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MUCH ADO ABOUT PREEMPTION

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ABSTRACT

“Preemption” has emerged as the leading contender for conceptual grounding of the patentable subject matter doctrine’s exclusion of abstract ideas and natural phenomena from patentability. Despite the Supreme Court’s frequent use of preemption rhetoric, however, the concept cannot provide a satisfactory explanation of the Court’s patentable subject matter jurisprudence or a sound theoretical basis for the doctrine. Patentable subject matter jurisprudence has two distinct threads, one concerned with overly broad impact on downstream innovation and the other based on per se exclusion of abstract ideas and natural phenomena from patentability. Most of the Court’s patentable subject matter decisions apply a per se exclusion analysis. While preemption is conceptually related to the downstream impact thread, the term is misleading even in that context. When preemption rhetoric is employed in the majority of cases, which are based on per se exclusion, it leads to confusion and incoherence. This Article disentangles the preemption rhetoric from the per se exclusion analysis in the Supreme Court’s cases. Per se exclusion analysis necessarily involves two steps: identifying the per se excluded elements in a claim and applying some

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rule to determine whether additional claim limitations render the claim patentable. The Article identifies these two steps within the Supreme Court's cases and seeks to prepare the ground for coherent theoretical analysis. Preemption rhetoric is a distraction from important questions that must be answered to give patentable subject matter doctrine a firm theoretical grounding. First, what are the normative bases of the per se exclusions? As the discussion of the cases shows, failing to answer this question leads to seemingly arbitrary (or result-driven) identification of the per se excluded elements in a claim. Second, what rules should be used to determine whether a particular claim incorporating per se excluded elements along with other limitations is patentable subject matter? The current muddle in patentable subject matter analysis is due largely to failure to moor these second-step rules to the normative basis for per se exclusion.

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I. INTRODUCTION

In recent opinions focused on business methods and medical diagnostics, the Supreme Court has called a halt to the seemingly unlimited expansion of patentable subject matter overseen by the Federal Circuit at the turn of the

twenty-first century.¹ Commentators have differed widely in their reactions to those opinions.² Citing the case law's frequent invocation of "preemption," many commentators argue that patentable subject matter exclusion is justified only when a claim has a very broad impact on downstream innovation.³

1. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012) (holding that a medical diagnostic process based on drug metabolite levels in the patient's blood is not patentable); *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010) (holding that claims interpreted as directed essentially to hedging, a basic business practice, were not patentable).

2. See, e.g., Bernard Chao, *Moderating Mayo*, 107 Nw. U. L. REV. COLLOQUY 82, 90–91 (2012) (arguing that *Mayo* has created "panic in the patent world"); Donald S. Chisum, *Weeds and Seeds in the Supreme Court's Business Method Patents Decision: New Directions for Regulating Patent Scope*, 15 LEWIS & CLARK L. REV. 11, 15–17 (2011); Kevin Emerson Collins, *Bilski and the Ambiguity of "An Unpatentable Abstract Idea,"* 15 LEWIS & CLARK L. REV. 37, 65–67 (2011); Rochelle C. Dreyfuss & James P. Evans, *From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1355–57 (2011) ("[T]he Supreme Court provided little concrete guidance on what endeavors were eligible for patenting."); John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1077–78 (2011) (stating that the "most definitive doctrinal outcome" of *Bilski* was its "sweeping aside of [established] formulations without the provision of any replacement"); Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315, 1318–19 (2011); Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1304–05 (2011); Joshua D. Sarnoff, *Patent-Eligible Inventions After Bilski: History and Theory*, 63 HASTINGS L.J. 53, 91–94 (2011); Ted Sichelman, *Funk Forward: Funk Brothers Seed Co. v. Kalo's Pernicious Effects on Patentable Subject Matter in Prometheus and Otherwise*, in INTELLECTUAL PROPERTY AT THE EDGE (Rochelle Dreyfuss, Jane Ginsburg & Carol Rose eds., forthcoming 2013) (manuscript at 1–2) (arguing that problems with today's patentable subject matter doctrine can be traced back to mistakes in a 1948 Supreme Court opinion); Allen K. Yu, *Within Subject Matter Eligibility—A Disease and a Cure*, 84 S. CAL. L. REV. 387, 391–95, 427–29 (2011).

3. See, e.g., Dreyfuss & Evans, *supra* note 2, at 1373–74; Lemley et al., *supra* note 2, at 1328–29. Several commentators who focus on preemption argue that patentable subject matter exclusions are unnecessary to constrain patent scope. Donald S. Chisum, *supra* note 2, at 19, 33–34, devotes most of his time to arguing that there is no need to use patentable subject matter as a scope-limiting doctrine, but also advocates the adoption of a "technological limitation" grounded in the statutory requirement that a patentable invention be "useful" and in the Constitution's grant of power to award patents in the "useful Arts." Ted Sichelman, *supra* note 2, at 6–7, argues that patentable subject matter exemptions should be limited to relatively "pure" abstract ideas, natural laws, and natural phenomena because other claim scope doctrines take care of most overbreadth concerns and the other requirements of patentability (most notably the nonobviousness requirement) are intended to limit patenting to inventions that require the inducement of a patent. See also Kristen Osenga, *Ants, Elephant Guns, and Statutory Subject Matter*, 39 ARIZ. ST. L.J. 1087, 1115–16 (2007) ("Although the proxy-type inquiries may be related to statutory subject matter, they raise separate issues and should be determined separately."). But see Oskar Liivak, *The Forgotten Originality Requirement: A Constitutional Hurdle for Gene Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 261, 264–65, 274 (2005) (arguing that the ban on patenting natural products is based in a constitutional originality requirement); Sarnoff, *supra* note 2, at 90–91 (arguing that "prior-art treatment of newly discovered science, nature, and ideas reflects long-standing

This Article contends that the preemption rhetoric is a red herring. A sole focus on broad downstream impact is unsatisfactory, both as a theoretical matter and as an explanation of the Supreme Court's patentable subject matter jurisprudence. Most of the Court's patentable subject matter decisions rely, instead, on the fact that the claims at issue incorporate subject matter that is deemed per se excluded from patentability. Their outcomes turn, not on overbreadth, but on determining whether the inventor's application of per se unpatentable elements is sufficiently inventive to traverse the boundary between unpatentable and patentable terrain. Current doctrinal and theoretical shortcomings and confusion are exacerbated by attempts to shoehorn this type of analysis into a misunderstood preemption mold.

The doctrine of patentable subject matter is the law's way of delineating the type of thing that cannot be claimed in a patent, no matter how new or useful it might be. Supreme Court case law, beginning in the mid-nineteenth century, has defined the boundary of patentable subject matter primarily by the exclusion of "abstract ideas" and "natural phenomena."⁴ The precise

and deeply held deontological *and* utilitarian moral commitments to protecting the public domain" and that the preemption test is misleading in its focus on claim scope and in its neglect of the requirement that patentable subject matter be sufficiently creative).

4. Recent cases list a trilogy of exclusions for "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Mayo*, 132 S. Ct. at 1293 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)); *Bilski*, 130 S. Ct. at 3253 (Stevens, J., concurring) (same). In other cases, the nature-related exclusions are also described as "natural products" and "scientific principle[s]." *E.g.*, *Chakrabarty*, 447 U.S. at 311 (natural products); *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931) (same); *Diehr*, 450 U.S. at 200 (Stevens, J., dissenting) (scientific principles); *Parker v. Flook*, 437 U.S. 584, 592 (1978) (same). Whether these are separate grounds for exclusion or simply different terms for a common issue has never been clear. Here I use the shorthand term "natural phenomena" to refer to all of these concepts, except where it is necessary to distinguish them. Similarly, the Court has sometimes referred to "mental processes," "abstract intellectual concepts," and simply "idea[s]" as unpatentable without distinguishing them from "abstract ideas." *E.g.*, *Bilski*, 130 S. Ct. at 3258 (Breyer, J., concurring) (quoting *Benson*, 409 U.S. at 67); *Flook*, 437 U.S. at 589 (quoting *Benson*, 409 U.S. at 67); *Benson*, 409 U.S. at 67; *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874). Here I use the term "abstract ideas," except where more specificity is required. The patent statute is of little help in understanding these exclusions, since it says little about patentable subject matter, except to direct that a patent is available for "any new and useful process, machine, manufacture, or composition of matter," that otherwise meets the requirements of patentability, 35 U.S.C. § 101—a formulation that has changed little since the enactment of the first patent statute in 1790. *Compare* 35 U.S.C. § 101 (2006), *with* Act of Apr. 10, 1790 (Patent Act of 1790), ch.7, § 1, 1 Stat. 109, 110 (repealed 1793) (limiting patent availability to "any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used"). Only "process" is defined in the statute and it is tautologically defined to mean "process, art, or method" along with any new use of a "process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b) (2006). Perhaps unsurprisingly, the doctrine of

reasons for these exclusions have been left murky, however, frustrating their implementation and often leading to incoherence in courts' reasoning about whether claims are too abstract or too "natural" to be patentable.

In the latter part of the twentieth century, the Court of Appeals for the Federal Circuit, which is responsible for virtually all appellate review of patent issues, responded to the doctrine's difficulties by nearly eliminating the boundaries of patentable subject matter. The Federal Circuit's test set a very low bar, asking only whether a claimed invention produced a "useful, concrete, and tangible result" (and emphasizing usefulness).⁵ Several commentators similarly advocate the marginalization, or complete abandonment, of the patentable subject matter limitation, arguing that the more manageable doctrines of novelty,⁶ nonobviousness,⁷ claim definiteness, enablement, and written description⁸ are sufficient to winnow out undesirable patent claims.⁹

In the wake of the Supreme Court's recent reaffirmation of patentable subject matter limits, the doctrine is in need of firmer theoretical grounding. As Rebecca Eisenberg recently noted, "patentable subject matter doctrine suffers from a lack of clarity not only as to what the applicable rules are, but also as to what those rules are supposed to accomplish."¹⁰ "Preemption" has emerged as the leading contender for an organizing principle. Preemption was first invoked as a rationale for patentable subject matter exclusion in the case of *Gottschalk v. Benson* in 1972.¹¹ It has been mentioned in nearly every Supreme Court opinion on the topic since.¹²

patentable subject matter has not focused on interpreting these statutory terms, except in the most formalistic sense.

5. *State St. Bank & Trust Co. v. Signature Fin. Grp.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), *abrogated by In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).

6. 35 U.S.C. § 102 (2006).

7. 35 U.S.C. § 103 (2006).

8. 35 U.S.C. § 112 (2006).

9. *See, e.g., Osenga, supra* note 3, at 1115–16 (arguing that patentable subject matter limitations often serve as a proxy for other patentability requirements); Michael Risch, *Everything is Patentable*, 75 TENN. L. REV. 591, 598 (2008).

10. Rebecca S. Eisenberg, *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski*, 3 CASE W. RES. J.L. TECH. & INTERNET 1, 7 (2012).

11. *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972).

12. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012); *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010); *Diamond v. Diehr*, 450 U.S. 175, 203–04 (1981) (Stevens, J., dissenting); *Parker v. Flook*, 437 U.S. 584, 587 (1978); *Benson*, 409 U.S. at 71–72. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), is the exception.

Despite the ubiquity of preemption rhetoric, the concept will not bear the weight of patentable subject matter doctrine. As I will argue, it is of little use in assessing a claim's potential to control or preclude downstream innovation. Moreover, breadth of impact on downstream innovation has not been the primary issue at stake in most of the Supreme Court's patentable subject matter cases. Indeed, *Benson* was arguably the last Supreme Court case in which broad downstream impact was at the heart of the analysis.¹³ Moreover, *Benson*'s reference to preemption was specific to its context, in which the downstream impact of the claims at issue was essentially coextensive with the downstream impact of the underlying algorithm.¹⁴

The emphasis on preemption distracts from analysis of more pertinent theoretical and policy questions: What justifies the per se exclusion of natural phenomena and abstract ideas from patentable subject matter? What can the theoretical inquiry tell us about the proper bounds of such exclusions? Is there theoretical justification for additional exclusions, perhaps for business methods, software, tax methods, or some other category? Or are some of the existing per se exclusions no longer justified? In light of the justifications for per se exclusions, what should an inventor be required to do to move a claim across the boundary from unpatentable to patentable terrain?

This Article begins to untangle these issues by making the case that "preemption" has been over-emphasized and mischaracterized. Per se exclusions, and their theoretical justifications, deserve more attention. This Article lays the groundwork for further theoretical analysis of these questions. In a follow-on article, I will argue that at least some per se exclusions, including notably the exclusion of natural phenomena, are best understood primarily as policy choices between alternative innovation regimes or institutions, rather than as philosophical necessities or moral imperatives. Such an institutional grounding for patentable subject matter doctrine may provide a path forward in dealing with both current and emerging technologies, as well as a theoretical

13. As discussed, *infra*, *Bilski*'s holding also may have been based on broad downstream impact, though the opinion is not clear on this point. See *Bilski*, 130 S. Ct. at 3231 (discussing that to allow a patent on risk hedging would "pre-empt the use of this approach in all fields, and would effectively grant a monopoly over an abstract idea"). In any event, the focus of the opinion was on the boundaries of the per se exclusion for abstract ideas. *Id.*

14. See *Benson*, 409 U.S. at 71–72 (reasoning that to allow a patent on an algorithm by itself would wholly preempt its use in the field).

basis for deciding when a claim has crossed into patentability.¹⁵

Part II of this Article identifies the two major threads—breadth of downstream impact and per se unpatentability—within the Supreme Court’s patentable subject matter case law and delineates their distinct analytical frameworks. Part III focuses on the Court’s analysis of per se patentable subject matter exclusions, demonstrating their prominence in the case law and attempting to disentangle them from the preemption rhetoric. Part IV illustrates the framework presented here by applying it to the case of DNA patents. Part V concludes.

II. RE-READING THE SUPREME COURT’S PATENTABLE SUBJECT MATTER JURISPRUDENCE

The Supreme Court’s articulated reasons for patentable subject matter exclusions consist of two main threads.¹⁶ One thread is concerned with upstream claims that have overly broad effects on downstream innovation.¹⁷ The second thread concerns itself with marking out realms of subject matter that are per se unpatentable. This unpatentable territory is identified in the

15. For discussions of institutional aspects of patentable subject matter, see John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 167–71 (2001); and Gerard N. Magliocca, *Patenting the Curve Ball: Business Methods and Industry Norms*, 2009 BYU L. REV. 875, 889–91. For further examination of the institutional aspects of patent doctrine, see Peter Lee, *The Evolution of Intellectual Infrastructure*, 83 WASH. L. REV. 39, 89 (2008); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 584–85 (1999); Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 U.C. IRVINE L. REV. 265, 280–81 (2011); and Liza Vertinsky, *An Organizational Approach to the Design of Patent Law*, 13 MINN. J. L. SCI. & TECH. 211, 222–26 (2012).

16. Any analysis of the Supreme Court’s patentable subject matter case law confronts a long-standing debate about which, if any, of the older cases cited as authority are “really about” patentable subject matter. Because the current statutory divisions in patentability analysis, not to mention the current requirements for patent claiming, were not always in place, commentators dispute whether pre-1952 Act cases frequently cited for patentable subject matter propositions are better understood as addressed to other aspects of patent doctrine, such as definiteness and scope of claims, enablement, and obviousness. See Golden, *supra* note 2, at 1075–76. I intend to skirt this debate here, because my interest is in parsing the Court’s reasons for drawing the line between the patentable and the unpatentable. Whether these reasons are sound and whether patentable subject matter is the best doctrinal hook for the expressed concerns is left to another day.

17. See, e.g., *Benson*, 409 U.S. at 68, 71–72 (“Here the ‘process’ claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion.”); *Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1, 538–39 (1888); *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1853) (noting that the broad claiming language at issue would allow the patentee to “avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light”).

case law as “laws of nature, physical phenomena, and abstract ideas.”¹⁸ In *Bilski v. Kappos*, four concurring justices argued that business methods also reside in presumptively unpatentable terrain.¹⁹

The downstream impact rationale asks whether a claim’s limitations sufficiently cabin its potential effects on downstream innovation. Often, the analysis focuses on claim scope overbreadth. The per se unpatentable subject matter analysis, on the other hand, considers whether the inventor has contributed a sufficient inventive concept, over and above the per se unpatentable elements.²⁰ In its 1972 opinion in *Benson*, the Court implemented the downstream impact rationale with a reference to “preemption.”²¹ As discussed below, however, the Court’s later references to preemption have not in fact focused the inquiry on the breadth of a claim’s effects on downstream innovation and often are made in the context of a per se exclusion analysis.²² The deployment of preemption as a one-size-fits-all rubric for assessing whether a claim’s limitations are sufficient to bring it within the realm of patentable subject matter is thus the source of considerable confusion.

