aff’d*, 196 F. 496 (2d Cir. 1912).

77. Federico, *supra* note 75, at 967.

78. John A. Dienger, *Patents for Biological Specimens and Products*, 35 J. PAT. OFF. SOC’Y

In sum, the unpatentability of plants and animals had a solid historical foundation; it was not a position that the PTO newly minted in the 1970s to deny Dr. Chakrabarty a patent.

Still, the Supreme Court's rejection of the old rule was justified. The rule against patenting living material had three significant weaknesses that were becoming all the more glaring as it was being carried forward into more modern times. First, although the prohibition against living matter had been viewed as a mere corollary to the larger principle forbidding patents on natural processes and products, that view was becoming increasingly difficult to sustain as technology marched forward. In earlier times, new types of living organisms had been developed with some assistance of human activity, but the new organisms had come from selective breeding, which relies heavily on *natural* chance and mutation.⁷⁹ In a real sense, nature produced the new organisms, humans merely *selected* the organisms with desirable qualities.

Because nature could be plausibly seen as the primary generator of these new types of living organisms, it was relatively easy to view them as unpatentable. Even some of the broadest words in the statutory definition of patentable subject matter carry definitions that tend to exclude natural phenomena. For example, the word "art," which also appears in the constitutional clause that provides the basic foundation for the federal patent system, was understood at the time when it was written into both statutory and constitutional patent law to refer to the "power of doing something *not taught by nature and instinct*."⁸⁰ The structure and purpose of the

286, 289-90 (1953). Dienner was simultaneously arguing for the enactment of a new system of patent-like protection that would cover all plants and animals, for he saw the limitations of patentable subject matter as retarding the progress of agriculture in comparison to the progress of industry:

The engineers go into manufacturing industry; and industry, being protected by the Patent System, flourishes mightly. Agriculture, on the other hand, being unprotected by any such system as the Patent System, and no incentive on the part of the individual farmer or agricultural worker to produce new varieties of plants and animals, has had to depend upon State subsidy of recent times, having suffered severe blows of deflation in prior times.

Id. at 289.

79. See *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (describing the claimed discovery in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948), as "only some of the handiwork of nature").

80. 1 SAMUEL JOHNSON, A DICTIONARY OF THE ENGLISH LANGUAGE 182 (6th ed. 1785),

Patent Act also strongly point toward an interpretation that excludes natural processes and the products of those processes. Thus, excluding natural products and processes from patentable subject matter seems a sensible interpretation of the statute (and it remains the Supreme Court's interpretation of the statute even after *Chakrabarty*).

The exclusion of living matter from patentability therefore had a firm theoretical basis as long as the rule was seen as deeply connected to the more general principle forbidding patents on natural products. That connection collapsed in the late twentieth century. For example, Chakrabarty's process for making his bacterium—which involved grafting cellular components called plasmids from one bacterium into another⁸¹—seemed to involve a greater degree of human intervention. He was doing more than just selecting the best of nature's products. Denying Chakrabarty a patent on his bacterium seemed to diverge from, and indeed to contradict, the traditional principle that forbade patents on nature's work, but allowed them on the works of human art.

Second, not only did Chakrabarty's invention seem more a product of human intervention and less about natural processes, but the type of human intervention involved was more amenable than selective breeding to the Patent Act's basic requirement that any patented invention must be disclosed through "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same."⁸² Breeders of new plants or animals could not explain through any written description how to recreate those living things. True, other breeders could go through a similar process of breeding, selecting, and breeding again, but there would be no guarantee that natural chance would produce anything similar to what the earlier breeders had found. Rather, to enable someone else to create the living organisms they developed, breeders would have to convey some living sample or specimen, which could then be used to grow or to

available at http://www.archive.org/stream/dictionaryofengl01_johnuoft#page/n182/mode/1up (emphasis added).

81. *Chakrabarty*, 447 U.S. at 305.

82. 35 U.S.C. § 112, ¶ 1 (2006).

create, through natural processes, new specimens.⁸³ In other words, the invention could not be created using information in a written document; a copy of the invention itself was necessary. Forbidding patents on such inventions seemed sensible given the written disclosure requirements in the statute.

Once again, that traditional basis for the rule against patenting living matter was eroding in the late twentieth century. Chakrabarty, in contrast to breeders, could set forth information in a written patent specification that would enable someone else to recreate the invention working from starting materials *other than the invention itself*.⁸⁴ Chakrabarty's work looked to be more scientific, and it was scientific in a way that linked up with a basic goal of the patent system: his work created information that could be disclosed and disseminated through a written document.

Third, and perhaps most importantly, Chakrabarty's case highlighted a significant weakness of any per se rule against patenting living matter: the rule was never thought to extend to prohibit the patenting of novel combinations of living and nonliving material.⁸⁵ That limitation meant that, while the PTO rejected Chakrabarty's claim to his new bacterium, the agency was perfectly willing to allow a claim to an inoculum composed of nothing more than the bacterium plus "a carrier material floating on water, such as straw."⁸⁶ Of course, all rules can lead to situations when a case on one side of the line looks only slightly different from the case on the other. But even accepting that general weakness of rules, the results reached by the PTO in evaluating Chakrabarty's patent claims seemed a little absurd. Under the agency's view, Dr. Chakrabarty's brilliantly constructed and engineered new bacterium was outside the patent system, but if he threw in a bit of

83. *Chakrabarty*, 447 U.S. at 310 (finding Chakrabarty's discovery patentable under § 101 because he had "produced a new bacterium with markedly different characteristics from any found in nature").

84. *Id.* at 305 n.1 (describing Chakrabarty's process).

85. See 1 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* 251-52 (1890) (noting that, in defining the elements of an invention, "[t]he elements, the earth, the animal creation, the members of the human body are as available as the machines and chemical compositions which have resulted from inventive skill"); see also Ruloff F. Kip, Jr., *The Patentability of Natural Phenomena*, 20 GEO. WASH. L. REV. 371, 408 (1951) (citing this passage from the Robinson treatise in support of the position that naturally occurring and living things could be the "constituents of patentable subject matter").

86. *Chakrabarty*, 447 U.S. at 306.

inanimate *straw* (which was dead but used to be alive!), he then had achieved a patentable invention. That result is hugely counter-intuitive, and it was surely one of the biggest weaknesses in the agency's case before the Supreme Court.

C. *The Unpatentability of New Uses*

The prohibition against patenting new uses of old machines is one of the most historically interesting and practically important rules of patentability. The rule is very old, was widely accepted in the nineteenth century,⁸⁷ was adopted by the Supreme Court,⁸⁸ and was ultimately overruled by Congress in 1952.⁸⁹ That last point is perhaps the most significant, for the prohibition on patenting new uses is a clear example in which the judicial gloss on patentable subject matter has been legislatively rejected.