A. *The Intertwined Threads of Overbroad Downstream Impact and Per Se Exclusion*

The earliest opinion usually cited in patentable subject matter cases is *Le Roy v. Tatham*, which involved a patent on the

18. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). *See also, e.g.*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012); *Bilski*, 130 S. Ct. at 3253 (Stevens, J., concurring) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)); *Parker v. Flook*, 437 U.S. 584, 589 (1978) (quoting *Benson*, 409 U.S. at 67); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (“The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.”); *Mackay Radio & Tel. Co. v. RCA, Inc.*, 306 U.S. 86, 98 (1939) (finding a general application of a scientific formula unpatentable); *DeForest Radio Co. v. Gen. Elec. Co.*, 283 U.S. 664, 684–85 (1931) (“It is the method and device which may be patented not the scientific explanation.”); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852) (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”).

19. *Bilski*, 130 S. Ct. at 3232.

20. *E.g., Mayo*, 132 S. Ct. at 1294 (citing *Flook*, 437 U.S. at 594); *Funk Bros.*, 333 U.S. at 130. *But see Diehr*, 450 U.S. at 177 (stating that industrial processes have historically been patentable subject matter); *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 10–13 (1931) (treating fruit as not patentable because there was insufficient transformation from the natural state).

21. *Benson*, 409 U.S. at 68, 71–72.

22. *See infra* Part III.A.

use of wrought lead rather than cast lead in pipe manufacture.²³ *Le Roy* contains traces of both of the threads woven into the Court's later discussions.²⁴ The opinion asserts, essentially as self-evident, that abstract "principles" and natural "powers" are unpatentable:

A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known. Through the agency of machinery a new steam power may be said to have been generated. But no one can appropriate this power exclusively to himself, under the patent laws. The same may be said of electricity, and of any other power in nature, which is alike open to all, and may be applied to useful purposes by the use of machinery.²⁵

Later, the opinion expresses concerns about the effects on downstream inventors of patents that broadly claim the "results" of a process, foreshadowing the broad downstream impact rationale:

A patent is not good for an effect, or the result of a certain process, as that would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws.²⁶

To round things out, *Le Roy* also explains how per se unpatentable subject matter can be applied in a patentable manner, stating that "the invention is not in discovering [natural powers], but in applying them to useful objects" and that "[a] new property discovered in matter, when practically applied in the construction of a useful article of commerce or manufacture, is patentable."²⁷

In later opinions, these threads are also intertwined, often more or less willy-nilly, and not generally recognized as distinct.²⁸

23. *Le Roy*, 55 U.S. at 167–68.

24. *Id.* at 187.

25. *Id.* at 175.

26. *Id.*

27. *Id.* Anticlimactically, the case was resolved on the comparatively boring basis of construing the scope of the claimed invention to be confined to the machinery used in the process, leaving generations of patent lawyers to speculate as to how "[t]he question whether the newly developed property of lead, used in the formation of pipes, might have been patented, if claimed as developed, without the invention of machinery" might have been resolved. *Id.* at 177.

28. See e.g., *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010); *Gottschalk v. Benson*,

While previous commentators have noted similar distinctions between scope-based and per se rationales for patentable subject matter,²⁹ the recent focus on preemption tends to read the second thread essentially out of the case law by focusing entirely on the overbreadth rationale.³⁰ An analysis that is particularly helpful for conceptually disentangling the threads of the Supreme Court's approach to patentable subject matter comes from Kevin

409 U.S. 63, 71–72 (1972). *Mayo* departs from this trend, however, by separating its primary analysis, based on the per se unpatentability of natural phenomena from a “reinforcing” analysis focusing on “preemption.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302 (2012). The opinion nonetheless adopts from earlier precedent a muddled approach to preemption that mixes rationales. *See id.* at 1294 (warning against “upholding patents that claim processes that too broadly preempt the use of a natural law”).

29. For example, in *The Rules and Standards of Patentable Subject Matter*, Tun-Jen Chiang identifies two different patentable subject matter approaches, which he distinguishes as bright-line rules against patenting certain subject matter and standards that delineate scope. Tun-Jen Chiang, *The Rules and Standards of Patentable Subject Matter*, 2010 WIS. L. REV. 1353, 1356, 1363. Chiang identifies these two approaches with the abstract idea and law of nature exclusions and the natural product and natural phenomenon exclusions, respectively. *Id.* at 1356, 1376, 1381. While I agree with Chiang about the rough contours of the two threads of patentable subject matter discussion and about much in his larger analysis, I do not believe that these two rationales can be allocated in any sensible way among the traditional patentable subject matter exclusions. Dreyfuss and Evans make a similar distinction between “whether” questions about whether inventions in a particular field should be patented and “how” questions about how inventions should be claimed (the preemption questions), but argue that courts focus on the “how” questions. Dreyfuss & Evans, *supra* note 2, at 1356–57. The two threads I identify here are essentially Dreyfuss and Evans’s “whether” and “how” questions. Though I agree with them that the case law provides few answers as to why natural phenomena, abstract ideas, and so forth should be per se unpatentable, I do not agree that concerns about broad downstream impact drive the Court’s analysis in most cases. *Id.* at 1354–55. I discuss this point further below. *See infra* Part III. Alan L. Durham, *Natural Laws and Inevitable Infringement*, 93 MINN. L. REV. 933, 957–58 (2009), distinguishes between patentable subject matter and claim breadth and critiques various justifications for the unpatentability of natural laws and natural phenomena, advocating a patentable subject matter doctrine based on avoiding human mental activity. Richard S. Gruner, *In Search of the Undiscovered Country: The Challenge of Describing Patentable Subject Matter*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 395, 439 (2007), argues for a three-pronged patentable subject matter test derived in part from case law, in which two of the prongs, (“useful design . . . described in sufficient detail to be presently evaluated and implemented by users” and “no special characteristics of . . . the field of the advance that specially justify the withholding of patent rights”) correspond in some respects to the primary threads identified here, while the third (“Use of the advance entails immediately transferable utility . . .”) is similar to the “practical use” strand described below. *Id.* (requiring the use of an advance to immediately transfer utility is essentially requiring the advance to have a practical use).

30. Dreyfuss & Evans, *supra* note 2, at 1356–60 (arguing for a patentable subject matter analysis based explicitly on potential impact on downstream innovation); Lemley et al., *supra* note 2, at 1317 (arguing that the abstract ideas exclusion should focus on “whether the scope of the patentee’s claims is commensurate with the invention’s practical, real-world contribution, rather than asserting coverage over general ideas unmoored to a specific application” and proposing a factor-based test).

Collins, who parses the ambiguities of the term “abstract idea.”³¹ Collins identifies four distinct ways in which a claim might be directed to an abstract idea.³² Two of these ways can be associated with concerns about downstream innovation.³³ First, a claim may be deemed abstract because its scope encompasses a wide swath of claim embodiments.³⁴ The connection with downstream innovation in this case is the concern that the inventor has been awarded rights over many embodiments that he or she did not invent, imposing unwarranted constraints on those who later invent them.³⁵ Second, and distinctly, a claim may be deemed abstract because the *use* of its embodiments is necessary to a wide swath of downstream innovation.³⁶ As Collins points out, this concern may arise even when a claim is limited to a narrow scope of embodiments.³⁷

Collins identifies two other ways in which a claim might be deemed to encompass an abstract idea. First, a claim may be directed to mental processes.³⁸ Second, the claim’s embodiments may be “insufficiently tangible.”³⁹ These, like “natural phenomena,” are examples of potentially per se unpatentable categories,⁴⁰ which are not premised on broad downstream impact.

1. *The Overbroad Downstream Impact Thread.* Though mentioned in passing in *Le Roy*,⁴¹ the downstream impact rationale for the traditional patentable subject matter exclusions gets its most definitive statement in *O’Reilly v. Morse*, where the Court invalidated Morse’s broad claim to “the use of the motive power of the electric or galvanic current, which I call electromagnetism, however developed, for marking or printing intelligible characters, signs, or letters, at any distances.”⁴² As the Court opined:

31. Collins, *supra* note 2, at 44–45 & fig.1.

32. *Id.*

33. *Id.* at 48–60.

34. *Id.* at 50.

35. *Id.* at 52.

36. *Id.* at 58–59.

37. *Id.*

38. *Id.* at 48.

39. *Id.* at 55. The category of insufficiently tangible inventions is of particular interest for its relationship to current debates over the patentability of business methods and the like. *See id.* at 48, 54–55.

40. *See id.* at 48, 54–55.

41. *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 187 (1852).

42. *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 113, 129 (1853).

If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

. . . The court is of opinion that the claim is too broad, and not warranted by law.⁴³

As Collins also discusses, *Morse* is based on a determination that the claim is overbroad in the number of embodiments it encompasses.⁴⁴ Overbreadth of this sort is a matter of claim drafting, rather than of any fundamental incompatibility between Morse's invention and the patent system. The Court specifically holds that Morse is the inventor of the telegraph, which clearly is a patentable technology.⁴⁵ The opinion does not disturb or criticize Morse's narrower claims to that technology.⁴⁶ The broadest claim is invalidated because the Court determines that its scope potentially encompasses so many later-developed embodiments that the patentee's reward of exclusive rights is out of line with his contribution to the technology.⁴⁷

Notably, the dissent in *Morse* articulates essentially what are still the two most common rebuttals to the argument for patentable subject matter exclusion based on overbroad downstream impact. One rebuttal argues that improvement patents will adequately divide returns between the pioneer and later inventors:

The reason given for thus confining the franchise of the inventor of an art to his machines and parts of machinery is, that it would retard the progress of improvement, if those who . . . can devise an improvement in it, should not be allowed to pirate it.

. . . An improvement in a known art is as much the subject of a patent as the art itself; so, also, is an

43. *Id.* at 113.

44. *Id.*; Collins, *supra* note 2, at 52.

45. *Morse*, 56 U.S. at 109.

46. *Id.* at 111–12.

47. *Id.* at 112–13.

improvement on a known machine. Yet, if the original machine be patented, the patentee of an improvement will not have a right to use the original. This doctrine has not been found to retard the progress of invention in the case of machines; and I can see no reason why a contrary one should be applied to an art.

. . . The court, by deciding that this claim is too broad, virtually decides that such an inventor of an improvement may pirate the art he improves, because it is contrary to public policy to restrain the progress of invention.⁴⁸

The second rebuttal argument asserts that a patentee is entitled to claim the full scope of what he has invented:

What is meant by a claim being to [sic] broad? The patent law and judicial decisions may be searched in vain for a provision or decision that a patent may be impugned for claiming no more than the patentee invented or discovered. It is only when he claims something before known and used, something as new which is not new, either by mistake or intentionally, that his patent is affected.⁴⁹

The dissent's argument that an inventor is entitled to a patent on the full scope of his invention, even when the invention is very general, essentially carried the day thirty years later in *Dolbear v. American Bell Telephone Co.*, which concerned Alexander Graham Bell's patent on the telephone.⁵⁰ Considering Bell's claim to "[t]he method of, and apparatus for, transmitting vocal or other sounds telegraphically, as herein described, by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds, substantially as set forth," the Court was unconvinced by an argument that "the claim, if given this broad construction, is virtually 'a claim for speech transmission by transmitting it; or, in other words, for all such doing of a thing as is provable by doing it.'"⁵¹ Emphasizing that Bell had discovered a particular way of transmitting speech "by changing the intensity of a continuous current so as to make it correspond exactly with the changes in the density of air caused by sonorous vibrations," and that this discovery "astonished the scientific world," the Court upheld the broad claim.⁵² As the opinion put it, "[s]urely a patent for such a

48. *Id.* at 133–34.

49. *Id.* at 135.

50. *Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1, 531–33 (1888).

51. *Id.* at 531, 538.

52. *Id.* at 532, 538–39, 572–73.

discovery is not to be confined to the mere means he improvised to prove the reality of his conception.”⁵³

A comparison of *Morse* with *Dolbear* illustrates two things about the overbroad claim scope strand of the overbroad downstream impact thread. First, unless a claim is drafted so broadly that it encompasses more than the inventor can describe and enable or is drafted so vaguely that one cannot determine whether or not a particular instantiation is within its scope, it is very difficult to make a rational determination as to when a claim is broad enough to be “too broad.”⁵⁴ Second, and relatedly, the claim scope rationale is unlikely to bite in cases in which the claims meet the modern requirements of definiteness, enablement, and written description.⁵⁵

In light of the foregoing points, it perhaps should not be surprising that it was nearly a hundred years before the downstream impact rationale again played an important role in a Supreme Court patentable subject matter opinion.⁵⁶ In *Gottschalk v. Benson*, the Court denied patentability to “a method for converting binary-coded decimal (BCD) numerals into pure binary numerals” that was foundational to the then-nascent computer industry.⁵⁷

The result in *Benson* is a relatively straightforward application of a subject matter exclusion based on overbroad downstream impact due to the wide range of potential uses of the claimed technology. Thus, as the Court noted:

[T]he “process” claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary

53. *Id.* at 539.

54. *Compare Morse*, 56 U.S. at 112–13 (“It is impossible to misunderstand the extent of this claim. He claims the exclusive right to every improvement . . .”), *with Dolbear*, 126 U.S. at 535 (“We see nothing in Morse’s case to defeat Bell’s claim It may be that electricity cannot be used at all for the transmission of speech except in the way Bell has discovered, and that . . . his patent gives him its exclusive use for that purpose . . .”). *See Lemley et. al., supra* note 2, at 1317, 1328–31 (comparing *Morse* and *Dolbear*).

55. Many commentators have pointed this out. *See Lemley, supra* note 2, at 1327, 1329–31.

56. *Gottschalk v. Benson*, 409 U.S. 63, 64, 68, 71–72 (1972). During the preceding years, *Morse* was distinguished by the U.S. Supreme Court in several cases involving whether a claim to the “function of a machine” was a patentable process. *See, e.g., Tilghman v. Proctor*, 102 U.S. 707, 708, 726–28, 734 (1880); *Risdon Iron & Locomotive Works v. Medart*, 158 U.S. 68, 71–72, 74–79 (1895); *Boyden Power-Brake Co. v. Westinghouse*, 170 U.S. 537, 578–79 (1898) (Shiras, J., dissenting); *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245, 254–58 (1928). It was also cited in a case interpreting the statutory definiteness requirement. *See Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 2–3, 12 (1946) (noting that patent claims can stifle innovation).

57. *Benson*, 409 U.S. at 64, 68.

conversion. The end use may (1) vary from the operation of a train to verification of drivers' licenses to researching the law books for precedents and (2) be performed through any existing machinery or future-devised machinery or without any apparatus.⁵⁸

The claims in *Benson* thus differed from those in *Morse* with respect to the type of concerns about overly broad downstream impact they raised. *Morse* was concerned with the potential number of downstream *embodiments* encompassed by the claim, while *Benson* is concerned primarily with the number of potential downstream *uses* of the claimed algorithm, rather than the number of potential embodiments.⁵⁹ The BCD conversion algorithm was basic to the use of computers,⁶⁰ which, as general purpose tools, are inputs to wide swaths of downstream innovation. If the use of the algorithm were necessary to the use of computers (or even necessary to a large number of uses of computers), a claim to the BCD conversion algorithm would indubitably have granted extremely broad downstream control over innovation.

Unfortunately, the *Benson* opinion conflated the two types of downstream impact concerns, by citing *Morse* without commenting on the distinction. It also conflated the downstream impact rationale with per se exclusion by equating “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts” with “basic tools of scientific and technological work.”⁶¹ The idea that patents on basic tools can have broad impacts on innovation has been widely discussed by commentators, particularly in the context of the debate over whether there should be a research exemption to patent infringement liability.⁶² Not all “[p]henomena of nature, though

58. *Id.*

59. This distinction is one way to solve the puzzle of the Court's utter lack of interest in the distinction between Claim 8, which is limited to implementing the algorithm using a “reentrant shift register” and Claim 13, which could be infringed using pencil and paper. *Id.* at 64, 73–74.

60. *Id.* at 64–65, 67–68, 71–72.

61. *Id.* at 67; see also *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (quoting *Benson*, 409 U.S. at 67); *Bilski v. Kappos*, 130 S. Ct. 3218, 3253, 3255 (2010) (Stevens, J., concurring) (same); *Parker v. Flook*, 437 U.S. 584, 589 (1978) (same); *In re Bilski*, 545 F.3d 943, 952 (Fed. Cir. 2008), *aff'd sub nom.*, *Bilski v. Kappos*, 130 S. Ct. 3218, (2010) (same); *Diamond v. Diehr*, 450 U.S. 175, 185, 191–93 (1981) (noting the unpatentability of claims to mathematical formulas, scientific principles, and laws of nature).

62. Dreyfuss and Evans make such an argument in the context of gene patenting. Dreyfuss & Evans, *supra* note 2, at 1365–67, 1369 (discussing influence of patenting on genetic research in the development of medical diagnosis techniques and treatments); see also Lee, *supra* note 15, at 64–66 (discussing, in terms of “intellectual infrastructure,” the

just discovered, mental processes, and abstract intellectual concepts” have sweeping downstream impact, however, and the Court’s language has led to confusion, as this Article explains.