The prohibition against new uses can be traced back at least to Thomas Jefferson. In his famous letter to Isaac McPherson, Jefferson explained that, during his tenure on the early Patent Board (which lasted only from 1790 to 1793), the Board developed some "general rules," including "that a machine, of which we were possessed, might be applied by every man to any use of which it is susceptible, and that this right ought not to be taken from him, and given to a monopolist, because he first perhaps had occasion so to apply it."⁹⁰ Jefferson's rule was endorsed by commentators throughout the nineteenth century, who generally maintained that a new use of an old machine, manufacture, or process was not patentable.⁹¹ By 1875, the rule had received the blessing of the Supreme Court, which unequivocally stated that "it is no new invention to use an old machine for a new purpose."⁹²

87. See *supra* notes 55-56 and accompanying text.

88. See *supra* note 58 and accompanying text.

89. See *supra* Part II.A.

90. Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), <http://memory.loc.gov/master/mss/mtj/mtj1/046/1000/1063.jpg>. Many transcriptions of this letter contain errors that alter the rationale given by Jefferson for the rule. See, e.g., 13 THE WRITINGS OF THOMAS JEFFERSON 326, 335 (Andrew A. Lipscomb ed., 1905) (mistranscribing the final clause in this passage as "because *the first* perhaps had occasion so to apply it" (emphasis added)).

91. See, e.g., CURTIS, *supra* note 19, § 3-4; PHILLIPS, *supra* note 17, at 102-03.

92. *Roberts v. Ryer*, 91 U.S. 150, 157 (1875). The Supreme Court had previously discussed the doctrine forbidding patents on "double uses." In some of those cases, the Court articulated the doctrine narrowly so that new use patents were only barred when the "structure and

Yet this rule did not endure. Even in the middle of the nineteenth century, sophisticated commentators such as George Curtis were hedging their articulations of the rule. Curtis left open the possibility that the rule barring patents on new uses—which he (and others) referred to as the “double use” doctrine—applied only when the new use was “merely analogous to the former occasions or purposes to which the same thing has been applied.”⁹³ But Curtis’s concept of “analogous” was sufficiently broad that it still left many new uses unpatentable. Thus, for example, Curtis expressly considered the case when “it is discovered that a medicine, known and used as a valuable remedy in one class of diseases, has also great efficiency in curing another and different disease.”⁹⁴ To Curtis, that case illustrated an example when the double use doctrine *did apply* and a patent on the new use was *not* available.⁹⁵

As the nineteenth century progressed, however, the “double use” doctrine eroded as the exception to the rule—a new use might be patentable if not analogous to prior uses—gained in importance. Thus, in 1890, William Robinson’s treatise criticized an 1843 circuit opinion by Justice Story because Story had not recognized that new uses were unpatentable only when the new use was “analogous to former uses.”⁹⁶ That same year, the Supreme Court in *Busell Trimmer Co. v. Stevens* opined that the use of gutta-percha as an electrically insulating cover for metallic wires *could be patented*, even though gutta-percha had previously been used as a covering for metallic wires to prevent mechanical abrasion.⁹⁷ The Court explained that the new use was not a

use for a purpose at all analogous to any before made of it; but that it was an entirely new use, the result of a discovery that gutta-percha was an electrical non-conductor, evolved by original

action” of the prior art “suggested to the mind of an ordinarily skilful mechanic this double use to which it could be adapted without material change.” *Tucker v. Spalding*, 80 U.S. 453, 455-56 (1872); *see also* *Washing-Machine Co. v. Tool Co.*, 87 U.S. 342, 351 (1874) (“[T]he new application, without any novel and useful result, could hardly be considered invention. It would be but a case of double use.”). However, these earlier mentions articulated a more limited version of the rule.

93. CURTIS, *supra* note 19, at 120.

94. *Id.*

95. *Id.*

96. ROBINSON, *supra* note 85, at 360.

97. 137 U.S. 423, 434 (1980).

thought, totally different from its quality previously known and applied, as a mere mechanical protector from external injuries.⁹⁸

The Court's teaching in *Busell Trimmer* meant that Jefferson's original rule against patenting new uses was largely dead, because it allowed the patenting of a new use if it was "an entirely new use" based on "original thought."⁹⁹ With that limitation, the new use doctrine, if not yet completely dead, was surely on life support with little chance of recovery. Gradually the courts and commentators began folding what was left of the doctrine into the branch of patentability analysis that would eventually be known as obviousness.¹⁰⁰ When Congress recodified the patent laws in 1952 and legislatively recognized the obviousness doctrine, it simultaneously included language in the new § 100(b) to abolish whatever was left of the old prohibition against patenting new uses.¹⁰¹

D. The Unpatentability of Methods of Medical Treatment

The rule against patenting medical methods is now largely forgotten, but it had life for about three quarters of a century until the Patent Office, which created it, destroyed it.

The rule's origins could be traced to a historically important controversy concerning a famous patent issued to Dr. William G. Morton, a Boston dentist who discovered that ether could be used safely to anesthize patients during surgery.¹⁰² Prior to Morton's work, pain during surgeries was such an enormous problem that surgery was considered "a desperate measure," "as much dreaded by the surgeon and by the patient," and was "employed only when the alternative appeared to be the death of the patient."¹⁰³ Ether had, however, long been known, and even ether's painkilling and sleep-

98. *Id.*

99. *Id.*

100. See Paul Cole, *KSR and Standards of Inventive Step: A European View*, 8 J. MARSHALL REV. INTELL. PROP. L. 14, 20 (2008).

101. See 35 U.S.C. § 100(b) (1952) ("The term process means process, art or method, and includes a new use of a known process, machine, manufacture, composition or matter, or material.").

102. See J.M. Fenster, *How Nobody Invented Anesthesia*, INVENTION & TECH., Summer 1996, at 24, 35.

103. Richard B. Berlin, *History of Anesthesia*, 64 SCI. MONTHLY 530, 530 (1947).

inducing qualities “were commonly known, though considered only for their entertainment value.”¹⁰⁴ Morton discovered the medical use of ether to render patients insensible to the pain of their surgeries, and for that invention he sought and obtained a patent.¹⁰⁵

Morton’s patent generated enormous controversy in part because the American Medical Association (AMA) was generally opposed to all medical patents which, in the AMA’s view, not only were connected with “base profiteering, medical monopolies, and quackery” but also “impeded science and unfettered inquiry, and turned matters of truth and knowledge into business concerns.”¹⁰⁶ Though Morton’s patent was eventually invalidated in the 1862 case *Morton v. New York Eye Infirmary*¹⁰⁷ (and Morton died poor six years later),¹⁰⁸ the *Morton* court did not announce a rule against patenting medical methods but instead relied on the nineteenth-century rule against new use patents. The court noted that, prior to Morton, it had “long been known” that the inhalation of ether “produced an effect like that of intoxication, exhilaration, and more or less stupefaction.”¹⁰⁹ Morton discovered a new use for ether but, the court held, “the application of a well-known agent, by well-known means, to a new or more perfect use” was not patentable.¹¹⁰ Thus, Morton’s patent was a casualty of the nineteenth-century’s rule against new use patents.