The conflation between downstream impact and per se exclusion was exacerbated by the Court’s cryptic “nutshell” explaining its ruling:

It is conceded that one may not patent an idea. But in practical effect that would be the result if the formula for converting BCD numerals to pure binary numerals were patented in this case. The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly preempt the mathematical formula and in practical effect would be a patent on the algorithm itself.⁶³

This nutshell makes sense within the downstream impact rationale. If the BCD conversion algorithm has sweeping downstream implications for innovation because of its many potential uses in digital computers, then Benson’s claims to the use of the algorithm in digital computers would result in essentially the same downstream implications as a claim to the algorithm itself, and thus “wholly pre-empt the mathematical formula.”⁶⁴

Unfortunately, the discussion in the *Benson* opinion is sufficiently opaque that the nutshell may also be read to apply a per se exclusion of abstract ideas, thus entangling per se exclusion with “preemption.” The *Benson* opinion’s conflation of the per se exclusion and overbroad downstream impact threads bears major responsibility for the confused way in which preemption has entered the patentable subject matter analysis, as will be explained in the next section.

Scholarly commentary has also tended to gloss over these distinctions. Thus, most discussions of the preemption rationale focus solely on claim scope overbreadth. Many scholars have argued that, because patent law provides other doctrines, such as enablement, written description, definiteness, and utility for cabining attempts to claim more broadly than warranted by the

effect on innovations of patenting basic tools); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 91–93, 99–100 (“Patents on research tools for which no close substitutes are available are ‘broad’ in the sense that they give the patent holder exclusive control over the development of the research they facilitate.”).

63. *Benson*, 409 U.S. at 71–72.

64. *Id.*

scope of one's invention, the patentable subject matter requirement should play only a modest role,⁶⁵ while some have argued that it is entirely unnecessary.⁶⁶

For example, Lemley and his coauthors, in *Life After Bilski*, see only a limited role for patentable subject matter doctrine, primarily where the disclosure doctrines are inadequate because they need to be satisfied only at the time of patenting.⁶⁷ Their proposed implementation of the preemption rationale focuses on ensuring that patentees do not obtain rights over vast swaths of technology that they did not foresee by considering (1) the “generativ[ity]” of the claimed invention; (2) the prevalence of cumulative innovation in the relevant industry; (3) the pace of innovation in the relevant industry; (4) the fit between the scope of enablement and the breadth of the claim; and (5) the importance of the patentee's advance over the prior art.⁶⁸

Most versions of the overbreadth argument effectively assume that broad effects on downstream innovation come only from claims encompassing a large number of embodiments. This assumption motivates the argument that the statutory claim scope and disclosure doctrines—written description, enablement, utility, and claim definiteness—have rendered patentable subject matter constraints unnecessary.⁶⁹ As noted, broad downstream effects can come not only from a claim's large number of potential embodiments, but also from a wide range of downstream uses.

A recent article by Dreyfuss and Evans recognizes the distinction between claim scope overbreadth and impact on downstream uses and develops an approach to patentable subject matter doctrine that encompasses both types of downstream uses. They argue that patentable subject matter doctrine most properly concerns itself with the stage in the development of a technology at

65. See *supra* note 3.

66. See *supra* note 3.

67. Lemley et al., *supra* note 2, at 1330–31, 1339.

68. *Id.* at 1339–41. Lemley and his coauthors limit their discussion to the “abstract ideas” exclusion, but it seems likely they would apply the same rationale to the exclusion of natural phenomena. Indeed, one coauthor has argued in earlier work that there should be no limits on patentable subject matter beyond those provided by other patent law doctrines. Risch, *supra* note 9, at 592, 596–98 (arguing that subject matter concerns are at bottom patentability concerns). Another coauthor, Ted Sichelman, has argued explicitly that the factors suggested in *Life after Bilski* should control the patentability of claims involving natural phenomena. See Sichelman, *supra* note 2, at 9–13 (applying a five-factor test to a patent claim involving natural phenomenon protection).

69. See Sichelman, *supra* note 2, at 6 (identifying but disagreeing with the view that novelty and nonobviousness serve as “gatekeepers” for patents of questionable validity due to abstract subject matter).

which patenting is appropriate:⁷⁰ “The issue, in short, is timing. Patent claims cannot be made too early in the development of a field because there is a danger of preemption: exclusive rights may preempt others from competing and thereby diminish the vibrancy of the marketplace or the vigor of the creative environment.”⁷¹ Dreyfuss and Evans argue that “there will be situations where even very narrow patents block off too much, especially in areas (like computer science and genetic diagnostics) where applications flow easily from basic discoveries.”⁷² What matters, in other words, is not the scope of a claim, but the size of the downstream innovation “prospect” the claim controls.⁷³ Recognizing this distinction breaks the presumed connection between overbroad downstream impact and scope of claim embodiments and thus explains why an overbreadth-based patentable subject matter limitation is not duplicative of patent law’s scope doctrines. It is also, as already discussed, a much better reading of *Benson*’s concern with patents on “basic tools of scientific and technological work.”⁷⁴

Dreyfuss and Evans take a further step toward a better theorized downstream impact thread when they suggest that the potential downstream impact of a claim should be judged by the degree to which it can be invented around.⁷⁵ They apply this insight to explain why claims to genetic material might be overbroad, even if they are limited to specific embodiments.⁷⁶

As Dreyfuss and Evans recognize, however, the concept of inventing around is dependent upon the level of granularity at which one views an innovative prospect and therefore on the

70. Dreyfuss & Evans, *supra* note 2, at 1357–61. Dreyfuss and Evans use the term “preemption” to mean the downstream impact of a claim. *See id.* at 1355–59 (discussing preemption as the ability of a patent to prevent competition and development). Though this is a very reasonable way to try to make sense of and build on the case law, I do not adopt that approach in this Article because I believe that the term is so thoroughly infected with confusion. I recognize, of course, that the term may be so completely woven into the precedent as to be unavoidable in legal argument.

71. *Id.* at 1356–58. Implicit in their argument is a rejection of any contention that patent incentives are particularly important in nascent technologies. For a contrary perspective, see Ted Sichelman, *supra* note 2, at 13–14 which notes that incentives to invent are provided by patent protection. Dreyfuss and Evans explicitly adopt the Merges and Nelson argument that downstream innovative progress is better produced by competition to make use of upstream technology. Dreyfuss & Evans, *supra* note 2, at 1357–61 (quoting Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 916 (1990)).

72. Dreyfuss & Evans, *supra* note 2, at 1359.

73. *Id.* at 1359–61.

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

75. *See* Dreyfuss & Evans, *supra* note 2, at 1360–61 (discussing the ability to invent around as a “way to grapple with preemption” and “as a clue to patentability”).

76. *Id.* at 1359, 1365–67.

context of a particular downstream innovation.⁷⁷ In the genetic context, for example, Dreyfuss and Evans explain that it may be impossible to invent around gene patents in the diagnostic context while entirely possible to do so in the context of therapeutic uses.⁷⁸ Because of such complexities in determining whether a downstream innovation prospect is too broad, Dreyfuss and Evans argue that the analysis should incorporate other “clues” including, for example, the identity of the inventor, particularly if she happens to be an academic or a user innovator.⁷⁹

Even with the Dreyfuss and Evans improvements, downstream impact alone is not a satisfactory basis for patentable subject matter doctrine. First, as Sichelman argues in *Funk Forward*, patentable subject matter exclusions based entirely on concerns about downstream innovation are questionable in principle essentially because they do not account for the importance of incentivizing the invention of broad upstream technologies.⁸⁰ After all, he argues, the requirements of novelty and nonobviousness are intended to screen out claims to advances that would have been made during the patent term even without the patent incentive.⁸¹ It thus seems ill-advised to exclude from patentability precisely those inventions that are most important for downstream innovation.⁸²

One type of response to arguments such as Sichelman’s (which Sichelman recognizes)⁸³ is that patentable subject matter exclusion is a necessary corrective to the erroneous issuance of invalid patent claims that grant very broad downstream rights.⁸⁴ That response does not adequately counter the contention that patents are needed to incentivize the invention, disclosure, and dissemination of nonobvious upstream technology. While a patentable subject matter exclusion might avoid the erroneous award of patents over *obvious* broad upstream technology, it

77. *Id.* at 1371–72.

78. *Id.* Peter Lee recognizes a similar issue in arguing that whether a particular technology functions as infrastructure can change over time. *See Lee, supra* note 15, at 74–75, 86, 89 (“Patented technologies themselves can rapidly attain infrastructural status as inventive communities come to rely on them as enablers of downstream invention.”).

79. Dreyfuss & Evans, *supra* note 2, at 1374–75.

80. *See Sichelman, supra* note 2, at 13–14.

81. *See id.* at 7.

82. *See id.* at 4–7 (“[O]ne need not eliminate conventional applications of laws of nature from patentability to ensure that future innovation involving those laws is not unduly retarded.”).

83. *Id.* at 7–8.

84. *See Eisenberg, supra* note 13, at 41–42.

simultaneously reduces the patent system's ability to incentivize the development of *nonobvious* broad upstream technology. Errors in both directions are likely to inflict high social costs, yet nothing internal either to the downstream impact thread or to the corrective argument permits one to determine which costs will be higher. Failure to account for incentives to invent upstream technology is a general weakness of the downstream impact rationale that deserves more theoretical attention.⁸⁵

In any event, while the downstream impact rationale can justify the unpatentability of *some* natural phenomena and abstract ideas, it is not an adequate explanation for their wholesale exclusion, nor can it make sense of the Supreme Court's patentable subject matter jurisprudence.

2. *The Per Se Exclusion Thread.* Many of the Supreme Court's patentable subject matter decisions rest on the per se exclusion of natural phenomena and abstract ideas rather than on the broad downstream reach of the claims at issue. To demonstrate this, one must show, first, that there are categories of subject matter that are excluded from patentability per se, without reference to their downstream impact on innovation and second, that the Court's application of those categories to particular claims is not simply equivalent to asking whether the claims at issue have overbroad downstream impact.

As to the first point, the rule that natural phenomena and abstract ideas are per se unpatentable, without regard for their downstream impact, is so deeply rooted in the case law as to be almost invisible. From *Le Roy v. Tatham* through *Mayo v. Prometheus*, the Supreme Court repeatedly simply states, categorically, that natural phenomena and abstract ideas are unpatentable.⁸⁶ The Court declares the unpatentability of the potentially mundane "new mineral discovered in the earth" and "new plant found in the wild," as well as of Einstein's "celebrated law that $E=mc^2$ " and Newton's "law of gravity."⁸⁷ While *Benson's* algorithm undoubtedly cut a very wide swath,

85. BRETT FRISCHMANN, INFRASTRUCTURE: THE SOCIAL VALUE OF SHARED RESOURCES ch.XII (2012), takes a step in this direction by conceptualizing patentable subject matter as a doctrine defining a set of "intellectual infrastructure" that, like other infrastructure, often is not best provided by the standard market approach.

86. *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Parker v. Flook*, 437 U.S. 584, 589 (1978); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Bilski v. Kappos*, 130 S. Ct. 3218, 3229–30 (2010); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012).

87. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Diehr*, 450 U.S. at 185 (quoting *Chakrabarty*, 447 U.S. at 309)).

the equally unpatentable algorithm for calculating an alarm limit for hydrocarbon processing in *Parker v. Flook* certainly cut a smaller one,⁸⁸ and the claims to methods of hedging risk in commodities trading considered in *Bilski v. Kappos* varied in the amount of downstream innovation they would have controlled.⁸⁹ It is hard to conclude that the claim to a combination of bacteria for inoculating seeds deemed unpatentable in *Funk Bros. v. Kalo* necessarily had broader downstream implications than the claim to a genetically modified oil-eating bacterium held patentable in *Diamond v. Chakrabarty*.⁹⁰

In its most recent, unanimous, treatment of patentable subject matter, *Mayo v. Prometheus*, the Court reaffirmed the per se approach and explicitly rejected an argument that only natural phenomena with broad downstream impact should be unpatentable.⁹¹ The natural phenomenon at issue in *Mayo* was the correlation between the blood level of a drug metabolite and the medical outcome.⁹² The claims were premised on the patentees' statistical analysis of clinical observations, which they used to determine numerical metabolite level thresholds correlated with toxicity and efficacy of the drug.⁹³ The Court specifically acknowledged that "[t]he laws of nature at issue here are narrow laws that may have limited applications," yet treated them as per se unpatentable.⁹⁴ Recognizing that prior "cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow," the Court declined to "draw distinctions

88. Compare *Benson*, 409 U.S. at 64–65, 68, 71–72 (noting that the claim to the BCD algorithm was "so abstract and sweeping as to cover both known and unknown uses"), with *Flook*, 437 U.S. at 585–86, 589–92, 594 (rejecting a claim that recites a step using an algorithm for updating a temperature alarm-limit value).

89. See *Bilski*, 130 S. Ct. at 3231 (describing limitations various claims added to the basic concept of hedging, but finding them insufficient to confer patentability).

90. Compare *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130–32 (1948), with *Chakrabarty*, 447 U.S. at 305–07, 309–10.

91. See *Mayo*, 132 S. Ct. at 1303 (noting that cases have "endorsed a bright-line prohibition against patenting laws of nature").

92. *Id.* at 1296–97.

93. See *id.* at 1294–95 (discussing the development of the process underlying the patent applicant's claim). In *Mayo*, the patentee had claimed methods of "optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder," of the following form: "(a) administering a drug providing [a particular metabolite] to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of [the metabolite] in [the subject] wherein the level of [the metabolite] [greater or less] than [a given threshold] indicates a need to [reduce or increase the dosage, respectively]." *Id.* at 1295 (quoting U.S. Patent No. 6,355,623 (filed Apr. 8, 1999)).

94. *Id.* at 1301–03, 1305.

among laws of nature based on whether or not they will interfere significantly with innovation in other fields now or in the future.”⁹⁵

An analysis of whether particular claims incorporating per se excluded elements are patentable is logically distinct from an inquiry into overbroad downstream impact. By definition, the rule defining a per se excluded category of inventions is independent of any particular claim. Therefore, whether a particular claim incorporating a per se excluded element meets the patentable subject matter requirement must be determined by applying an additional rule. In other words, as an analytical matter, a per se exclusion approach to patentable subject matter doctrine must provide two types of rules: (1) rules for identifying the per se excluded material in a patent claim; and (2) rules for determining whether the additional claim limitations move the claim into patentable territory.

To see this, it may help to imagine a box of per se unpatentable items. The first set of rules defines which items go in the box. When one of these per se unpatentable items is used in a claim, it remains a per se excluded item. One can sensibly say, for example, that the elements of a particular claim include an unpatentable scientific principle and an unpatentable mental process.⁹⁶ The per se unpatentability of these elements alone cannot tell a court how to determine whether the claim as a whole is patentable, however. To determine whether the claim is patentable, some second rule must be applied.⁹⁷

The analysis of overbroad downstream impact, by contrast, involves only one rule, which might be stated as: “If the claim as a whole encompasses an overly broad swath of downstream innovation potential, the claim is unpatentable.” *Morse* and *Dolbear* conduct the analysis in exactly this way.⁹⁸ *Morse*, for example, had patented both overbroad and appropriately limited claims, as assessed by the above rule.⁹⁹ Downstream impact

95. *Id.* at 1303.

96. *See id.* at 1298–99 (2012).

97. This is emphatically not to say that a per se exclusion analysis is necessarily or should be a “point of novelty” analysis. One can imagine any number of forms for the second rule, some of which would have nothing to do with whether the per se excluded element is novel. “Point of novelty” is one example of the second type of rule. As we shall see, the courts have considered a number of such rules.

98. *See Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1, 538–39 (1888); *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1853) (positing that allowing a patent on an overly broad claim would effectively preclude others from making improvements on the invention and deprive the public of the benefit of future innovation).

99. *Morse*, 56 U.S. at 101, 112–13 (invalidating the broad claim to any use of

analysis may be conducted in several stages for convenience or clarity; for example, by determining that an independent claim is overbroad and then comparing dependent claims to it to see how much they restrict the downstream impacts on innovation. Nonetheless, the crucial point is that an analysis of overbroad downstream impact, such as that in *Morse*, *Dolbear*, and *Benson*, involves only one question and hence only one rule.

One could, in principle, formally cast overbroad downstream impact analysis into something that looks like the two-step per se framework. First, one could define a per se excluded category composed of elements with broad downstream impact. Given a claim containing such an element, as well as other limitations, one could then employ a “second rule” that asked, “Does this claim, with the additional limitations, still have overly broad downstream impact?” But this purported two-step process is effectively just a way of applying the single downstream impact rule. In any event, the per se exclusion thread of the Supreme Court’s patentable subject matter opinions does not apply a test that is equivalent to a downstream impact rule. To begin with, the per se unpatentable categories defined with the case law include elements that do not have the kind of broad downstream impact envisioned by the Court’s distinction between *Morse* and *Dolbear*. In addition, as discussed in detail in Part III, the second stage rules applied in the Court’s per se exclusion cases do not turn on downstream impact.

The fact that courts applying per se patentable subject matter exclusions necessarily are applying a two-stage framework may not always be immediately evident. There are several particular situations in which the two-step analysis may not need to be spelled out explicitly. For example, the entire claim may be made up of per se excluded material, so that it is unnecessary to apply the second rule explicitly, whatever it may be. Alternatively, the second rule might be trivial to apply. For example, the second rule could be “the addition of any further limitations that are not themselves per se unpatentable renders the claim patentable.” The Federal Circuit’s useful, concrete, and tangible result test functioned essentially in this way.¹⁰⁰ A similar

electromagnetic power to print characters at a distance while upholding more limited claims).

100. See *State St. Bank & Trust Co. v. Signature Fin. Grp.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (upholding claims involving computer algorithm where “the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces ‘a useful, concrete and tangible result’”), *abrogated by In re Bilski*, 545 F.3d 943 (Fed. Cir.

rule would be “the claim is unpatentable only if the claim as a whole, with all of its limitations, is in the per se excluded category.” An approach based on per se exclusion of “nontechnological inventions” might, for example, adopt this rule. Another trivially applied second rule would be “the claim remains unpatentable no matter what additional limitations are added.” In fact, as discussed in more detail below, the Supreme Court considered, and rejected, this rule in its opinion in *Flook*.

In sum, the Supreme Court’s case law contains two distinct threads of patentable subject matter analysis, one based on overbroad downstream impact and the other on per se exclusion. These two threads are not redundant. As discussed in more detail in Part III.B, the Court treats natural phenomena and abstract ideas as per se unpatentable, regardless of the downstream scope of the specific phenomenon or idea at issue in a given case.

III. DISENTANGLING PER SE EXCLUSION ANALYSIS.

To illuminate the Supreme Court’s per se exclusion jurisprudence, we must first disentangle it from the preemption rhetoric. Subpart A takes up that task, describing how preemption has invaded patentable subject matter analysis since *Benson* and arguing that preemption is not a useful lodestar for either thread of patentable subject matter analysis. Subpart B reviews the major patentable subject matter opinions to illustrate the Court’s application of the two-step per se exclusion framework and, in particular, to disentangle the rules that the Court has actually applied in the second stage of the analysis from the preemption rhetoric.

For the per se exclusion thread of patentable subject matter doctrine to make normative sense, both the rule for defining the per se exclusion and the rule for determining the patentability of a claim incorporating excluded material should arise from some rationale for the per se exclusion. Unfortunately, most of the case law discussion of patentable subject matter is devoted to the second stage of the analysis: determining when a patent claim involving per se excluded material traverses the boundary from unpatentable to patentable.¹⁰¹ Discussion of the rationale for per se exclusions

2008).

101. See, e.g., *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010) (citing *Flook* for the proposition that “[l]imiting an abstract idea to one field of use or adding token postsolution components” does not render a per se unpatentable concept patentable).

is usually absent or perfunctory and frequently mixes distinct concerns.¹⁰² The lack of theoretical justification for the per se exclusions makes it difficult to make normative sense of the case law and is a major theoretical gap, which has been only partially addressed by scholars. Indeed, most discussion of per se exclusion has focused on specific controversial topics, such as the patentability of business methods.¹⁰³ This Part attempts to clear the underbrush so as to motivate more general theoretical consideration of per se patentable subject matter exclusions.

A. *The Preemption Muddle*

As discussed above, *Benson* is an excellent example of patentable subject matter exclusion based on overbroad impact of downstream uses of the claimed invention. Unfortunately, *Benson's* main legacy has been to conflate the downstream impact and per se exclusion frameworks, leading to the current preemption muddle. The confusion stems primarily from *Benson's* nutshell, which I repeat here:

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

102. See, e.g., *Bilski*, 130 S. Ct. at 3225 (justifying per se exclusion on stare decisis); *Benson*, 409 U.S. at 67, 71–72 (citing case law in cursory explication of per se exclusion); *In re Taner*, 681 F.2d 787, 789 (C.C.P.A. 1982) (following precedent without mention of reasoning for exclusion).

103. See, e.g., Jay Dratler, Jr., *Does Lord Darcy Yet Live? The Case Against Software and Business-Method Patents*, 43 SANTA CLARA L. REV. 823 (2003); Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263 (2000); Robert M. Hunt, *You Can Patent That? Are Patents on Computer Programs and Business Methods Good for the New Economy?*, BUS. REV. Q1, 5, 8 (2001) (computer programs); Keith E. Maskus & Eina Vivian Wong, *Searching for Economic Balance in Business Method Patents*, 8 WASH. U. J.L. & POL'Y 289 (2002); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 581 & n. 10 (1999); Michael J. Meurer, *Business Method Patents and Patent Floods*, 8 WASH. U. J.L. & POL'Y 309, 311–12 (2002) (arguing that the courts have repeatedly failed to “state comprehensive principle[s] for dividing patentable from unpatentable processes” involving business methods); Malla Pollack, *The Multiple Unconstitutionality of Business Method Patents: Common Sense, Congressional Consideration, and Constitutional History*, 28 RUTGERS COMPUTER & TECH. L.J. 61 (2002); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139, 1145–46 (1999) (noting that, as early as 1869, business method patents such as case bookkeeping were contrary to the purpose of the patent laws).

the mathematical formula and in practical effect would be a patent on the algorithm itself.¹⁰⁴

As explained earlier, this nutshell is sensibly understood as part of a downstream impact analysis. The fact that claims to digital computer implementation of the BCD conversion algorithm wholly preempt the algorithm is important to the analysis only because it helps the Court to evaluate the potential downstream impacts of the claims at issue: preemption implies that if the algorithm has broad downstream impacts, the claim's downstream implications are equally broad.¹⁰⁵

However, it is also possible, in the context of *Benson's* rather opaque discussion, to read the nutshell as describing a per se exclusion analysis. In that reading, the nutshell appears to imply the following two rules:

- (1) abstract ideas are excluded from patentability per se. (The BCD conversion formula is an abstract idea and hence is unpatentable);
- (2) to determine whether claims incorporating an abstract idea are patentable, consider whether the claims wholly preempt the idea.

The Court's rhetoric in later opinions often sounds as though it has adopted those rules. Reference to preemption thus has become a routine part of the second step of the patentable subject matter analysis of claims involving phenomena of nature and abstract ideas.¹⁰⁶ As a purely formal matter, preemption could be a workable rule for the second stage of a per se exclusion analysis. Normatively, however, the preemption rule has been given no justification and, in fact, makes little sense. As a result, courts that have taken the rule seriously have found it nearly impossible to apply in a rational manner.

The preemption references have their roots in *Benson's* very particular context, which involved an algorithm with an extremely broad sweep of downstream uses and claims that had a virtually coextensive downstream impact.¹⁰⁷ As a general rule, however, preemption of a natural phenomena or abstract idea is not a good test for determining whether a claim has overbroad downstream impact. On the one hand, a claim that wholly

104. *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972).

105. *See supra* Part II.A.

106. *See, e.g.*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293–94 (2012); *Bilski v. Kappos*, 130 S. Ct. 3218, 3229–30, 3231 (2010); *Diamond v. Diehr*, 450 U.S. 175, 185, 187 (1981).

107. *See Benson*, 409 U.S. at 64 (1972).

preempts a natural phenomenon of minor importance will itself have minor impact. On the other hand, while a claim that wholly preempts a very broad abstract idea or natural phenomena will certainly have broad downstream impact, preemption cannot take the analysis any farther. If a claim is limited so that it does not wholly preempt a broadly sweeping idea or phenomenon, the claim may or may not still sweep too broadly downstream. Consider, for example, a hypothetical claim similar to Benson's except that it is limited to use of the BCD conversion algorithm in computers used in law schools. Does such a claim "wholly preempt" access to the algorithm? Under any ordinary meaning of the phrase, it certainly does not. Though those of us at law schools would miss our access to the algorithm, the number of downstream uses remaining accessible to the public is vast, so the algorithm is not wholly preempted. In fact, only a tiny portion of its downstream impact is affected. On the other hand, it may well be (we hope!) that the claim's downstream effects remain unacceptably broad. Presence or absence of preemption simply cannot tell us the answer, because preemption is the wrong question. To assess whether the overbroad downstream impact thread of patentable subject matter exclusion should apply, we must ask directly whether the hypothetical claim itself has unacceptably broad downstream impact.

Attempts to shoehorn analysis of overbroad downstream impact into preemption terms have led to highly artificial (and unexplained) corollaries to the supposed preemption rule, which state that limitations to particular fields of use and additions of "post-solution activity" cannot render claims incorporating abstract ideas or natural phenomena patentable.¹⁰⁸ As implementations of the overbroad downstream impact rationale, these corollaries may be either wrong or right in a given instance. It all depends on the particular context and, in particular, on the breadth of downstream impact of the underlying natural phenomenon or abstract idea. At the other extreme, as the Court recognizes in *Mayo*, if an abstract idea or natural phenomenon has relatively narrow downstream impact on innovation, even a claim that wholly preempts it will have similarly narrow downstream effects.¹⁰⁹ Unfortunately, not only has preemption taken on a

108. See *Flook*, 437, U.S. at 590 ("[The notion that post-solution activity . . . can transform an unpatentable principle in a patentable process exalts form over substance.]; *Diehr*, 450 U.S. at 191-92 & n.14 (stating that limiting a mathematical formula to a particular technological use does not render it patentable).

109. See *Mayo*, 132 S. Ct. at 1303.

life of its own in the case law, but the field of use and post-solution activity corollaries have moved across town and set up shop on their own as well. The result is often a preemption analysis that is thrice removed from the issue at hand: Should this claim (which incorporates some per se unpatentable elements) be deemed patentable?

Defenders of the preemption rule might argue that the downstream impact and per se exclusion rationales are not as distinct as I have made them appear. Suppose that the Court has adopted a per se exclusion of natural phenomena and abstract ideas because it believes they are likely to have broad impacts on downstream innovation, but does not believe courts can effectively conduct a downstream impact analysis of each claim (or believes that conducting such an analysis would be too costly). Indeed, the Court suggests something like this in *Mayo*, where it states that “even a narrow law of nature (such as the one before us) can inhibit future research” to some extent and asserts, in light of this possibility, that a “bright-line prohibition against patenting laws of nature, mathematical formulas and the like” is needed as a “proxy for the underlying ‘building-block’ concern” because “[c]ourts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature.”¹¹⁰ If this is a convincing rationale for a per se exclusion of natural phenomena and abstract ideas, a preemption rule, which asks how much the claim has limited the downstream impact of the natural phenomenon or abstract idea, makes some sense as a second step. But note that by adopting such an analysis one simultaneously assumes two things: (1) one can say nothing about the relative downstream impact of various natural phenomena and abstract ideas, so must assume the downstream impact is the same; and (2) one nonetheless can effectively compare the downstream impact of a patent claim incorporating a natural phenomenon or abstract idea to the downstream impact of that phenomenon or idea in isolation so as to determine whether the claim preempts it. These are strong assumptions and, to me, implausible as a general matter.

If a preemption rule is applied as the second step in evaluating a claim containing elements that are per se excluded on some other basis, the results are even more peculiar. In such cases, preemption is simply orthogonal to the underlying rationale for the exclusion, whereas the optimal rule for the second part of a per se exclusion analysis would be tightly tied to

110. *Mayo*, 132 S. Ct. at 1303.

the rationale for the exclusion. Suppose, for example, that the rationale for the per se exclusion of abstract ideas from patentability were that patents should not intrude on the autonomy of human thought. Once we determine that a claim incorporates a particular mental process, the second rule should help us determine whether the additional limitations have sufficiently reduced the claim's intrusion on autonomous thought. Whether the claim wholly preempts the downstream innovative uses of the mental process is beside the point. Similarly, if the rationale for a per se exclusion is that natural products should be left in an unpatentable public domain in order to encourage widespread attempts to find their practical applications (which would then be patentable), the second part of the analysis likely should depend on whether the claim is to a practical application of the natural product. The fact that a claim covering the use of a particular natural substance as a cancer drug might wholly preempt the substance's downstream effects on innovation (if curing cancer is the substance's only practical use) is irrelevant.

With this background discussion in mind, the next section turns back to the case law applying per se exclusions and interrogates the Court's analysis.

B. *The Supreme Court's Two-Step Per Se Exclusion Analysis*

It is convenient to discuss the Supreme Court's approach to applying per se patentable subject matter exclusions by considering relevant cases in chronological order. *American Fruit Growers, Inc. v. Brogdex Co.*¹¹¹ is a good starting point. In that

111. *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11–12 (1931). An earlier series of cases deals with the distinction between a patentable “art” or process and the unpatentable “function of a machine, or the effect produced by it on the material subjected to the action of the machine.” *Corning v. Burden*, 56 U.S. (15 How.) 252, 267–68 (1853); see also Sarnoff, *supra* note 2, at 66–67 (noting that pure method patents were ineligible for patent protection until the late nineteenth century). Though of some relevance to patentable subject matter discussion, these cases are primarily concerned with the acceptable scope of process claims and not of direct relevance to this discussion. See Risch, *supra* note 9, at 600–05 (revealing that the Court often rejected the patentee's process claims because they recited more than what the patentee actually invented or described in the patent application). Other early cases often cited for their statements of the per se unpatentability of natural phenomena and abstract ideas are more concerned with issues of novelty than of patentable subject matter. See, e.g., *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 603–04 (1874) (rejecting patent for want of novelty); *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 505, 507 (1874) (holding that the patent although useful was not new). See Christopher Beauchamp, *Pure Thoughts of Judge Hand: A Historical Note on the Patenting of Nature* (2012), http://www.law.nyu.edu/ecm_dlv3/groups/public/@nyu_law_website_engelberg_center_on_innovation_law_and_policy/documents/documents/ecm_pro_071307.pdf; Jon M.

case, the inventor developed a means for applying borax to citrus fruit rinds as a preservative and the claim at issue was to the treated fruit.¹¹² The issue in the case is framed as the definition of “manufacture” in the patent statute, but the Court’s reasoning is of interest for present purposes.¹¹³ The Court assumes without discussion, as had the appellate court, that the fruit at issue is a per se unpatentable natural product.¹¹⁴ The appellate court had analyzed the patentability issue by asking whether the final product was itself a product of nature, concluding: “The product is a combination of the natural fruit and a boric compound carried by the rind or skin in an amount sufficient to render the fruit resistant to decay. The complete article is not found in nature and is thus an article of manufacture.”¹¹⁵ In essence, the appellate court applied this second-step rule: a claim is excluded from patentable subject matter only if the claim as a whole, with all of its limitations, is in the per se excluded category. Because the treated article was not itself a natural product, the claim was patentable.¹¹⁶

Though in agreement as to the per se exclusion of the “natural fruit,”¹¹⁷ the Supreme Court reversed by applying a different rule to the second stage of the analysis:

Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial uses as theretofore.

. . . .

. . . “Manufacture implies a change, but every change is not manufacture, and yet every change in an article is the

Harkness, *Dicta on Adrenalin(e): Myriad Problems with Learned Hand’s Product-of-Nature Pronouncements in Parke-Davis v. Mulford*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 363, 389–92 (2011); Risch, *supra* note 9, at 600–03; and Sarnoff, *supra* note 2, at 66–69, for discussions of these early cases.

112. *Brogdex*, 283 U.S. at 6.

113. *Id.* at 11.

114. *See id.* at 11–12; *Am. Fruit Growers, Inc. v. Brogdex Co.*, 35 F.2d 106, 107–08 (3d Cir. 1929), *rev’d*, 283 U.S. 1 (1931).

115. *Am. Fruit*, 35 F.2d at 108.

116. *See id.* at 108–09.

117. *See supra* note 114 and accompanying text. Of course, and pertinent to the question of the scope of the per se natural product exclusion, the fruit in question was cultivated fruit. *See Brogdex*, 283 U.S. at 11.

result of treatment, labor and manipulation. But something more is necessary There must be transformation; a new and different article must emerge ‘having a distinctive name, character or use.’”¹¹⁸

The Supreme Court’s second-step rule thus was that the patentee’s addition to the natural product must transform it sufficiently to imbue the claimed product with a distinctive character or use.¹¹⁹ Though the precise scope of the Court’s rule is not entirely clear, the Court seemed to require a change that affected the “beneficial uses” of the product before patentability would be conferred.¹²⁰ (Why longer shelf life is not a beneficial use was not explained.¹²¹)

Funk Bros. Seed Co. v. Kalo Inoculant Co. involved claims to “[a]n inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria.”¹²² The inoculant could be applied to seeds of a variety of plant species, so as to enhance their capacity for nitrogen fixation.¹²³ The bacteria in question were already used separately by farmers for this purpose.¹²⁴ The novel aspect of the invention was the selection of bacteria that could be combined in a single inoculant for use with a variety of types of seeds.¹²⁵ The difficulty in selecting appropriate bacterial strands was that they tended to inhibit one another’s nitrogen-fixing capacity.¹²⁶ In analyzing patent eligibility, the Court presumed the per se unpatentability of the “state of inhibition or non-inhibition in the bacteria,” which it deemed the “handiwork of nature.”¹²⁷ It then considered whether the patentee’s contribution was sufficient to confer patentability.¹²⁸

The appellate court had found the inventor’s contribution sufficient because his “new and different composition of non-inhibitive strains . . . contributed utility and economy to the

118. *Brogdex*, 283 U.S. at 11–13 (quoting *Anheuser-Busch Brewing Ass’n v. U.S.*, 207 U.S. 556, 562 (1908)).