Two decades after the *Morton* case, the Patent Office announced in *Ex parte Brinkerhoff* that “methods or modes of treatment of physicians of certain diseases are not patentable.”¹¹¹ Although it

104. Fenster, *supra* note 102, at 28.

105. Morton’s patent was U.S. Patent No. 4848 (1846). Though Morton was widely and popularly credited with the invention of ether as a surgical anesthetic—his 1846 demonstration of ether as an anesthesia astounded the Boston medical community—his claim to being first was hotly disputed throughout his lifetime. See Stephanie Browner, *Ideologies of the Anesthetic: Professionalism, Egalitarianism and the Ether Controversy*, 51 AM. Q. 108, 109-11 (1999) (detailing the enormous controversy over the patent); Fenster, *supra* note 102, at 35.

106. Browner, *supra* note 105, at 124.

107. 17 F. Cas. 879 (C.C.S.D.N.Y. 1862) (No. 8865).

108. Browner, *supra* note 105, at 111.

109. *Morton*, 17 F. Cas. at 882.

110. *Id.* at 883.

111. *Ex parte Brinkerhoff*, 24 Comm’r Manuscript Decision 349 (Pat. Comm’n 1883) (Case No. 182), reprinted in 27 J. PAT. OFF. SOC’Y 797, 798 (1945).

cited and relied on the judicial *Morton* decision,¹¹² the Patent Commissioner's decision was obviously much different, for it barred patents on all methods of treatment even if they did not fall within the traditional restriction of the new use doctrine. The *Brinkerhoff* decision also used different reasoning, claiming that, since treatment methods do not always produce the desired result, patents on such methods "would have a tendency to deceive the public by leading it to believe that the method therein described and claimed would produce the desired result in all cases."¹¹³ That reasoning, like the reasoning that once barred patents on living things, was ultimately grounded in the concern that the written description of the invention would be somehow defective. Yet, as was also the case with the living matter prohibition, the agency stated its rule as a categorical limit on patentable subject matter.

Brinkerhoff's questionable logic was officially abandoned in the 1954 decision *Ex parte Scherer*.¹¹⁴ As noted in *Scherer*, the "only specific reason given" in *Brinkerhoff* to sustain a rule against patenting therapeutic methods was that the patented method might have some "uncertainty of results."¹¹⁵ But that "does not appear to be a valid reason for categorically refusing all methods."¹¹⁶ It is instead "more properly considered under the question of utility,"¹¹⁷ and utility doctrine generally recognizes that an invention may be useful even if it is successful only part of the time.¹¹⁸

The history of the rule against medical treatment patents did not end with *Scherer*. In 1996, Congress granted "medical practitioner[s]" a special immunity against all infringement suits arising

112. *Id.*

113. *Id.* at 798.

114. 103 U.S.P.Q. (BNA) 107, 110 (Pat. Off. Bd. App. 1954) (expressly overruling *Brinkerhoff*). Even before *Scherer*, the Patent Office had issued patents on medical treatments. See William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651, 658-60 (1995) (listing forty-eight selected medical process patents, five of which were issued prior to *Scherer*, and maintaining that such patents are "not a recent phenomenon").

115. *Scherer*, 103 U.S.P.Q. at 110.

116. *Id.*

117. *Id.*

118. See, e.g., *Freedman v. Overseas Scientific Corp.*, 248 F.2d 274, 276 (2d Cir. 1957) (holding that an invention "may have Patentable utility even though the Patented device is not unfaillingly operable in all its applications").

out of any “medical activity.”¹¹⁹ Under the statute, patents covering medical activity are still valid, but one class of potential defendants is exempt from liability.¹²⁰ Thus, the law has given up any exclusion of treatment methods from patentability and has instead focused more narrowly on curtailing the liability of particular defendants. This example illustrates a point previously mentioned: there are alternatives to rules restricting patentable subject matter, and those alternatives may be better able to address any underlying policy concerns. Here, the AMA had long been trying to protect its members (doctors) from legal liability. The AMA concern seems better addressed by a statutory immunity, which accomplishes the organization’s specific goal without completely foreclosing the possibility that the granting of patents for medical treatment could be socially worthwhile.

The four examples of failed rules detailed above—the rules against patenting (i) changes in form and proportions, (ii) living matter, (iii) new uses, and (iv) methods of medical treatment—are only examples of failures, and they are only from the United States doctrine. Other, lesser known failures exist even within United States doctrine.¹²¹ Rules also do not seem to fare better in other

119. 35 U.S.C. § 287(c) (2006).

120. See generally Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PAT. & TRADEMARK OFF. SOC’Y 789 (1996) (describing the history of the 1996 amendment bill and the AMA’s role in supporting it).

121. For example, the Supreme Court once suggested in dicta that buildings and other large structures could not be patented because they were not machines, compositions of matter, or manufactures. See *Jacobs v. Baker*, 74 U.S. (1 Wall.) 295, 297 (1869). That rule of unpatentability was occasionally applied in the lower courts. See *Am. Disappearing Bed Co. v. Arnaelsteen*, 182 F. 324, 325 (9th Cir. 1910) (invalidating a patent on a design for an apartment having a bed that “disappeared” into a recessed compartment). Still, the rule was so nonsensical that, even though it was articulated in Supreme Court dicta, it was eventually thoroughly rejected in the courts of appeals. See, e.g., *Park-In Theaters, Inc. v. Rogers*, 130 F.2d 745, 747 (9th Cir. 1942) (rejecting a categorical prohibition on patents for buildings or structures); *In re Hadden*, 20 F.2d 275, 276 (D.C. Cir. 1927) (holding that a novel grandstand was eligible for a design patent); *Int’l Mausoleum Co. v. Sievert*, 213 F. 225, 228 (6th Cir. 1914) (rejecting the statement in *Jacobs* as dicta and sustaining the patentability of novel burial crypts); *Riter-Conley Mfg. Co. v. Aiken*, 203 F. 699, 702 (3d Cir. 1913) (holding that “the term ‘manufacture’ in the patent law embraces buildings” and that “factors of size and immobility” should not be considered in determining whether an invention falls under this definition). The oddity of the doctrine was apparent. Indeed, in evaluating the eligibility of a grandstand for a design patent, even the Commissioner of Patents remarked that, “[c]uriously enough,” the invention would be clearly patentable “if the grandstand as made by appellant were of a toy character, one that could be picked up and carried around, purchased in a store

countries. For example, the 1973 European Patent Convention attempted to codify a rule forbidding patents on “programs for computers,”¹²² and yet that rule has been so eroded that most commentators and practitioners believe that computer programs have become as patentable in Europe as they are in the United States.¹²³ The failure of patent eligibility rules appears to be a general phenomenon spanning time and geography.