119. *See id.* at 12–13.

120. *See id.* at 12.

121. *See id.* at 8, 11–12 (finding that the process prolonged the life of the fruit but holding that the fruit had only the “same beneficial uses as theretofore”).

122. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128 n.1 (1948) (quoting U.S. Patent No. 2,200,532 (filed Aug. 24, 1938)).

123. *Id.* at 128–30.

124. *Id.* at 129.

125. *See id.* at 130.

126. *Id.* at 129–30.

127. *Id.* at 130–31.

128. *Id.*

manufacture and distribution of commercial inoculants.”¹²⁹ The Court rejected this approach, which might be characterized as a rule of practical improvement bearing some similarity to the *Brogdex* rule.¹³⁰ Instead, the Court applied a rule that required that the inventor’s contribution be “inventive,” over and above whatever creativity was involved in the discovery of the natural phenomenon:

The aggregation of select strains of the several species into one product is an application of [a] newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. . . . The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning.

. . . The application of this newly-discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance. But once nature’s secret . . . was discovered, the state of the art made the production of a mixed inoculant a simple step. . . . That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough.¹³¹

In summary, the Court in *Funk Bros.* first identified a per se excluded natural phenomenon in the claims and then, as a second step, applied a rule requiring that the inventor’s practical application of that natural phenomenon must itself be inventive, even if the inventor himself had discovered the natural phenomenon at issue.¹³²

Parker v. Flook involved claims to a method for computing an “alarm limit” in a process for the catalytic conversion of hydrocarbons.¹³³ The method, which was computer-implemented, incorporated a mathematical formula.¹³⁴ Adjudicators at every level who considered patent eligibility were in agreement that the formula was per se unpatentable but, in analyzing the

129. *Id.*

130. *See id.* at 131–32.

131. *Id.*

132. *See id.* at 130–32.

133. *Parker v. Flook*, 437 U.S. 584, 585–86 (1978).

134. *Id.*

patentability of the claims incorporating the formula, they applied different approaches to the second step of the patentable subject matter analysis.¹³⁵ The patent examiner and the Board of Patent Appeals and Interferences (BPAI) employed a “point of novelty” rule, denying the claims because the per se unpatentable mathematic formula was the only difference between the claimed invention and the prior art.¹³⁶ The Court of Custom Claims and Patent Appeals (CCPA), which reviewed patent denials prior to the establishment of the Federal Circuit, applied a version of preemption analysis that found no preemption “since the mere solution of the algorithm would not constitute infringement of the claims” and reversed.¹³⁷ Note that, unlike *Benson’s* nutshell, the CCPA’s preemption rule did not assess the extent to which the claims preempted the downstream impact of the algorithm.¹³⁸

The Supreme Court explicitly rejected the CCPA’s preemption rule, which had defined preemption such that simply adding any specific, practical limitation would render a claim patentable (“respondent incorrectly assumes that if a process application implements a principle in some specific fashion, it automatically falls within the patentable subject matter of § 101”).¹³⁹ Interestingly, the Court also, in a footnote, questioned the rationale behind preemption analysis, stating that “it is not entirely clear why a process claim is any more or less patentable because the specific end use contemplated is the only one for which the algorithm has any practical application.”¹⁴⁰ The Court also rejected a rule at the opposite extreme under which any claim incorporating per se excluded material would be unpatentable (“respondent [incorrectly] assumes that the fatal objection to his application is the fact that one of its components—the mathematical formula—consists of unpatentable subject matter”).¹⁴¹

Instead, the Court reiterated its *Funk Bros.* rule for determining the subject matter eligibility of a claim incorporating a per se excluded element,¹⁴² making three

135. *See id.* at 587.

136. *Id.*; *In re Flook*, 559 F.2d 21, 22 (C.C.P.A. 1977).

137. *Flook*, 437 U.S. at 587; *In re Flook*, 559 F.2d at 22.

138. *See In re Flook*, 559 F.2d at 23. The CCPA’s rule would seemingly also have found *Benson’s* Claim 8, which would only have been infringed by implementation in a computer, patentable. *See id.*

139. *Flook*, 437 U.S. at 590–94.

140. *Id.* at 590 & n.11.

141. *Id.* at 593–94.

142. *Id.* at 591, 594 (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S.

important points. First, it is not enough simply to apply an abstract idea in a practical way:

The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques.¹⁴³

Note that the Court's consideration of post-solution activity here was not related to how much the activity or the resulting claim preempted use of the unpatentable idea.¹⁴⁴ The Pythagorean Theorem would not be wholly (or even significantly) preempted by a claim to its application in surveying.¹⁴⁵ The problem the Court identified was with "conventional or obvious" applications, using "existing surveying techniques," that could be devised by a "competent draftsman."¹⁴⁶

This leads to the second point, which was that the discovery or conception of the per se unpatentable abstract idea itself does not "count" at the second stage, when evaluating how the claim applies it. "If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end."¹⁴⁷ Hence, "the novelty of the mathematical algorithm is not a determining factor at all."¹⁴⁸ The Court's third point was that, for the claim to be patentable, its application of the per se unpatentable element must involve an inventive concept: "Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application."¹⁴⁹ In the discussion that follows, I will refer to the second-stage rule laid out in *Funk Bros.* and *Flook* as the "inventive concept rule."

127, 130–32 (1948)).

143. *Id.* at 590.

144. *See id.*

145. *See id.* at 594 ("Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented.").

146. *Id.* at 590.

147. *Id.* at 591 (quoting *Funk Bros.*, 333 U.S. at 130).

148. *Id.*

149. *Id.* at 594.

Diamond v. Chakrabarty concerned the patent eligibility of a bacterium that had been genetically engineered so as to be capable of breaking down the components of crude oil.¹⁵⁰ (Its intended use was to clean up oil spills.¹⁵¹) The *Chakrabarty* opinion is known for its quotation of a statement from the Senate Report accompanying the 1952 Patent Act that patentable subject matter extends to “anything under the sun that is made by man”¹⁵² and its determinations that living things generally, and genetically modified organisms in particular, are not excluded from patentable subject matter per se.¹⁵³ The relevant part of the decision for our purposes, however, is the opinion’s approach to the per se exclusion for natural phenomena.¹⁵⁴

While the Court spent considerable time discussing the “broad construction” of § 101 of the Patent Act (hence the “anything under the sun that is made by man” quote), that discussion was animated by the central question in the case—whether there is a per se exclusion for living things—and seems to have had little to do with the Court’s application of the per se exclusion for natural phenomena.¹⁵⁵ In considering the natural phenomena exclusion, the Court first explained that its discussion of the broad scope of the statute, “is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.”¹⁵⁶ (The Court cited its prior cases from *Flook* back to *Le Roy* and quoted *Funk Bros.* at some length on this point.¹⁵⁷) The opinion then turned to the patentability of Chakrabarty’s genetically engineered bacteria in light of the natural phenomena exclusion.¹⁵⁸ On that question, the Court’s analysis was brief, and

150. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

151. *Id.*

152. *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2399; H.R. REP. NO. 82-1923, at 6 (1952)); see Yu, *supra* note 2, at 390, 445 (discussing *Chakrabarty* and the Supreme Court’s famous pronouncement).

153. See A. Samuel Oddi, *Assault on the Citadel: Judge Rich and Computer-Related Inventions*, 39 HOUS. L. REV. 1033, 1074–76 (2002) (discussing how the Court’s decision in *Chakrabarty* became a landmark decision because of its holding that microorganisms were patentable subject matter).

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

155. *Id.* at 307–10.

156. *Id.* at 308–09 (citing *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 112–21 (1854); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853)). The Court also goes on to quote *Funk Bros.* at some length on this point. *Chakrabarty*, 447 U.S. at 309–10 (1980) (quoting *Funk Bros.*, 333 U.S. at 130).

157. *Id.* at 309–10.

158. *Id.*

based primarily on distinguishing Chakrabarty's invention from the unpatentable claims in *Funk Bros.*:

Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.¹⁵⁹

Nothing in this brief section of the opinion is inconsistent with a routine application of the second-stage inventive concept rule expressed in *Funk Bros.* and *Flook*.¹⁶⁰ While the Court did not evaluate Chakrabarty's inventive concept explicitly, its description of his inventive activity suggests that it was in no way conventional, routine, or obvious. As the Court described it, "Chakrabarty discovered a process by which four different plasmids [subcellular components of naturally-occurring bacteria], capable of degrading four different oil components, could be transferred to and maintained stably in a single *Pseudomonas* bacterium, which itself has no capacity for degrading oil."¹⁶¹

Notably, in describing Chakrabarty's work, the Court distinguished between Chakrabarty's earlier research, in which he "discovered that plasmids control the oil degradation abilities of certain bacteria" and "discovered plasmids capable of degrading camphor and octane, two components of crude oil" and the work underlying the patent, which required him to invent a process for combining the natural plasmids he had discovered into a single, viable bacterium.¹⁶² The earlier research investigated the properties of naturally occurring bacteria; the later work devised an inventive means of using that knowledge to create something new.¹⁶³ The *Chakrabarty* analysis of the natural phenomena exclusion fits comfortably with the second-stage inventive concept rule.

In *Diamond v. Diehr*, however, the Court did not apply the inventive concept rule.¹⁶⁴ *Diehr* considered the patentability of a "process for curing synthetic rubber which includes in several of its steps the use of a mathematical formula and a programmed digital

159. *Id.* at 310.

160. *Id.* at 309. Indeed, the dissent, which focused on the question of the per se patentability of living things, did not dispute this aspect of the majority's analysis. *See id.* at 318–22 & n.1 (Brennan, J., dissenting).

161. *Id.* at 305 n.1; *see also* HARVEY LODISH, ET AL., *MOLECULAR CELL BIOLOGY* 209 (1986).

162. *Charkrabarty*, 447 U.S. at 305 n.1.

163. *Id.*

164. *See* *Diamond v. Diehr*, 450 U.S. 175, 191 (1981).

computer.”¹⁶⁵ The formula involved was a well-known equation for calculating cure time using the even more well-known Arrhenius law.¹⁶⁶ According to the majority, the patentee’s contribution “reside[d] in the process of constantly measuring the actual temperature inside the mold. These temperature measurements are then automatically fed into a computer which repeatedly recalculates the cure time by use of the Arrhenius equation.”¹⁶⁷ The claims were not limited to any particular method of measuring the temperature.¹⁶⁸

The patent examiner had rejected the claims by “determin[ing] that those steps in respondents’ claims that are carried out by a computer under control of a stored program constituted nonstatutory subject matter under this Court’s decision in *Gottschalk v. Benson*.”¹⁶⁹ Thus, the examiner’s definition of the per se exclusion differed from the majority’s. The examiner applied a per se exclusion of computer-implemented steps despite *Benson*’s explicit statement that it did “not so hold” and its plea for Congress to decide that question.¹⁷⁰ Moreover, the rule the examiner applied to determine whether *Diehr* claimed a patentable application of the excluded computer-implemented steps was not the “inventive concept” rule the Supreme Court had adopted in its earlier opinions.¹⁷¹ Rather than asking whether the application of the per se unpatentable subject matter embodied in the claims was merely conventional, the examiner asked the subtly different question of whether the remaining steps *themselves* were conventional and necessary to the claimed process.¹⁷² According to the examiner, “[t]he remaining steps—installing rubber in the press and the subsequent closing of the press—were conventional and necessary to the process and cannot be the basis of patentability.”¹⁷³

165. *Id.* at 177.

166. *Id.* at 177–78 & n.2, 187.

167. *Id.* at 178.

168. *See id.* at 179–80 n.5 (listing several of *Diehr*’s submitted claims, which show that the claims merely encompassed “constantly determining the temperature” but did not specify a particular method of doing so); U.S. Patent No. 4,344,142 (filed Aug. 6, 1975).

169. *Diehr*, 450 U.S. at 179–80.

170. *Id.*; *Gottschalk v. Benson*, 409 U.S. 63, 71, 73 (1972).

171. *See Parker v. Flook*, 437 U.S. 584, 594 (1978) (“[T]he discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.”); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (“If there is to be invention from [discovery of an unknown phenomenon of nature], it must come from the application of the law of nature to a new and useful end.”).

172. *Diehr*, 450 U.S. at 180–81.

173. *Id.* (internal quotation omitted).

The CCPA reversed,

not[ing] that a claim drawn to subject matter otherwise statutory does not become nonstatutory because a computer is involved. The respondents' claims were not directed to a mathematical algorithm or an improved method of calculation but rather recited an improved process for molding rubber articles by solving a practical problem which had arisen in the molding of rubber products.¹⁷⁴

The CCPA's first point both rejected the examiner's definition of the per se exclusion and reiterated *Flook's* rejection of a second-stage rule that any claim incorporating patentable subject matter is unpatentable.¹⁷⁵ The second point emphasized both the tangibility of the claimed process and the practical usefulness of the patentee's invention.¹⁷⁶ The CCPA did not consider whether the claimed application of the unpatentable equation involved an inventive concept.¹⁷⁷

The Supreme Court began its analysis by returning to an old debate about the patentability of processes that are not limited to or characterized by implementation on particular machines.¹⁷⁸ Quoting *Cochrane v. Deener*, the Court stated:

That a process may be patentable, irrespective of the particular form of the instrumentalities used, cannot be disputed. . . . A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery.¹⁷⁹

The patentability of a physical process for molding rubber was, of course, not in dispute in 1981.¹⁸⁰ The question at issue, which the Court answered in the affirmative, was whether Diehr's claims, in which physical details of the rubber molding process did not play an important role, should be viewed as directed to such an "industrial process."¹⁸¹

174. *Id.* at 181 (discussing the lower court's analysis from *In re Diehr*, 602 F.2d 982, 985 (C.C.P.A. 1979), *aff'd sub. nom.*, *Diamond v. Diehr*, 405 U.S. 175 (1981)).

175. *In re Diehr*, 602 F.2d at 984–87.

176. *Id.* at 988.

177. *See id.* (declining to discuss the novelty or inventiveness of the claimed application of the equation because "[t]he novelty . . . of any element or even of all the elements or steps, or of the combination has no bearing on whether the process is encompassed by § 101").

178. *See Diehr*, 450 U.S. at 182–84.

179. *Id.* at 182–83 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787–88 (1876)).

180. *Id.* at 184 & n.8.

181. *See id.* at 179–80 n.5, 191–93.

The Court then turned to the impact on patent eligibility of the claims' incorporation of "a mathematical equation and a programmed digital computer."¹⁸² After reaffirming the per se unpatentability of "laws of nature, natural phenomena, and abstract ideas," the Court also reaffirmed that mathematical algorithms and formulae are included within the per se exclusion.¹⁸³ The Court then defined the per se unpatentable element of *Diehr's* claims as the "well-known mathematical equation" rather than the entirety of the computer-implemented steps.¹⁸⁴

In assessing the patentability of the application of this per se unpatentable equation, *Diehr* famously did not apply the "inventive concept" rule established in the earlier cases.¹⁸⁵ The opinion sets out less of a substantive explication of the Court's rationale for not applying that rule than may at first appear, however, because much of what the opinion says is in agreement with *Funk Bros.* and *Flook*. Like those earlier opinions, *Diehr* rejected a second-stage rule that would find any claim that merely incorporated a law of nature or abstract idea unpatentable.¹⁸⁶ Much of *Diehr's* remaining discussion focuses on a straw man point of novelty rule, which would "dissect the claims into old and new elements and then . . . ignore the presence of the old elements in the analysis," failing to consider the claims "as a whole."¹⁸⁷ Such a point of novelty rule was (as *Diehr* points out) rejected in *Flook* as well.¹⁸⁸

182. *Id.* at 185.

183. *See id.* at 185–86 ("[A]n algorithm, or mathematical formula, is like a law of nature, which cannot be the subject of a patent.").

184. *See id.* at 187 (stating that while the claimed process for curing synthetic rubber 'employs a well-known mathematical equation,' the claims do not patent a mathematical formula).

185. *See* Daniel J. Klein, *The Integrity of Section 101: A "New and Useful" Test for Patentable Subject Matter*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 287, 306–08 (2011) (discussing how *Diehr* "further depicts the inconsistencies" of the Supreme Court and stating that the "broad effect of *Diehr* was to vitiate *Flook's* application of an inventive concept requirement"). The *Diehr* dissent applied the inventive concept rule (though only after becoming mired in a long and off-point discussion of what the inventor "considers his inventive concept to be"). *Diehr*, 450 U.S. at 212, 216 (Stevens, J. dissenting).