III. THE MODEST SUCCESS OF PATENTABILITY STANDARDS

Patentability determinations are dominated by standards. Generally speaking, an invention may be patented if new, useful, and nonobvious.¹²⁴ The most rule-like of those three requirements—the novelty requirement—nevertheless incorporates standards requiring judgments to be based on multiple factors.¹²⁵ Indeed, the

and carried home, or delivered by the use of a delivery vehicle.” *Hadden*, 20 F.2d at 276 (quoting the decision of the Commissioner of Patents). Yet, as the court of appeals reasoned in *Hadden*, there seems to be no good reason for “size and immobility” to decide patent eligibility issues. *Id.* The modern PTO now devotes an entire art classification (class 52) to “buildings.” See U.S. Patent & Trademark Office, Class 52 Static Structures, <http://www.uspto.gov/go/classification/uspc052/sched052.htm> (last visited Oct. 27, 2009).

122. Convention on the Grant of European Patents (European Patent Convention) art. 52(2)(c), Oct. 5, 1973, 1065 U.N.T.S. 199. The exclusion of patents on “programs for computers” remains in the version of the European Patent Convention that is currently in force. See Convention on the Grant of European Patents (European Patent Convention) art. 52(2)(c), Oct. 5, 1973, as revised by Act Revising the Convention on the Grant of European Patents, Nov. 29, 2000, available at <http://www.epo.org/patents/law/legal-texts/epc.html>.

123. See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 191 (4th ed. 2007) (reviewing the case law and commentary on European software patenting and concluding that “[b]y the early 1990’s, the *de facto* practice of the EPO in the software field was not radically different from that of the U.S. PTO”).

124. *Id.* at 611.

125. A claimed invention is not novel if “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). While that articulation of novelty might sound like a rule, the underlying concepts of “express[.]” and “inherent[.]” description are based on standards that take into account some range of considerations. Thus, an invention will be held to be inherently disclosed only “if it is the ‘natural result flowing from’ the explicit disclosure of the prior art.” *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (quoting *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001)). That standard requires significant judgment about what constitutes a “natural result.” Also, both express and inherent anticipation require a sufficient disclosure so that “[a] person of ordinary skill in the art could practice [the subject matter] without undue experimentation.” *Id.* at 1381. This standard depends on numerous factors to decide the level of “ordinary” skill and the amount of experimentation considered “undue.”

seemingly hard-edged “priority” rules governing which of multiple inventors should be deemed first to invent have been held to be “based on equitable principles and public policy as applied to the facts of each case.”¹²⁶ The requirements of utility and nonobviousness are governed by general standards requiring judgments on a range of factors that admit of no precise lines.¹²⁷ Finally, the amount of disclosure necessary to sustain a patent is similarly regulated by “a standard of reasonableness, having due regard for the nature of the invention and the state of the art.”¹²⁸

This overarching structure of patentability determinations is to be expected because inventions are, by definition, *sui generis* events with which the legal system has no previous familiarity.¹²⁹ It would be wholly surprising if standards did not also dominate in governing what has historically been the most unruly of patentability areas, patentable subject matter. In fact, most patentable subject matter decisions are accounted for by two legal doctrines: (i) the prohibition against natural principles and natural phenomena, and (ii) the doctrine forbidding patents on abstract ideas. Both of these operate much more like standards than rules, and their very malleability has led to their longevity.

A. The Unpatentability of Natural Principles and Phenomena

Beginning in the early nineteenth century, the most important part of patentable subject matter case law has been the doctrine

126. *Paulik v. Rizkalla*, 760 F.2d 1270, 1273 (Fed. Cir. 1985) (interpreting 35 U.S.C. § 102(g) (1982)).

127. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007) (eschewing “rigid and mandatory formulas” in obviousness analysis); *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966) (holding that an invention cannot be considered “useful” within the meaning of 35 U.S.C. § 101 unless the invention has a “substantial utility” with “specific benefit exist[ing] in currently available form”); *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (defining “specific” utility to mean a use that is “not so vague as to be meaningless”).

128. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (citing *Ansul v. Uniroyal, Inc.*, 448 F.2d 872, 878-79 (2d Cir. 1971)) (noting that an invention will be considered enabled if the patent specification can “teach those in the art to make and use the invention without undue experimentation,” and the test of “undue experimentation ... is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations”).

129. See Sunstein, *supra* note 2, at 1003 (noting that rules are less likely to be desirable “when the applications of the legal provision are few in number or relevantly different from one another”).

that a patent could not cover a natural principle. The doctrine might superficially seem to be so clear as to be categorized as a “rule,” but any detailed examination of the case law shows that the doctrine operates much more as a standard, with a wide range of uncertainty and numerous considerations governing its application.

In England, the doctrine was applied in the influential case of *Neilson v. Harford*.¹³⁰ Even in this early case, the uncertainty associated with the doctrine was evident. Neilson discovered that the efficiency of furnaces was increased if the air fed into the furnace to sustain combustion was *hot* air, as opposed to *cold* air.¹³¹ Neilson’s patent covered any furnace having a receptacle for heating the air placed between the apparatus blowing the air into the furnace and the furnace itself. One objection to the patent was that it covered a mere “principle” (neither the court nor the advocates framed the objection as being that the patent covered a “*natural* principle”), and the court seemed to assume that any “patent on a principle” would be void.¹³² Ultimately, however, the court decided that Neilson’s patent was “not merely claim[ing] a principle, but a machine, embodying a principle.”¹³³

Baron Parke’s opinion for the court does not give a full explanation for the reasoning by which the court reached that conclusion. The questioning of counsel, however, reveals that the arguments focused on the degree of disclosure given in the patent. Thus, even the party challenging the patent conceded that the rule against patenting a principle

is theoretically true, but practically it is not true. Practically, you can have a patent for a principle, that is, if you embody your principle in any clear, definite, and distinct form, no other

130. (1841) 151 Eng. Rep. 1266 (Exch.).

131. As the United States Supreme Court would later recognize, Neilson’s contribution could be viewed as “the discovery that hot air would promote the ignition of fuel better than cold.” *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 116 (1853).

132. *Neilson*, 151 Eng. Rep. at 1273 (opining that it was “very difficult” for the judges to distinguish Neilson’s patent specification from “a patent for a principle”); *see also* *Neilson v. Harford*, 1 Webs. Pat. Cas. 295, 342 (1841) (setting out a report of the argument in which Baron Alderson distinguishes “between a patent for a principle, and a patent which can be supported”).

133. *Neilson*, 151 Eng. Rep. at 1273.

person shall be allowed to take that principle and embody it in some other form merely copied from yours.¹³⁴

The crucial difference between the lawyers for the plaintiff and the defendant concerned the degree of specificity needed in the patent. While the defendants maintained that a patentee must “put [the principle] in some *shape*” and the protection of the patent required that “the jury think that that [accused infringer’s] shape is an imitation of [the patentee’s] shape,”¹³⁵ the plaintiffs successfully contended that Neilson did not have to specify any particular form of the air-heating receptacle because modes of heating air were “perfectly well known and practised at the time.”¹³⁶ The split between the plaintiffs and the defendants turned on the sufficiency of Neilson’s specification, and thus the court introduced the “question itself” in the case as “depend[ing] on the proper construction to be put on the specification itself.”¹³⁷

The *Neilson* doctrine against patenting a principle was imported into U.S. law in the celebrated case of *O’Reilly v. Morse*,¹³⁸ which also demonstrated that, in practice, the no-patents-on-principles doctrine turned on the standard for sufficiency of the specification. The *Morse* case restated the rule against patenting principles, though it articulated the doctrine as a prohibition against patenting a “discovery of a principle in natural philosophy or physical science.”¹³⁹ Yet in explaining the invalidity of the broadest claim in Morse’s patent, the Court specifically relied on the statutory requirements for adequate disclosure in the specification and held that “the specification filed” did not support the claim because Morse was attempting to claim “outside of it.”¹⁴⁰

George Ticknor Curtis, the leading American patent commentator at the time, read the *Morse* case as teaching that patentability was

134. *Neilson*, 1 Webs. Pat. Cas. at 343 (argument of Sir F. Pollack for the accused infringer).

135. *Id.* (emphasis added).

136. *Id.* at 345.

137. *Neilson*, 151 Eng. Rep. at 1273.

138. 56 U.S. (15 How.) 62 (1853).

139. *Id.* at 116.

140. *Id.* at 119-20. Earlier in its opinion, the Court also made clear that Morse’s broadest claim was invalid because it failed to meet the written description requirement of the Patent Act. *See id.* at 113 (describing Morse as attempting to claim “a manner and process which he has not *described* and indeed had not *invented*” (emphasis added)).

closely “connected with the construction of particular [patent] specifications.”¹⁴¹ Under *Morse*, Curtis taught, patents could issue for “*the application* of a newly discovered truth in physics,” but the claim must not be “divested” of “all conditions” so as to make the claim “an abstraction.”¹⁴²

In reading *Morse* to turn both on the scope of the disclosure in the patent specification and on the connection between that disclosure and the scope of the patent claim, Curtis was explaining that the apparently rule-like doctrine embraced in *Morse* actually operated more like a standard. As Curtis summarized it, the relevant question was: “*How far* can the characteristic principle of a discovery or an invention be made to extend by letters-patent, when that principle consists in a novel and useful application of some physical law, property of matter, or natural force?”¹⁴³ Yet if the doctrine against patenting principles boiled down to a matter of degree (“How far”), then the doctrine did not have the certitude of a rule. Indeed, in concluding his discussion of the “principle” doctrine, Curtis warned both that “[n]o particular form of words can be suggested capable of general use as a formula,” and that “formularies are of very little use in this branch of the law.”¹⁴⁴

The doctrine against patenting principles was the subject of much commentary and great uncertainty throughout the second half of the nineteenth century.¹⁴⁵ Near the end of the century, William Robinson remarked on the apparent internal contradiction in the judicially made doctrine on patentability: “No proposition has been more frequently or positively stated by the courts than that a principle is not a patentable invention, and yet with almost equal positiveness and frequency they have declared that the subject-matter covered by a patent is the principle of the invention.”¹⁴⁶ A simplistic rejoinder to this apparent internal contradiction is that

141. CURTIS, *supra* note 19, § 124, at 140.

142. *Id.* § 159, at 184-85 (emphasis added).

143. *Id.* § 124, at 140 (emphasis added).

144. *Id.* § 166, at 191-92.

145. *See, e.g.*, ROBINSON, *supra* note 85, § 134, at 190-92 & nn.1-3 (chronicling the uncertainty in the nineteenth-century cases applying the doctrine forbidding patents on principles); S.H.H., *Patenting a Principle*, 7 AM. L. REG. (n.s.) 129, 129 (1868) (introducing the subject with the observation that “[t]he opinions of professional men are far from being settled, apparently, upon all the questions involved in patenting a principle”).

146. ROBINSON, *supra* note 85, § 134, at 190-91 (citations omitted).

the unpatentability of principles always referred to “natural physical force[s],”¹⁴⁷ while patents were supposed to cover the inventor’s principle or contribution, which was properly attributable to the hand of mankind rather than to nature.¹⁴⁸ Yet that distinction is not especially helpful because inventors’ contributions—their principles—function only because they are all grounded in nature’s principles.

Consider, for example, Alexander Graham Bell’s patent, the validity of which was sustained in *The Telephone Cases*.¹⁴⁹ Bell’s claim to telephone technology—his process for transporting speech using undulating electrical current—covers a useful and workable method of telephony only because it is a “natural” principle that a continuous undulating current is capable of carrying the sound of a human voice with sufficiently small distortions that human ears can understand it.¹⁵⁰ Alternatively, if Bell’s invention is considered not to be a “natural” principle merely because nature itself never transports speech using electrical current—that is, nature needs to be artificially harnessed to accomplish that end—then the Supreme Court’s invalidation of Samuel Morse’s broadest patent claim seems unjustifiable. Morse claimed an apparatus capable of using electric current to print characters at a distance,¹⁵¹ and certainly no naturally occurring phenomenon such as electricity accomplishes that goal without human intervention.

One conspicuous passage from *The Telephone Cases* provides the best illustration of why the prohibition against patenting “principles of nature” could not be viewed as a bright-line rule. The Court in *The Telephone Cases* distinguished its earlier ruling in the *Morse* case and held that Bell’s patent could be sustained because Bell did not make any claim covering “the use of a current of electricity in its natural state as it comes from the battery.”¹⁵² The *natural* state of current as it emerges from the *battery*? If the product of a human-made battery is considered a “natural” principle, then it is pretty

147. *Id.* § 138, at 197.

148. *Id.* § 139, at 198.