186. *Diehr*, 450 U.S. at 187 (majority opinion) ("[A] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer."); *see also* *Parker v. Flook*, 437 U.S. 584, 590 (1978) ("[I]t is equally clear that a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm."); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (discussing the unpatentable nature of bacteria and laws of nature but stating that "invention from such a discovery" is possible if it "come[s] from the application of the law of nature to a new and useful end").

187. *See Diehr*, 450 U.S. at 188–89.

188. *See Flook*, 437 U.S. at 594 (rejecting the point of novelty rule and supporting the decision that a patent claim must be considered as a whole); *Diehr*, 450 U.S. at 188–89 &

Perhaps less apparently, *Flook* and *Diehr* also are essentially in agreement that “[t]he ‘novelty’ of any element or steps in a process . . . is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.”¹⁸⁹ While *Flook* instructs the patentable subject matter analyst to treat newly discovered natural phenomena or abstract ideas as “well known,” the real point of *Flook*’s “inventive concept” rule is that *only the inventor’s activities over and above the discovery of the per se unpatentable subject matter count*.¹⁹⁰ In other words, the rule would obtain precisely the same results if it were stated as “determine whether the claim reflects an inventive concept in the application of the unpatentable natural phenomenon or abstract idea, independent of whether the unpatentable element is new or old.”

Indeed, the opinion’s lengthy discussion of the impact of presuming that a per se unpatentable mathematical algorithm is old was utterly irrelevant to *Diehr*’s patent claims;¹⁹¹ both the Arrhenius law and the equation using it to calculate curing times during rubber molding were, *in fact*, well known.¹⁹² Therefore, any impact on the patentable subject matter question of the novelty (or lack thereof) of particular claim elements was truly neither here nor there for the claims at issue.¹⁹³

Finally, both *Flook* and *Diehr* maintained that patentable subject matter must be assessed separately from novelty and nonobviousness under the other sections of the Patent Act.¹⁹⁴ *Diehr* stated that “[t]he question . . . of whether a particular invention is novel is ‘wholly apart from whether the invention falls into a category of statutory subject matter,’” while *Flook* opined that “[t]he obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious.”¹⁹⁵

n.12 (rejecting petitioner’s argument for applying the point of novelty rule and claiming it to be a misinterpretation of the Court’s holding in *Flook*).

189. *Diehr*, 450 U.S. at 188–89; *see also Flook*, 437 U.S. at 591 (“[T]he novelty of the mathematical algorithm is not a determining factor at all.”).

190. *See Flook*, 437 U.S. at 591–92, 594 (“Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.”).

191. *See Diehr*, 450 U.S. at 188–89 n.12 (noting that although Arrhenius’ equation is not patentable itself, a process that incorporates the equation is what is analyzed to determine the threshold of patentable subject matter).

192. *Id.* at 177–78 & n. 3, 187.

193. *Id.* at 188–89.

194. *See, e.g., id.* at 189–91; *Flook*, 437 U.S. at 588.

195. *Diehr*, 450 U.S. at 190 (alteration in original) (quoting *In re Bergy*, 596 F.2d

The difference between the inventive concept rule and the *Diehr* approach thus came down to what second-stage rule to apply in considering the claims “as a whole” to assess their patent eligibility in light of their incorporation of a well-known mathematical equation. The inventive concept approach would have asked whether *Diehr*’s application of the well-known equation for calculating cure time in the claimed computerized process was conventional. *Diehr* did not ask that question.¹⁹⁶ Instead, the Court relied on the following reasoning:

[*Diehr* and his co-applicant] seek patent protection for a process of curing synthetic rubber. Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process. These include installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time. Obviously, one does not need a “computer” to cure natural or synthetic rubber, but if the computer use incorporated in the process patent significantly lessens the possibility of “overcuring” or “undercuring,” the process as a whole does not thereby become unpatentable subject matter.¹⁹⁷

In summarizing its approach at the end of the opinion, the Court concluded:

We view respondents’ claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula. . . . [W]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101. Because we do not view respondents’ claims as an attempt to patent a mathematical formula, but rather to be drawn to an industrial process for the molding of rubber products, we affirm the judgment. . . .¹⁹⁸

952, 961 (C.C.P.A. 1979); *Flook*, 437 U.S. at 593.

196. See *Diehr*, 450 U.S. at 188–91 (discussing the Court’s decision not to consider the issue of novelty).

197. *Id.* at 187.

198. *Id.* at 191–93.

The second-stage rule that the Court eventually applied in *Diehr* thus seems to have been that a claim incorporating a mathematical formula is patentable subject matter if the claim as a whole is drawn to a process that “perform[s] a function which the patent laws were designed to protect;” in other words, an “industrial process.”¹⁹⁹ The Court did not expound in detail the characteristics of a “function which the patent laws were designed to protect,” but emphasized two aspects: (1) such a function should be “useful;” and (2) “transforming or reducing an article to a different state or thing” is a core example of such a function.²⁰⁰ The Court thus essentially, though without saying as much, applied a version of a technological arts requirement.²⁰¹

Though the “function which the patent laws were designed to protect” rule is the gist of the *Diehr* analysis, the opinion did not avoid getting caught up in the preemption tangle. It noted the fact that Benson’s algorithm was applicable only in a digital computer and referred to Flook’s lack of disclosure of how to determine the various variables needed in his algorithm, apparently to suggest the comparative specificity of the *Diehr* claims.²⁰² It also repeated the preemption corollaries that the unpatentability of a mathematical formula “cannot be circumvented by attempting to limit the use of the formula to a particular technological environment” or by adding “insignificant postsolution activity” to the process.²⁰³ Finally, it maintained that *Diehr*’s claims did not “pre-empt” the use of the well-known equation for calculating rubber curing time.²⁰⁴

This discussion in *Diehr* is notable mostly for the way in which it illustrates the baroque character of the preemption rule. It is trivially evident, without resorting to any preemption epicycles, that the claims at issue in *Diehr* do not have overbroad downstream effects in the sense of either *Morse* or *Benson*.²⁰⁵

199. *See id.* at 192–93.

200. *Id.* at 181, 189, 192.

201. *Compare id.* at 191–93 & n. 15 (emphasizing that the claims are drawn to an industrial process), *with id.* at 200–01 (Stevens, J., dissenting) (tracing the development of the technological arts standard articulated by the CCPA and highlighting that computers have been held to be within the technological arts), and *In re Musgrave*, 431 F.2d 882, 893 (C.C.P.A. 1970) (defining “technological arts” in light of § 101 and Article I, Section 8 of the U.S. Constitution).

202. *Diehr*, 450 U.S. at 185–87.

203. *Id.* at 191–92.

204. *Id.* at 187.

205. *Compare Diehr*, 450 U.S. at 191–93 (claiming only a rubber curing process implementing a mathematical algorithm but not the mathematical algorithm itself), *with O’Reilly v. Morse*, 56 U.S. 62 (15 How.), 112–13 (1853) (claiming all present and future uses of electromagnetism), and *Benson*, 409 U.S. at 71–73 (claiming a mathematical

Overbroad downstream impact was not the issue in *Diehr*; the patentability of claims involving computer calculations was. Of course, Diehr's claims did not preempt the rubber curing formula because one can continue to cure rubber without updating the curing time based on the internal temperature.²⁰⁶ But is this really the point? Suppose one accepted the dissent's characterization of the unpatentable algorithm encompassed by the claim as a "method of programming a digital computer in order to calculate—promptly and repeatedly—the correct curing time in a familiar process."²⁰⁷ In that case, Diehr's claims would have wholly preempted the algorithm in much the same way as Benson's claims preempted the BCD conversion algorithm. (What other application is there for a calculation of when to open the mold?) Nonetheless, it cannot seriously be maintained that this preemption indicates that Diehr's claims would have broad downstream effects on innovation.

Diehr raises one more important, but inadequately appreciated point. The inventive concept test of *Funk Bros.* and *Flook* was designed to deal with claims incorporating natural phenomena and abstract ideas *newly discovered by the patent applicant*.²⁰⁸ In such cases, the distinction between the inventive concept test for patentable subject matter and the statutory inquiry into novelty and nonobviousness matters. Under § 102 and § 103, Bond's discovery of the non-inhibition properties of the bacteria in *Funk Bros.* would not have been included within the prior art and thus might have assisted him in demonstrating the nonobviousness of his claims.²⁰⁹ The inventive concept test, however, asks whether Bond contributed some unconventional, inventive concept over and above the discovery of those natural properties. Bond's claims failed that test.²¹⁰

For claims involving well-known natural phenomena and abstract ideas, however, the inventive concept test is subsumed within the statutory novelty and obviousness inquiries. In the

algorithm that had "no substantial practical application except in connection with a digital computer").

206. *Id.* at 187.

207. *Id.* at 212–15 (Stevens, J., dissenting).

208. *See* *Parker v. Flook*, 437 U.S. 584, 593–94 (1978) (emphasizing that discoveries of phenomena of nature or mathematical formulas are unpatentable "unless there is some other inventive concept in [their] application"); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131–32 (1948) (stating that a mixed inoculant was "no more than the discovery of some handiwork of nature and hence is not patentable").

209. *See* 35 U.S.C. §§ 102–03 (2006).

210. *See* *Funk Bros.*, 333 U.S. at 130–31 ("If there is to be invention from discovery, it must come from the application of the law nature to a new and useful end.").

majority opinion in *Diehr*, once the per se unpatentable mathematical algorithm was defined to be the well-known rubber curing equation, the debate over whether to employ “practical application” or “industrial process” or “inventive concept” as the second part of the patentable subject matter analysis was moot. The end result of the overall patentability inquiry, which would have included analysis under § 102 and § 103, would have been unaffected by the choice of second-stage rule.

Those who argue that patentable subject matter analysis is unnecessary in light of the novelty and nonobviousness requirements are thus correct if: (1) the patentable subject matter framework is one of per se exclusion; (2) the per se exclusion is well defined so there is no debate as to its boundaries; (3) the rule for the second step of the analysis is “inventive concept” (or one of a few others, such as “practical application”); and (4) the per se unpatentable element of a particular claim is within the prior art that will be considered for novelty and nonobviousness. These conditions often do not hold, however.

In *Diehr*, given the majority’s definition of the per se unpatentable algorithm, applying the inventive concept rule would not have made any difference. If the dissent’s approach to that first step had been adopted, however, the end of the story would have been different. The real issue in *Diehr* was the disagreement between the majority and dissent about how to define the per se unpatentable mathematical algorithm exclusion. While the majority took the unpatentable element to be the equation for calculating curing time, the dissent regarded the claims’ entire “method of programming a digital computer in order to calculate—promptly and repeatedly—the correct curing time in a familiar process” as the per se unpatentable algorithm at issue.²¹¹ Of course, nothing could be more conventional than to apply an algorithm for computing rubber curing time by opening the mold at the appropriate time, so the dissent would have applied the inventive concept rule and denied patentability. Since the unpatentable algorithm, as defined by the dissent, was not previously known, however, it would not have come in to the obviousness analysis. Thus the inventive concept analysis and the obviousness analysis might well have reached different conclusions.

211. Compare *Diehr*, at 187–88 (majority opinion) (discussing the equation for calculating curing time itself as the unpatentable element), with *id.* at 212–13, 216 (Stevens, J., dissenting) (discussing the entire process of calculating the correct curing time as the unpatentable element).

In the eyes of many, a major take-away point from the Court's complex set of opinions in *Bilski v. Kappos* was the centrality of preemption analysis,²¹² as reflected in Justice Breyer's articulation of four points of agreement among the justices. Point one of the four states that "the Court has long held that '[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable' under § 101, since allowing individuals to patent these fundamental principles would 'wholly pre-empt' the public's access to the 'basic tools of scientific and technological work.'"²¹³ This blessing of the preemption rationale for the per se exclusion of abstract ideas and natural phenomena was unfortunate (as became apparent soon afterward when the Court considered *Mayo v. Prometheus*).²¹⁴ In fact, preemption had little to do with the questions truly at issue in *Bilski* itself, which centered around defining the boundaries of the per se abstract ideas exclusion.²¹⁵

In *Bilski*, the Supreme Court reviewed the Federal Circuit's application of the second-stage "machine-or-transformation-of-matter" analysis, which the Federal Circuit had christened the "sole test" for patentable subject matter in its en banc opinion below.²¹⁶ *Bilski* involved claims to methods of hedging risk in commodity trading in the energy market.²¹⁷ Virtually everyone—the PTO, nearly every Federal Circuit judge (the only holdout was Judge Newman), and all nine Supreme Court justices—agreed that *Bilski*'s claims were directed to unpatentable subject matter.²¹⁸ They disagreed only as to the rationale for the unpatentability of the claims.²¹⁹ The disagreement focused on

212. See, e.g., Dreyfuss & Evans, *supra* note 2, at 1355; Lemley et al., *supra* note 2, at 1336 (emphasizing how the scope of *Bilski*'s first claim was tantamount to an attempt to preempt the entire idea of hedging); Menell, *supra* note 2, at 1304 (observing that the Court's confusing opinion used preemption analysis as a basis to reject *Bilski*'s claim).

213. *Bilski v. Kappos*, 130 S. Ct. 3218, 3258–59 (2012) (Breyer, J., concurring) (quoting *Gottshalk v. Benson*, 409 U.S. 63, 67, 72 (1972)).

214. See *supra* notes 99–106 and accompanying text.

215. See Golden, *supra* note 2, at 1060–64 (reviewing *Diehr*, *Bilski*, and *Benson* and arguing that the deeper issue and inquiry is a categorical analysis).

216. *Bilski*, 130 S. Ct. at 3223–28 (Kennedy, J., opinion of the court) (quoting *In re Bilski*, 545 F.3d 943, 949, 955–56 (Fed. Cir. 2008) (en banc)).

217. *Id.* at 3223–24.

218. See *id.* at 3224–25, 3231; *id.* at 3232 (Stevens, J., concurring); *id.* at 3257 (Breyer, J., concurring); *In re Bilski*, 545 F.3d at 966 (Dyk, J., concurring); *id.* at 976, 997–98 (Newman, J., dissenting); *id.* at 998 (Mayer, J., dissenting); *id.* at 1011, 1015 (Rader, J., dissenting); *Ex parte Bilski*, No. 2002-2257, 2006 WL 5738364, at *1, *29 (B.P.A.I. Sept. 26, 2006).

219. See *Bilski*, 130 S. Ct. at 3224, 3231 (Kennedy, J., opinion of the court) (holding that the claims at issue were directed towards an unpatentable abstract idea that would

different ways of defining per se unpatentable abstract ideas, rather than on the second part of the patentable subject matter analysis.²²⁰ As discussed in more detail below, the Court majority rejected a number of proposed first-stage tests for defining a per se excluded abstract idea, but did not provide a clear replacement, other than to refer to its precedents on the abstract idea exclusion.²²¹ Near the end of a many-page opinion, the *Bilski* majority simply concluded, bolstered only by the assertion “[h]edging is a fundamental economic practice,” that “[t]he concept of hedging . . . is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*.”²²²

Having devoted nearly its entire opinion to discussing and rejecting various potential definitions of per se unpatentable abstract ideas, the Court in the end appeared to base its holding largely on a *Benson*-esque overbreadth analysis.²²³ The Court first opined that two of the claims were so general as to amount to patenting of “[t]he concept of hedging” itself and hence unpatentable: “Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively

preempt the use of the formula in all fields and noting that the patent examiner rejected the claims for being only a manipulation of an abstract idea and not limited to a practical application); *id.* at 3257 (Stevens, J., concurring) (opining that the claims were not directed to a “process’ within the meaning of § 101” and that business method patents are, and have always been, per se unpatentable); *In re Bilski*, 545 F.3d at 963–66 (holding that the process claims failed to “transform any article to a different state or thing”); *id.* at 966 (Dyk, J., concurring) (writing separately to emphasize the longstanding view that “processes not involving manufactures, machines, or compositions” are unpatentable); *id.* at 998 (Mayer, J., dissenting) (concluding that the claims were unpatentable on the grounds of per se exclusion for business method patents); *id.* at 1011 (Rader, J., dissenting) (concluding that claims were barred based on a per se exclusion of claims drawn to abstract ideas); *Ex Parte Bilski*, 2006 WL 5738364, at *27, *29–30 (noting that the claims at issue do not transform physical matter and were written so broadly that they preempted “any and every way to perform the steps”).