149. 126 U.S. 1, 572-73.

150. *See id.* at 6-7, 40.

151. *See O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 69 (1854).

152. *Telephone Cases*, 126 U.S. at 534.

easy to see that the distinction between natural and artificial was not the most clear or stable in the law.

Unlike the failed rules of patentable subject matter,¹⁵³ the prohibition against patenting principles of nature still survives, but it survives only because it has incorporated a complex set of factors into its analysis and has thereby heeded Curtis's warning that "formularies are of very little use in this branch of the law."¹⁵⁴ In short, the doctrine has survived precisely because it has been applied more like a standard than a rule.

B. The Unpatentability of Abstract Ideas

The 1978 decision in *Parker v. Flook* was the first Supreme Court opinion to state that the category of "abstract ideas" was unpatentable subject matter.¹⁵⁵ Since then the Court has repeatedly referred to the concept as well-established law.¹⁵⁶ Yet despite its apparently recent origins, the doctrine is in fact quite old,¹⁵⁷ although in the past it was often blended together with the prohibition against patenting mere principles and was grounded in other statutory provisions.¹⁵⁸ History explains why the prohibition against abstractions has been so long-lived: it has textual support in other provisions of the Patent Act, and far from being a crisp rule, it has operated more like one consideration that the courts weigh in judging patentability.¹⁵⁹

These points are evident in two of the early Supreme Court cases applying the doctrine. In the 1853 case of *Le Roy v. Tatham*, the Court used the concept of abstraction in describing the type of principle that was unpatentable, stating, "[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these

153. See *supra* Part II.A-B.

154. CURTIS, *supra* note 19, § 166, at 192.

155. 437 U.S. 584, 589 (1978).

156. See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); see also *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, J., dissenting); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

157. One of the earliest of all Supreme Court patent opinions, *Evans v. Eaton*, noted that the trial judge in that case instructed the jury that "a mere abstract principle cannot be appropriated by patent." 16 U.S. 454, 475 (1818).

158. See *supra* notes 145-49 and accompanying text.

159. See *supra* notes 145-49 and accompanying text.

cannot be patented.”¹⁶⁰ In the 1864 case of *Burr v. Duryee*, the Court identified statutory language to justify the patent law’s hostility to abstractions.¹⁶¹ The Court quoted the statutory requirement that patent applicants disclose their inventions and “particularly point out the part, improvement, or combination which he claims as his own invention or discovery.”¹⁶² Based on that language, the Court held that it found “no authority to grant a patent for a ‘principle’ or a ‘mode of operation,’ or an *idea*, or any other abstraction.”¹⁶³

The Court’s reasoning in *Burr* reveals the textual foundation in the statute that is both the true basis for the prohibition against patents on abstract and the secret to its longevity. Quite apart from § 101 of the Patent Act, an abstract idea could not be patented because abstraction is the very antithesis of the precision required by the disclosure provisions of the Patent Act. For example, under § 112 of the current statute and under similar provisions in all prior patent acts since 1836, the inventor must be able both to write “claims particularly pointing out and distinctly claiming the subject matter” of the invention and to provide a “written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable” the practice of the invention.¹⁶⁴

It may seem to be a puzzle why the prohibition against abstraction has migrated into patentable subject matter doctrine, so that it is now thought of as an interpretation of § 101 rather than § 112, its more obvious textual home. But a similar migration occurred with the doctrines restricting the patentability of living things. There too the true barrier to patentability was the breeder’s inability to satisfy the disclosure requirements, but the problem

160. 55 U.S. (14 How.) 156, 175 (1853).

161. 68 U.S. (1 Wall.) 531, 570 (1864).

162. *Id.* (quoting then existing statutory requirements).

163. *Id.*

164. 35 U.S.C. § 112 (2006). Similar requirements have existed ever since the 1836 Patent Act, which required both a “full, clear, and exact” specification and claims that “particularly specify and point out” the invention. Patent Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119 (repealed 1860). While earlier Patent Acts lacked a claiming requirement, they too demanded precision, not abstraction, in the inventor’s disclosure of the invention. *See* Patent Act of Feb. 21, 1793, ch. 11, § 3, 1 Stat. 318, 321 (repealed 1836) (requiring a disclosure in “full, clear and exact terms”); Patent Act of April 10, 1790, ch. 7, § 2, 1 Stat. 109, 110 (repealed 1793) (requiring the patent specification to be “so particular” and the models or drafts “so exact” as to enable the practice of the invention).

came to be thought of as a patentable subject matter issue.¹⁶⁵ Perhaps there is a fair explanation for these migrations. When the very nature of the alleged invention makes it impossible to satisfy the Patent Act's disclosure requirements, that problem might be better expressed as a patentable subject matter issue than as a failure of disclosure, for that characterization clearly indicates that the barrier to obtaining a patent lies in the nature of the alleged discovery, not simply in the words chosen by the applicant—or more frequently, by the applicant's attorney—to describe and disclose it.

Expressing the doctrine against abstractions as a patentable subject matter issue also produces a collateral benefit. Because the doctrine against abstractions is a general standard without crisp delineations, it is easy to combine with the other patentable subject matter standards. Thus, the doctrine against abstractions may assist in giving content to the doctrine against patenting principles, which has an unavoidable vagueness.¹⁶⁶ The Court's decision in *Parker v. Flook* provides a good example. There the applicant sought a patent on a method for updating an alarm limit for chemical processes, yet the application did “not purport to explain how to select the appropriate margin of safety, the weighting factor, or any of the other variables” and also lacked “any disclosure relating to the chemical processes at work, the monitoring of process variables, or the means of setting off an alarm or adjusting an alarm system.”¹⁶⁷ The Court repeatedly referred both to the doctrine forbidding the patenting of principles or scientific principles and to the doctrine against abstractions.¹⁶⁸ The ambiguity in whether the Court was relying on one or the other is in fact a strength of the opinion, and it is this type of reasoning that should be expected in an area of law unavoidably dominated by standards.

In sum, the traditional doctrines of patentable subject matter—the prohibition against patenting abstract ideas, natural phenomena, and principles of nature—have survived because they have textual bases in the statute and because they have been amorphous.

165. *See supra* Part II.B.

166. *See supra* Part III.A.

167. *Parker v. Flook*, 437 U.S. 584, 586 (1978).

168. *Id.* at 589, 591-92, 599.

IV. THE FATE OF THE RULE FROM THE *BILSKI* EN BANC

The Supreme Court will hear arguments in *Bilski* on November 9, 2009, and thereafter the Court will decide the fate of the rule articulated by the Federal Circuit in its en banc decision.¹⁶⁹ Any discussion of what the Court may do may seem like pointless speculation at this time, but it is not so. This Article puts forward a theory about patentable subject matter doctrine, and the true test of any theory is whether it can render accurate predictions about events in the real world. Thus, the predictions here will eventually serve to validate or to falsify the theory.