220. *See Bilski*, 130 S. Ct. at 3224, 3231 (Kennedy, J., opinion of the court) (focusing on per se exclusion of subject matter as the basis for rejecting petitioners’ claims); *id.* at 3232 (Stevens, J., concurring); *id.* at 3257–58 (Breyer, J., concurring); *In re Bilski*, 545 F.3d at 963–64, 966; *id.* at 966 (Dyk, J., concurring); *id.* at 998 (Mayer, J., dissenting); *id.* at 1010–11 (Rader, J., dissenting); *Ex parte Bilski*, 2006 WL 5738364, at *22–23 (relying on preemption and the machine-or-transformation test to reject the claims); Chao, *supra* note 2, at 84–85 (observing that the *Bilski* courts failed to provide guidance on what additional limitations change an unpatentable idea into a patentable application).

221. *Bilski*, 130 S. Ct. at 3224–25, 3227, 3229–31 (Kennedy, J., opinion of the court); Dreyfus & Evans, *supra* note 2, at 1359 (observing that the Court rejected the useful, concrete, and tangible result test and was unclear about the import of the machine-or-transformation test).

222. *Bilski*, 130 S. Ct. at 3231 (quoting *In re Bilski*, 545 F.3d at 1013 (Rader, J., dissenting)).

223. *Id.* at 3225–31 (relying on the guideposts in *Benson*, *Flook*, and *Diehr* to hold that *Bilski*’s claims are overbroad and would preempt the use of risk hedging).

grant a monopoly over an abstract idea.”²²⁴ There is probably little disagreement that the concept of hedging, like the BCD conversion algorithm in *Benson*, is involved in a large swath of downstream uses.²²⁵ Because the Court characterized those two claims as entirely commensurate with claims to the concept itself, the use of preemption here is, for once, consistent with its original usage in *Benson*.²²⁶

The Court devoted only a single paragraph to its analysis of the remaining, more limited, claims, which it described only as “broad examples of how hedging can be used in commodities and energy markets.”²²⁷ In concluding that those claims also were unpatentable, the Court alluded to the preemption corollaries concerning field-of-use limitations and token postsolution activity²²⁸ and to *Flook*’s inventive concept approach: By

“attempt[ing] to patent the use of the abstract idea of hedging risk in the energy market and then instruct[ing] the use of well-known random analysis techniques to help establish some of the inputs into the equation[,] . . . these claims add even less to the underlying abstract principle than the invention in *Flook* did.”²²⁹

The Court’s treatment of the more limited claims was so cursory, however, that it is impossible to determine exactly what test was applied or even whether the same analysis was applied to all of those claims.

Interestingly, four concurring justices, who would have held the claims unpatentable based on a per se exclusion of business methods, argued that the majority’s description of the claims as directed to “the basic concept of hedging” inappropriately “discounts the application’s discussion of what sorts of data to use, and how to analyze those data, as mere

224. *Id.* at 3231.

225. Dreyfuss & Evans, *supra* note 2, at 1359 (illustrating how an understanding of the likely downstream impact of a patent on hedging helps to explain the Court’s reasoning in *Bilski*).

226. *See Bilski*, 130 S. Ct. at 3231 (Kennedy, J., opinion of the court); Dreyfuss & Evans, *supra* note 2, at 1354–56 (explaining how *Bilski* relies upon and utilizes *Benson*’s formulation of preemption).

227. *Bilski*, 130 S. Ct. at 3231.

228. *Id.*

229. *Id.*; *see also* Parker v. Flook, 437 U.S. 584, 594–95 (emphasizing that there is no inventive concept in the application of an algorithm if the applicant does nothing more than “provide[] a new and presumably better method for calculating alarm limit values”).

‘token postsolution components.’”²³⁰ “In other words, the Court artificially limits petitioners’ claims to hedging, and then concludes that hedging is an abstract idea rather than a term that describes a category of processes including petitioners’ claims.”²³¹ The implication was that, because the majority did not define a workable per se exclusion rule so that it could apply an appropriate two-step analysis, the majority punted instead by mischaracterizing the breadth of *Bilski*’s claims and then rejecting them as overbroad.²³² Given the fact that the majority’s focus throughout the opinion was on how to approach the per se exclusion question and that it eventually threw up its hands and simply referred to precedent, this accusation has something of the ring of truth.²³³

In any event, in light of the way the preemption analysis fits into the opinion as a whole, it seems likely that the majority justices were convinced that the claims were unpatentable for reasons that had nothing to do with the purported preemption analysis. (Indeed, the word is barely used in the opinion: twice by the majority; twice by the four-justice concurrence, and once in the list of “points” in Justice Breyer’s concurrence.²³⁴) Though Justice Breyer’s concurrence has highlighted “preemption” for those seeking clarity from *Bilski*, the preemption discussion in the majority opinion has the look of window dressing to cover a failed effort to define the boundaries of the per se exclusion for abstract ideas, despite agreement that the claims at issue fell within the boundaries.²³⁵

In *Mayo v. Prometheus*, a unanimous Supreme Court resoundingly reaffirmed the inventive concept approach that it

230. *Bilski*, 130 S. Ct. at 3235–36 (Stevens, J., concurring) (quoting the opinion of the court at 3231).

231. *Id.* at 3235.

232. *See id.* at 3235–36 (arguing that the majority mischaracterizes *Bilski*’s claims by artificially limiting them to hedging); Menell, *supra* note 2, at 1304–05 (arguing that the Court’s decision to resolve *Bilski* on preemption grounds “provided no effective guidance on how to distinguish between general ideas and the processes that implement them”).

233. *See Bilski*, 130 S. Ct. at 3223–31 (Kennedy, J., opinion of the court) (analyzing various per se exclusion tests and stating that they “need not define further what constitutes a patentable process, beyond pointing to the definition of that term in § 100(b) and looking to the guideposts in *Benson*, *Flook*, and *Diehr*”); *id.* at 3235–36 (Stevens, J., concurring) (“The Court, in sum, never provides a satisfying account of what constitutes an unpatentable abstract idea.”).

234. *Bilski*, 130 S. Ct. at 3230–31 (Kennedy, J., opinion of the court); *id.* at 3235, 3253 (Stevens, J., concurring); *id.* at 3258 (Breyer, J., concurring).

235. *Id.* at 3258 (Breyer, J., concurring) (acknowledging how preemption is a point of agreement among all the opinions).

had refused to apply in *Diehr*.²³⁶ The claims at issue in *Mayo* were of the form:

A method of optimizing . . . treatment of an immune-mediated gastrointestinal disorder, comprising:
[A]dministering a drug providing [a particular metabolite] to a subject;
[D]etermining the level of [the metabolite] in [the] subject;
[W]herein the level of [the metabolite] less than [a particular threshold] indicates a need to increase the amount of drug administered [construed by the court to mean that the physician consider increasing the dosage].²³⁷

The Federal Circuit had held that the claims passed its machine-or-transformation test based on the physicality of the “administering” and “determining” steps.²³⁸ The Federal Circuit then purported to apply a preemption analysis to determine whether the claims impermissibly preempted the natural phenomenon (the correlation between metabolite and medical condition) upon which they relied.²³⁹ Notably, however, the Federal Circuit’s analysis did not really focus on whether the claims preempted downstream uses of the specific correlations at issue.²⁴⁰ In fact, the Federal Circuit’s analysis was much more consistent with a direct evaluation of potential downstream impact. The analysis relied heavily on the fact that the claims were limited by reciting “specific treatment steps” and involved a “particular application[:] the treatment of a specific disease by administering specific drugs and measuring specific metabolites.”²⁴¹ The court also argued implicitly that there was room to design around the claims by stating that “[o]ther drugs might be administered to optimize the therapeutic efficacy of the claimed treatment.”²⁴² These features of the claims were irrelevant to assessing the extent to which they preempt specific

236. See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (suggesting that the “inventive concept” test is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself”); *supra* note 164 and accompanying text (noting that the Court did not apply the “inventive concept” test in *Diehr*).

237. *Mayo*, 132 S. Ct. at 1295 (quoting U.S. Patent No. 6,355,623 col.20 ll. 10–25 (filed Mar. 12, 2002)).

238. *Prometheus Labs., Inc., v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1356 (Fed. Cir. 2010), *rev’d*, 132 S. Ct. 1289 (2012).

239. See *id.* at 1355.

240. See *id.* at 1355–59 (holding that the claims directed towards the naturally occurring correlations do not attempt to preempt all uses of the correlations).

241. *Id.* at 1355.

242. *Id.*

correlations between particular metabolite levels and patients' reactions to particular drugs.²⁴³ Instead, they relate to the relatively narrow downstream impact of the claims overall.²⁴⁴ In fact, the Federal Circuit's patentable subject matter analysis did not depend in any significant way on the fact that the claims involved a natural phenomenon. Essentially the same questions could have been asked about any claim.

The Supreme Court's analysis in *Mayo* departed radically from the Federal Circuit's approach. Rather than focus on overbroad downstream impact or deploy the machine-or-transformation inquiry, the Court analyzed whether the inventor had added anything to the natural correlations other than "well-understood, routine, conventional activity already engaged in by the scientific community."²⁴⁵ Because the claimed application of the per se unpatentable natural correlations would have been routine for the medical community, the claims were unpatentable.²⁴⁶ Thus, the Court employed the second-stage inventive concept test that it had adopted in *Funk Bros.* and *Flook*.²⁴⁷

After conducting this clean inventive concept analysis, the Court unfortunately muddied the waters by discussing its earlier cases without parsing the distinct aspects of patentable subject matter at issue in each.²⁴⁸ For example, the opinion somewhat implausibly interpreted *Diehr* as having implicitly conducted an inventive concept analysis and determined that the steps in the industrial molding process over and above the equation for

243. *See id.* at 1355–57 (noting the specific relationship between the correlation and the particular drugs recited in the claims).

244. *See id.* at 1355–58 (interpreting the claims at issue as "specific treatment steps, not just the correlations themselves" that comprise "particular methods of treatment," which could be designed around simply by administering different drugs).

245. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294–1302, 1305 (2012); Daniel Fisher, *Court Strikes Down Prometheus Patent on Drug-Dosage Method*, FORBES (Oct. 17, 2012, 1:48 PM), <http://www.forbes.com/sites/danielfisher/2012/03/20/supreme-court-strikes-down-patent-on-drug-dosage-method/> (noting the Court's lack of emphasis on the scope of patent protection and shift in focus to judge-made exclusions).

246. *Mayo*, 132 S. Ct. at 1297–98.

247. *See id.* (identifying four points as a part of the inventive concept analysis to determine that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of the natural phenomenon); *Parker v. Flook*, 437 U.S. 584, 594 (1978) ("[T]he discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application."); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 117, 130 (1948) ("If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.").

248. *See Mayo*, 132 S. Ct. at 1298–1302 (analogizing to *Flook*, *Diehr*, and other older cases without specific reference to a particular test).

curing time added enough to have “transformed the process into an inventive application of the formula.”²⁴⁹

The confusion was exacerbated by the Court’s attempt to wedge the *Mayo* claims into a preemption rubric,²⁵⁰ forcing the opinion to contend with the relative narrowness of the natural correlations involved, as has already been discussed. Apparently, the Court itself was unconvinced by this discussion, as it felt the need to say that “[w]e need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them.”²⁵¹ By this point, the Court’s discomfort should be understandable. The preemption rubric simply doesn’t fit with the inventive concept rule that the Court applies in cases involving newly discovered natural phenomena.

To summarize, the Supreme Court’s cases mostly have been concerned with how to apply a per se exemption for natural phenomena and abstract ideas and not with the overbreadth concerns suggested by the preemption rubric. With the possible exception of *Bilski*, every opinion involving a natural phenomenon or abstract idea that was discovered by the inventor has employed (or been consistent with) the inventive concept test established in *Funk Bros.* and reaffirmed in *Mayo*.²⁵² *Brogdex*, in which the natural product was the well-known orange, emphasized the degree to which the claimed product had beneficial uses different from those of the natural product,²⁵³ while *Diehr*, in which the mathematical equation at issue was well known, emphasized that the claims were drawn to a “function which the patent laws were designed to protect.”²⁵⁴ Preemption analysis was not central to any of the Court’s determinations of how to apply per se patentable subject matter exclusions, nor, as we have seen, has it been particularly useful as a tool for analyzing potential overbroad downstream impact.

249. *Id.* at 1298–99.

250. *See id.* at 1301–03 (concluding that the claims at issue would “tie up too much future use of the laws of nature”).

251. *Id.* at 1302.

252. *Compare id.*, at 1294, 1299 (endorsing the “inventive concept” doctrine), with *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980) (contrasting the patentee’s claim against that in *Funk*), and *Parker*, 437 U.S. at 594 (indicating that the inventive application, but not the discovery of natural phenomena is patentable), and *Funk Bros.*, 333 U.S. at 130–31 (outlining the “inventive concept” doctrine), and *Bilski v. Kappos*, 130 S. Ct. 3218, 3229–3231 (2010) (likening petitioner’s claim to that of *Benson*’s binary code algorithm before finding that the claim was an attempt to patent an abstract idea and preempt the use of the formula in all other fields).

253. *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11–14 (1931).

254. *Diamond v. Diehr*, 450 U.S. 175, 187, 192 (1981).

Instead, the preemption rubric has served mainly to muddy the water and to distract from more pertinent questions.

IV. DNA PATENTS: AN ILLUSTRATION OF THE PER SE EXCLUSION FRAMEWORK

This Article leaves all the hard questions open. While I plan to tackle some of them in follow-on work, the remainder of this Part provides a brief illustration of the potential payoff from the analytical framework suggested here. The illustration concerns whether DNA sequences are patentable subject matter, which is the subject of the Federal Circuit's opinions in *Association for Molecular Pathology (AMP) v. USPTO*.²⁵⁵ *AMP*, which may well be headed for Supreme Court consideration, involves claims by Myriad Genetics to DNA sequences for mutations relating to breast cancer.²⁵⁶

Analysis of whether DNA sequences should be unpatentable subject matter generally proceeds by assuming that the per se exclusion for products of nature applies to genes within a natural organism (such as a human being) and then focusing on whether claimed DNA sequences, which are either extracted from nature or artificially constructed, are sufficiently different from natural DNA to be patentable.²⁵⁷ This is fine as far as it goes, but the analysis begs the usual questions. First, what is the scope of the per se exclusion and what is its rationale? The answer to this question, which is usually not addressed, has determinative consequences for the bottom-line outcome of the inquiry. Second, given the rationale for the per se exclusion, what second-stage rule should be used to determine the patentability of various types of DNA claims?

At least three potential rationales for per se excluding genetic materials from patentable subject matter have been advanced. Some have argued that DNA patents interfere with human autonomy.²⁵⁸ I set this rationale aside for purposes of this

255. *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1309 (Fed. Cir. 2012); see also *Ass'n for Molecular Pathology v. USPTO*, 653 F.3d 1329, 1334 (Fed. Cir. 2011), vacated, 132 S. Ct. 1794, 1794 (2012), remanded for consideration, 103 U.S.P.Q.2d (BNA) 1681 (Fed. Cir. Aug. 16, 2012) (vacated and remanded for reconsideration in light of *Mayo*).

256. *Ass'n for Molecular Pathology*, 689 F.3d at 1314.

257. See, e.g., Robert A. Pollock et al., *2011 Patent Law Decisions of the Federal Circuit*, 61 AM. U. L. REV. 785, 862–65 (2012).

258. See Pilar N. Ossorio, *The Human Genome as Common Heritage: Common Sense or Legal Nonsense?*, 35 J.L. Med. & Ethics 425, 427–29 (2007); David Selene Kaye, *Who Owns Your Genes?*, ACLU BLOG OF RIGHTS, (May 12, 2009, 7:45 PM), <http://www.aclu.org/blog/free-speech-womens-rights/who-owns-your-genes> (“The government should not be granting private

discussion, though a per se exclusion based on human autonomy concerns could in principle be developed along the same framework as any other per se exclusion. More often, it is argued that DNA sequences fall within the traditional per se exclusion for natural products.²⁵⁹

Two distinct approaches to the natural product exclusion have at least some support in the case law. Dana Irwin, in a useful discussion of these issues, notes that natural phenomena have been defined alternatively as (1) that which exists in nature outside of human control; and (2) that which is the subject of scientific inquiry.²⁶⁰ She argues that, during the nineteenth century, technology was defined, consistent with Enlightenment thinking, by mastery or control over nature.²⁶¹

Consistent with this way of thinking, per se exclusions from patentable subject matter represented “aspects of nature that had not yet been brought under human control,” in the form of discoveries that had not yet been applied and “un-embodied innovations that remained within an inventor’s mind.”²⁶² Many patentable subject matter cases describe natural phenomena and abstract ideas as pre-existing human intervention in a kind of commons, where they are available to all of humanity’s use.²⁶³ Judge Rader of the Federal Circuit echoed this perspective in his dissent in *In re Bilski*: “Natural laws and phenomena can never qualify for patent protection because they cannot be invented at all. After all, God or Allah or Jahveh or Vishnu or the Great Spirit provided these laws

entities control over something as personal and basic to who we are as our genes.”) (statement of Anthony D. Romero, Executive Director, ACLU). In fact, an argument of this sort was originally made in the *AMP* case, based on the First Amendment. Ass’n. for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 184 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (2011), *vacated*, 132 S. Ct. 1794 (2012), *remanded for reconsideration*, 103 U.S.P.Q. 1681 (Fed. Cir. Aug. 16, 2012); *Court Reaffirms Right of Myriad Genetics to Patent Genes*, N.Y. TIMES (Aug. 16, 2012), <http://www.nytimes.com/2012/08/17/business/court-reaffirms-right-of-myriad-genetics-to-patent-genes.html>.

259. See, e.g., Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 732–38, 741 (describing the basis for the argument that the natural product doctrine is intertwined with DNA patentability).

260. Dana Remus Irwin, *Paradise Lost in the Patent Law? Changing Visions of Technology in the Subject Matter Inquiry*, 60 FLA. L. REV. 775, 788–89, 803–04, 810–11 (2008).

261. *Id.* at 782–85.

262. *Id.* at 785–86, 788–89.

263. See, e.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (“The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.”).

and phenomena as humanity's common heritage."²⁶⁴ Under this rationale for per se exclusion, the second-stage rule for evaluating a patent claim incorporating a natural product would set out the requisite degree and type of human intervention. This type of approach is exemplified by *Brogdex*, discussed earlier, in which the Court focused on whether the patentee's interventions had produced new characteristics or "beneficial uses" for the treated fruit.²⁶⁵ The purified product of nature doctrine, as set out by Learned Hand, has been the standard basis for DNA patentability. That doctrine also reflects the mastery of nature rationale. Hand opined that the patentability of an isolated natural product depends upon whether the patentee was "the first to make it available for any use [such that] it became for every practical purpose a new thing commercially and therapeutically." Hand's opinion thus employs a second-step test of human intervention and control focused on practical use.

Eventually, Irwin argues, technology came to be viewed less as mastery over nature than as applied science.²⁶⁶ Patentable subject matter doctrine thus evolved to emphasize the distinction between science and technology, and exclusions were redefined in terms of keeping the basic results of open science in the public domain.²⁶⁷ One may debate Irwin's picture of the historical progression of the doctrine, given how far back the discussions of the unpatentability of scientific activity go.²⁶⁸

264. *In re Bilski*, 545 F.3d 943, 1013 (Fed. Cir. 2008) (Rader, J., dissenting), *aff'd sub nom.*, *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

265. *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11–12 (1931).

266. *See Irwin, supra* note 260, at 802–03 (utilizing the USPTO's position on medical procedure patents for illustration).

267. *Id.* at 810–11.

268. Even *Morse's* discussion of the potential effects of broad claims on downstream innovation is partially dependent upon the assumption that scientific work is unpatentable and freely available to all. *See O'Reilly v. Morse*, 56 U.S. (How. 62) 62, 112–13 (1853). Thus, *Morse* argues that the patentees' ability to make free use of scientific advances, while keeping his own advances secret, is part of the problem with an overbroad claim:

[W]hile he shuts the door against inventions of other persons, the patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light New discoveries in physical science may enable him to combine it with new agents and new elements, and by that means attain the object in a manner superior to the present process and altogether different from it. And if he can secure the exclusive use by his present patent he may vary it with every new discovery and development of the science, and need place no description of the new manner, process, or machinery, upon the records of the patent office. And when his patent expires, the public must apply to him to learn what it is.

Historical debate aside, the scientific activity rationale remains a plausible justification for a per se natural product exclusion. The scope of the per se exclusion might include only the *results* of scientific activity or, more expansively, anything that is within the ordinary purview of the scientific enterprise. The second-stage rule might then investigate whether the inventor has contributed something over and above the results of conventional scientific activity. The Supreme Court's inventive concept rule is understandable in roughly this way: discovery of natural phenomena is ordinary scientific activity and thus within the per se exclusion, while an inventive application over and above the results of conventional scientific inquiry is patentable.

The recent opinions of the three Federal Circuit judges in *AMP* provide examples of different approaches to DNA sequence patentability. The framework set out in this Article is helpful in parsing their different approaches. The Federal Circuit addressed three types of sequences in *AMP*:²⁶⁹ (1) isolated full gene sequences; (2) short sequences isolated from the full gene; and (3) cDNA sequences produced in the laboratory to include only the active or "coding" sections of human DNA sequences.²⁷⁰ The court upheld the subject matter patentability of all three types, over a dissent by Judge Bryson with regard to the full and short isolated DNA sequence claims.

Judge Lourie, in his opinion for the court, applied a mastery of nature approach. In his view, cDNA molecules were almost trivially patentable because they were the result of such significant human intervention.²⁷¹ His analysis for the other two types of claims more discloses the second-stage rule that he applied to determine whether claims incorporating per se excluded material are patentable.²⁷² Judge Lourie defined the per se exclusion according to the chemical structure of the DNA molecules.²⁷³ His emphasis on DNA as a chemical entity led him to adopt a second-stage rule that essentially any change in

Id. at 113. Morse's broad upstream claim, in other words, would have allowed him not only to tax and potentially obstruct downstream *commercial* innovators but also to take advantage of freely disclosed *scientific* developments without reciprocating by disclosing the improvements based upon them.

269. *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1309 (Fed. Cir. 2012).

270. *Id.* at 1329.

271. *Id.*

272. *Id.* at 1327–28.

273. *Id.* at 1328–29 ("[I]solated DNA . . . has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body.").

chemical structure resulting from the human intervention of isolating the DNA imparted patentability.²⁷⁴ While the isolated molecules covered by the full gene claims might have the same genetic code as naturally occurring DNA, their chemical structure is changed by the isolation process.²⁷⁵ Shorter DNA fragments also are obviously different in chemical structure from their equivalents within the body.²⁷⁶ Because “[c]reating a new chemical entity is the work of human transformation, requiring skill, knowledge, and effort,” Judge Lourie deemed the claims to both full DNA sequences and short DNA sequences to be patentable.²⁷⁷

Judge Moore concurred with Judge Lourie, both in the result and in applying a control of nature approach, but she applied a somewhat different second-stage rule to evaluate whether the claims reflect sufficient human intervention.²⁷⁸ Rather than basing her test on minor changes in chemical structure as indicators of human intervention,²⁷⁹ she requires a greater degree of control,²⁸⁰ and like Judge Hand, emphasizes the degree to which human intervention has resulted in new practical uses for the sequences.²⁸¹ Because using a short DNA sequence “as a primer or probe to determine whether a patient has a mutation is a new and important utility substantially different from the role of that DNA as it occurs in nature,” Judge Moore easily found that claims to isolated short DNA sequences are patentable.²⁸² She had more difficulty with the claims to isolated full gene

274. *Id.* at 1327–29 (“[Genes] in their isolated states are different molecules from DNA that exists in the body.”).

275. *Id.* at 1328 (“[I]solated DNA [is left with] a distinctive chemical identity as compared to native DNA.”); *id.* at 1350–51 (Bryson, J., concurring in part and dissenting in part) (arguing that the majority elevates form over substance because although the BRCA genes were isolated, the BRCA sequence itself is the same as that found in nature).

276. *See id.* at 1328 (majority opinion).

277. *Id.* at 1333.

278. *Compare id.* at 1327–28 (emphasizing the chemical distinction between isolated and native DNA.), *with id.* at 1341–42 (Moore, J., concurring in part) (focusing on the added utility of the isolated claimed sequences).

279. *Compare id.* at 1327–29 (majority opinion) (proclaiming that the claimed isolated DNAs “constitute an *a fortiori* situation” based on the differences in structure, character, and use when compared to simply purified native DNA), *with id.* at 1342–43 (Moore, J., concurring in part) (arguing that “[i]t is not the chemical change alone, but that change combined with the different and beneficial utility” that renders the isolated DNAs patentable).

280. *See id.* at 1342–43 (Moore, J., concurring in part).

281. *See id.* at 1341–43 (emphasizing that the DNA products recited in the claims “are not naturally produced without the intervention of man” and describing the new utility characteristic of the claimed products).

282. *Id.* at 1342.

sequences, however, concluding that an “isolated full length gene does not clearly have a new utility and appears to simply serve the same ends devised by nature, namely to act as a gene encoding a protein sequence.”²⁸³ Nonetheless, Judge Moore ruled these claims patentable, not because of the degree of human intervention involved, but because of the reliance interests that the PTO’s practice of granting such claims over many years has produced.²⁸⁴

Judge Bryson’s dissenting approach differs in many respects from the approaches of Judges Lourie and Moore. His opinion is notable in that it separately applies more than one test for patentable subject matter analysis, grounded in different rationales.²⁸⁵ Like the other judges, he defines the per se excluded category to encompass only naturally occurring DNA.²⁸⁶ Unlike the others, however, he believes that distinctions between naturally occurring DNA and the claimed isolated DNA sequences should be judged according to the “conventional nomenclature” of the relevant scientific field, which is genetics, rather than chemistry.²⁸⁷

In analyzing the cDNA and full gene sequence claims, Judge Bryson applies the control of nature paradigm.²⁸⁸ Thus, he would uphold the patentability of cDNA as a “human-made invention,” based on differences in structure and utility from naturally occurring DNA, but would find the isolated full gene sequences unpatentable based on his view that the relevant comparison is to the genetic sequence, in terms of which the inventions are claimed.²⁸⁹ From Judge Bryson’s genetics-based perspective, the full gene claims do not reflect any more human intervention than “snapping a leaf from a tree.”²⁹⁰

While Judge Bryson did not consider defining the per se exclusion by the realm of scientific activity,²⁹¹ he did opine that

283. *Id.* at 1342–43.

284. *Id.* at 1343–44 (“The settled expectations of the biotechnology industry . . . cannot be taken lightly and deserve deference.”).

285. *See id.* at 1349–51 (Bryson, J., concurring in part and dissenting in part) (drawing from *Chakrabarty*, *Funk Bros.* and *Bilski* to illustrate the natural phenomenon exclusion).

286. *See id.* at 1327–28 (majority opinion); *id.* at 1340–42 (Moore, J., concurring in part); *id.* at 1350 (Bryson, J., concurring in part and dissenting in part).

287. *Id.* at 1351. (Bryson, J., concurring in part and dissenting in part).

288. *See id.* at 1354–56.

289. *See id.* (finding that a focus on the informational content of DNA as a basis of comparison between the claimed DNA products and native DNA is appropriate).

290. *Id.* at 1352.

291. *Compare* Irwin, *supra* note 260, at 810–12 (describing a rationale aimed at preserving the tools of scientific activity from patentability), *with Ass’n for Molecular*

the Supreme Court's inventive concept test, reaffirmed in *Mayo*, applies to the analysis of gene patents.²⁹² Applying the inventive concept test to the isolated DNA sequences, he would have ruled those claims unpatentable because the isolation of DNA requires nothing more for genetic science than conventional, routine activity analogous to the way in which the "isolation of interesting compounds is a mainstay of the chemist's art."²⁹³ Because he takes the need for an inventive concept seriously, Judge Bryson generally focused much more than the other judges on the scientific activity surrounding DNA isolation.²⁹⁴ He thus distinguished Myriad's unpatentable scientific discovery of the DNA sequences relevant to breast cancer from the application of the discoveries.²⁹⁵

Finally, Judge Bryson undertook a downstream impact analysis of the claims to short fragments of the natural gene sequences.²⁹⁶ His analysis did not depend on the downstream impact of particular DNA sequences, but, as in *Morse*, on the impact on downstream innovation that would result from the "brehtaking[]" number of embodiments covered by the claims.²⁹⁷ He would have found the short fragment claims unpatentable, pointing out that the inventors could have claimed their inventions more narrowly to avoid the overbreadth issue.²⁹⁸

This brief consideration of the DNA patent eligibility question illustrates the way in which different rationales for per se exclusion and different second-stage tests for moving a claim

Pathology, 689 F.3d at 1350–53 (focusing on the genetic differences between natural DNA and the claimed DNA rather than the preservation of the scientific tools).

292. *Compare Ass'n for Molecular Pathology*, 689 F.3d at 1326–31 (majority opinion) (reading *Mayo* as a preemption analysis and concluding that the claimed DNA molecules, unlike the method claims in *Mayo*, are compositions of matter and do not preempt a law of nature), and *id.* at 1340–41 (Moore, J., concurring in part), with *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012) (reaffirming the inventive concept test and finding the process claims unpatentable on the basis that there is no inventive step and the patent might "disproportionately [tie] up the use of the underlying natural laws, inhibiting their use in the making of further discoveries"), and *Ass'n for Molecular Pathology*, 689 F.3d at 1348–55 (Bryson, J., concurring in part and dissenting in part) (finding a lack of inventive concept beyond the chemical distinctions incidental to the isolation process).

293. *Ass'n for Molecular Pathology*, 689 F.3d at 1355 (Bryson, J., concurring in part and dissenting in part) (quoting *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1302 (Fed. Cir. 2007)).

294. *See id.* ("Neither isolation of the naturally occurring material nor the resulting breaking of covalent bonds makes the claimed molecules patentable.").

295. *Id.* at 1349.

296. *Id.* at 1356–57.

297. *Id.*; see also *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112–13 (1853).

298. *Ass'n for Molecular Pathology*, 689 F.3d at 1356 (Bryson, J., concurring in part and dissenting in part).

into patentable terrain can lead to different outcomes. It also illustrates that both threads of patentable subject matter analysis may apply in a single case. Thus, a DNA claim might be unpatentable both because it reflects insufficient human intervention or inventive activity and because its downstream impact is unacceptably broad. The analysis also suggests a possible explanation of the difference in views between the Federal Circuit and many genetic scientists, who find the patentability of DNA sequences highly objectionable.²⁹⁹ From the scientists' perspective, all three types of DNA sequences at issue in *AMP* are routinely produced as a result of conventional scientific activity for which patents are unnecessary.³⁰⁰ Their normative rationale for the unpatentability of DNA sequences may be based not so much on whether a sequence is in the natural realm, untouched by human intervention, but on its role in scientific activity, for which patents are not the relevant innovation system.

V. CONCLUSION

Patentable subject matter doctrine should further society's goals for the patent system.³⁰¹ Patentable subject matter doctrine thus has a pragmatic purpose: to promote innovation while respecting other values that are important to us. Determining subject matter eligibility should not be either a matter of arcane philosophical distinctions or a sort of Rube Goldberg experience of applying meaningless and unrelated "tests" in the hope that a result will pop out at the end.

This Article attempts to facilitate a systematic theoretical inquiry that remains grounded in pragmatic concerns by laying out a consistent framework for patentable subject matter doctrine. The framework first disentangles two threads of patentable subject matter analysis, separating concerns about overbroad impacts on downstream innovation from per se exclusions on other grounds.

299. See, e.g., Dreyfuss & Evans, *supra* note 2, at 1365–67 (illustrating some of the harms arising from patenting DNA sequences).

300. See Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1677–78 (2003) (explaining that techniques like isolation are routine and, therefore, not incentivized by patent protection); Irwin, *supra* note 260, at 801–04.

301. See, e.g., ROBERT E. SCHECTER & JOHN R. THOMAS, *INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS* 288–89 (2003) (identifying the instrumental rationales and rights behind patent policy); David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMPLE L. REV. 181, 192–95 (2009).

The framework next describes the two steps that must be taken to apply per se patentable subject matter exclusions to particular claims. Determining the rationale for a per se exclusion is logically prior to answering questions about how it should be applied. Focusing solely on the second-stage rule of application or failing to distinguish the two parts of the analysis, as courts have tended to do, is a recipe for confused analysis, as is illustrated by the current confused rhetoric about preemption.

Because different per se exclusions may have different rationales, it is unlikely that a single rule for assessing patentability of claims incorporating per se excluded elements will produce logically consistent and normatively desirable results. The failure of the Federal Circuit's attempt to require a "machine-or-transformation-of-matter" test in all patentable subject matter cases illustrates this difficulty.³⁰²

The ultimate goal of this Article's analysis is to provide a foundation for further theoretical inquiry. In a follow-on article, I will consider whether per se patentable subject matter exclusions are best understood by focusing on the availability of alternative innovation institutions. Any per se exclusion is almost inevitably both under- and overbroad. If per se exclusions are conceptualized at the level of the individual claim, the advantages and disadvantages of the exclusion are likely to vary so much between claims that it is hard to avoid making laundry list arguments, which may quickly become result-oriented and even contradictory.³⁰³ Conceptualizing per se exclusions at the institutional level, thus allowing comparison with the patent system as a means for incentivizing innovation, may be a more promising approach.

302. See *supra* text accompanying notes 237–243.

303. The concurring opinion of the four justices in *Bilski* is somewhat infected with this problem in its discussion of policy justifications for excluding business method patents, which include, for example, both an argument that business methods do not need patent incentives for invention because they can be practiced in secrecy and an argument that business methods do not need patent incentives for disclosure because they are practiced publicly. *Bilski v. Kappos*, 130 S. Ct. 3218, 3254–55 (2010) (Stevens, J., concurring). Presumably each of these concerns applies to some business method patents, but listing them will not convince skeptics that they should be the subject of a per se exclusion.