The chief prediction of this Article is that the en banc rule will not endure, but this does not necessarily mean that the Supreme Court will reverse the Federal Circuit. Rather, there seem to be three likely outcomes of the case, none of which will produce an enduring and crisp rule of patentability.

First, the Supreme Court could conceivably endorse the Federal Circuit's machine-or-transformation rule. Yet even under this outcome, the crucial issue will be whether that test will endure *as a rule*. The answer already seems apparent in the way the PTO and the lower courts have applied the machine-or-transformation test over the last two years. During this time, the agency has repeatedly held that processes executed on a computer sometimes do *not* qualify as patentable under the machine-or-transformation test. The reasoning is that, if "[a]ny and all computing systems will suffice, [then] the claim is not directed to the function of any particular machine."¹⁷⁰ Yet the agency has not been entirely consistent, and

169. *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008), *cert. granted sub nom. Bilski v. Doll*, 129 S. Ct. 2735 (2009).

170. *Ex parte Langemyr*, Appeal 2008-1495, slip op. at 22 (B.P.A.I. May 28, 2008), *available at* <http://www.uspto.gov/web/offices/dcom/bpai/its/fd081495.pdf>. Similarly, another decision reasoned that a computerized invention was outside of patentable subject matter because it would "cover any and every possible digital computer for executing the [claimed] transformer program." *Ex parte Snyder*, Appeal 2008-4598, slip op. at 22 (B.P.A.I. May 12, 2009), *available at* <http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&fINm=fd20084598-05-12-2009-1>; *see also Ex Parte Nawathe*, Appeal 2007-3360, slip op. at 8 (B.P.A.I. Feb. 9, 2009), *available at* <http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&fINm=fd20073360-02-09-2009-1> (holding a method to be unpatentable because it is tied to "a general purpose processor ... as opposed to a particular computer specifically programmed for executing the steps of the claimed method").

has sometimes held that merely “includ[ing] a step of outputting information from a computer” may be sufficient to make a patent claim “tied to a particular machine or apparatus.”¹⁷¹

Lower courts have also held invalid some process patents even though they are tied to computers. For example, the court in *DealerTrack, Inc. v. Huber* embraced the theory that a “central processor” of “a general purpose computer” does not always “constitute a ‘particular machine.’”¹⁷² Nevertheless, that court hedged its holding, noting that a general purpose computer did not qualify as a particular machine “in this case” where the computer had “been programmed in some unspecified manner.”¹⁷³ Similarly, the court in *Cybersource Corp. v. Retail Decisions, Inc.* reasoned that a patent claim limited to functioning on the Internet was not tied to a particular machine because “the internet is an abstraction. If every computer user in the world unplugged from the internet, the internet would cease to exist, although every molecule of every machine remained in place.”¹⁷⁴

The logic from *Cybersource* may seem especially odd: a car might no longer be called a “car” if it were disassembled into its constituent parts, but that hardly seems sufficient to prove the car to be an abstraction. But the more important lesson from these administrative and judicial rulings is that the machine-or-transformation rule is already disintegrating as a fixed rule. Instead, the decisions are showing inconsistency, as at the PTO; or the reasoning is being limited to the particular facts of “this case,” as the court in *DealerTrack* did; or the machine-or-transformation test is being blended with the doctrine forbidding abstractions, as the *Cybersource* court seemed to be trying to do. If the reasoning of these cases remains incomplete or faulty (and it seems very hard to accept the claim by the *Cybersource* court that disassembly demonstrates abstraction), the explanation is that the machine-or-transformation test itself is not satisfactory and is already evolving into something different that neither the courts nor the agency can yet articulate.

171. See, e.g., *Ex parte Dickerson*, Appeal 2009-001172, slip op. at 16 (B.P.A.I. July 9, 2009), available at <http://des.uspto.gov/Foia/RetrievePdf?system=BPAI&fNm=fd2009001172-07-09-2009-1>.

172. No. CV 06-2335 AG (FMOx), 2009 WL 2020761, at *4 (C.D. Cal. July 7, 2009).

173. *Id.*

174. 620 F. Supp. 2d 1068, 1077 (N.D. Cal. 2009).

Thus, even if it survives Supreme Court review, the machine-or-transformation rule will likely evolve. Perhaps it will follow the path of the old rule against patenting mere changes in form or proportions, which was ultimately transformed into the nonobviousness doctrine. Or perhaps it will follow the path of the rule against patenting new uses, which became so heavily qualified that it was ultimately abandoned. But whatever the direction of its evolution, the machine-or-transformation test is unlikely to remain a crisp, clear rule of patentability.

A second possible outcome of the *Bilski* case is that the Court will reject the machine-or-transformation test, but endorse another rule of the Court's own formulation. Given the breadth of alternatives argued by various amici in the Federal Circuit, the Court will have a large variety of alternative possible rules from which to choose. Yet the possibility of the Court embracing another rule does not seem great. Any such alternative rule would share the greatest legal vulnerability of the machine-or-transformation test—it would lack any textual basis in the governing statute—and in addition, it would lack the support of the agency that would have to administer the rule. But even if the Court were willing to overlook such problems and endorse a rule other than the machine-or-transformation test, that rule would also seem to have little hope of long term survival.

Consider, for example, a rule against patenting any business methods, which might well be the leading contender if the Supreme Court were to adopt a rule other than the machine-or-transformation test. That rule has at least some tradition behind it. Yet that very tradition demonstrates that any prohibition against business methods would not long endure as a “rule.”

Between 1949 and 1995, the Patent Office maintained in its Manual of Patent Examining Procedure (MPEP) a tepid endorsement of a “business method” exception. The 1949 edition of the MPEP stated: “Though seemingly within the category of an ‘art’ or method, the law is settled that a method of doing business can be rejected as not being within the statutory classes.”¹⁷⁵ Two features of that passage are striking. First, the agency conceded that methods of doing business fell within the apparent literal scope of the

175. U.S. PATENT & TRADEMARK OFFICE, U.S. DEPT OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 706.03(a) (1st ed. 1949), available at http://www.uspto.gov/web/offices/pac/mpep/old/mpep_E1R0.htm (citing *Hotel Sec. Checking Co. v. Lorraine Co.*, 160 F. 467 (2d Cir. 1908)).

statutory provisions governing patentable subject matter. Second, the passage stated merely that a method of doing business “can be”—not “must be”—rejected as being outside of patentable subject matter. The case cited by the MPEP relied on the theory that “a mere abstraction” is unpatentable and reasoned that “[a] system of transacting business *disconnected from the means for carrying out the system*” was unpatentable.¹⁷⁶

The traditional reasoning underlying the business method exclusion suggests that the exclusion was never a bright-line rule against patenting the processes and methods of business. It was instead merely a specific articulation of the more general doctrine against patenting abstractions. Indeed, prior to its elimination from the agency’s MPEP in 1995, the PTO was not enforcing the business method exception as a bright-line rule. Patents like the one at issue in *State Street Bank & Trust*—which was directed to a data processing system for “Financial Services”—were being issued while the agency was still enforcing its policy that *some* business methods could be rejected as nonstatutory.¹⁷⁷ Thus, even if a business method exception were revived by the Supreme Court, it would likely return to its preexisting evolutionary course away from being a rule.

The third possible outcome at the Supreme Court is that the rule from the en banc decision in *Bilski* will be rejected. That outcome would not necessarily mean that the inventors in the *Bilski* case would ultimately receive a patent. The claims in the patent would still have to survive scrutiny under the traditional standards associated with patentable subject matter doctrine. One judge at the Federal Circuit suggested that the inventors’ claims might have trouble surviving scrutiny under the prohibition against abstract ideas.¹⁷⁸ And even if the claims are patentable subject matter, they will still need to be evaluated under the statutory standards for novelty, utility, and nonobviousness. If the Supreme Court rejects the en banc rule in *Bilski*, the attempt to articulate a new rule of

176. *Hotel Sec.*, 160 F. at 469 (emphasis added).

177. *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368, 1370 (Fed. Cir. 1998) (noting that the patent at issue was on a “Data Processing System for Hub and Spoke Financial Services Configuration”). That patent had been issued in 1993, years prior to the agency’s repeal of its business method exception rule. See U.S. Patent No. 5,193,056 (filed Mar. 11, 1991) (issued Mar. 9, 1993).

178. *In re Bilski*, 545 F.3d 943, 1011 (Fed. Cir. 2008) (Rader, J., dissenting) (suggesting that the court could have affirmed the rejection of *Bilski*’s patent with “a single sentence: ‘Because Bilski claims merely an abstract idea, this court affirms the Board’s rejection’”).

patentable subject matter will in some sense be a failure, as have been prior attempts to impose limiting rules in the area. Yet even that failure is not without value.

CONCLUSION: THE FAILURE OF RULES AND THE VALUE OF FAILURE

While the historical record shows that relatively clear rules governing patentable subject matter pass away with time, these failures do have value. First and foremost, these rules may provide the necessary stability to allow patents to serve as property rights generally. Even when they are not perfectly clear, rules can serve this function by marking some approximate boundary so that inventors well away from the boundary have more stability. For example, the rule against patenting surgical methods provided some certainty that innovators in medical equipment and pharmaceuticals could continue to receive patents despite more general opposition by doctors and their professional association to any patents in the medical field. The rule barring patents on surgical methods was a temporary compromise that gave a degree of certainty to each side of the debate over medical patents.

The rules of patentability can also promote stability if the rules are generally successful in removing some troubled areas from the patent system. The rules prohibiting new use patents and patents covering mere changes in form and proportions might very well have been somewhat successful in excluding subject matter that today would be barred by the nonobviousness requirement. In a legal system that lacks or is still developing such a requirement, such rules may have been valuable as means for excluding socially pernicious patents that, if they had been issued by the Patent Office and enforced by the court, would have brought the entire patent system into popular contempt.

The ultimate failure of rules might also promote the long term improvement of the law of patents. Several historical examples prove this point. For example, the rule against surgical method patents ultimately led to a restriction on the infringement remedies available against doctors and other medical professionals.¹⁷⁹ So too, the rule against patenting mere changes in form and proportions sparked the development of the nonobviousness requirement in this

179. See 35 U.S.C. § 287(c) (2006).

country,¹⁸⁰ and experiences with the rule against patenting new uses also seems to have contributed to the development of the nonobviousness requirement.¹⁸¹

While each of those last two rules was legislatively repealed or expressly repudiated,¹⁸² their existence during the nineteenth century provides powerful evidence that a legal system lacking a crucial doctrine (as nonobviousness is in patent law) may be forced to develop ad hoc rules to serve the ends that eventually will be filled by a more theoretically rigorous doctrine. Indeed, the temporary rules of patentable subject matter might properly be viewed as experiments in adjusting and refining the patent system. The doctrinal area is a hotbed of evolution; it is where subtle intuitions about the patent system have an initial effect. Those intuitions are encoded into approximate rules, but in the long run, more nuanced and theoretically rigorous doctrine supplants the approximations.

The newly announced patentability rule from the *Bilski* en banc decision, like its predecessors, should not be expected to be a permanent feature of the law. It is a way station from which the law will eventually depart, sooner if the Supreme Court rejects the rule in its upcoming decision, later and in a more evolutionary manner if the rule survives Supreme Court review.

The *Bilski* rule may also provide a hint of the lesson that will ultimately come from this latest attempt to cabin invention with rules: by demanding ties to “particular machines” or “transformations of articles,”¹⁸³ the en banc *Bilski* court was requiring new innovations in business, information processing, and organizational technologies to be tied back to a physical realm in which, through long experience, our language and institutions are better developed for defining inventions. Under this view, the en banc court’s curb on patentable subject matter might not represent hostility to innovations in such newly emerging technologic fields, and indeed the *Bilski* court itself ringingly reaffirms the view that patentable subject matter does not have a “categorical exclusion[]” for business methods.¹⁸⁴ Rather, the en banc court’s restriction might have been grounded in the legitimate concern that the language of business

180. See *supra* Part II.A.

181. See *supra* Part II.C.

182. See *supra* notes 57, 110 and accompanying text.

183. *Bilski*, 545 at 956, 962.

184. *Id.* at 960.

and information technologies has not yet developed sufficiently to support property rights absent some connection to older and more developed fields of engineering.

Such a concern would make sense given the general structure of the Patent Act, which assumes that patented inventions can be described in “full, clear, concise, and exact” language.¹⁸⁵ This concern would also find historical support in prior doctrines that temporarily imposed restrictive rules on patentable subject matter while technological, linguistic, and legal conventions developed sufficiently to manage property rights along new frontiers of innovation. Nevertheless, the overarching lesson from the history of patentable subject matter is very clear: no field of engineering or applied science has long remained outside the boundaries of patentable subject matter. As engineering and applied science develops new fields that are not tied to physical articles, physical machines, and physical sciences, the *Bilski* en banc court’s rule can be expected to follow the path toward obsolescence that no prior rule of patentable subject matter has escaped.

185. 35 U.S.C. § 112, ¶ 1 (2006); *see also id.* ¶ 2 (requiring patents to “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention”).