Washington University Law Review

Volume 94 | Issue 4

2017

Patent-Ineligibility as Counteraction

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PATENT-INELIGIBILITY AS COUNTERACTION

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ABSTRACT

Today, normative debates over restrictions on patent-eligibility are uniformly premised on a discrimination theory *of patent-ineligibility: the restrictions are assumed to cause the patent regime as a whole to discriminate against, and thus grant weaker patent protection for, the affected technology. Under discrimination theory, the justification for a rule of patent ineligibility turns on whether there is a good reason to treat the affected technology differently and grant it only relatively weak protection. In contrast, this Article articulates a novel* counteraction theory *of patent-ineligibility. Counteraction theory adopts the default premise that all technologies merit roughly the same strength of patent protection, and it recognizes that, in some circumstances, a well-tailored restriction on patent-eligibility can be the most effective means of achieving that rough equality. The weakening of patent protection caused by restrictions on patent-eligibility can sometimes offset the unusually strong protection that is created by inherent, technology-specific biases in the patent doctrines other than patent-eligibility, including novelty, nonobviousness, and enablement. A restriction on the patent-eligibility of a technology can thus bring the strength of the patent protection available for the technology back closer to the norm of protection granted for all technologies.*

A full account of counteraction theory entails an explanation of when and how the inherent, technology-specific biases in favor of strong protection can arise in the patent doctrines other than patent-eligibility, such as novelty, nonobviousness, and enablement. This Article focuses on one such explanation: the dematerialization of technology in today's knowledge-age economy has led to technology-specific regulatory

∗ Professor of Law, Washington University School of Law. This Article evolved in iterative drafts over several years. I thank many people for their insightful discussions during its evolution, including Scott Baker, Mario Biagioli, Oren Bracha, Dan Burk, Tun-Jen Chiang, Julie Cohen, David Deal, John Duffy, Rebecca Eisenberg, John Golden, Justin Hughes, Dmitry Karshtedt, Jeff Lefstin, Mark Lemley, Oskar Liivak, Lydia Loren, Glynn Lunney, Chuck McManis, Laura Pedraza-Fariña, Laura Rosenbury, Rachel Sachs, Pam Samuelson, Josh Sarnoff, Jacob Sherkow, Ted Sichelman, Kathy Strandburg, and Jay Thomas. I am also grateful for helpful comments during workshops, conferences, and colloquia hosted by Vanderbilt, Georgetown, Boston University, the University of San Diego, UC Davis, Lewis and Clark, University of Houston, Washington University, and Intellectual Property Scholars Conferences at DePaul, Stanford, and Cardozo. I thank Megan Lasswell and Cameron Clawson for their excellent research and comments.

inefficacy *in these doctrines. Certain non-eligibility patent doctrines cannot do the work of regulating patent validity that we expect them to be able to do when they are brought to bear on certain intangible technologies, meaning that they sanction unusually strong protection for those technologies. Technology-specific regulatory inefficacy sets the stage for a counteraction-oriented justification of restrictions on patent-eligibility. The restrictions can counteract or neutralize the unusually strong protection created by the inefficacy of the non-eligibility doctrines, bringing the strength of the patent protection that is available for the affected technology back into closer alignment with the protection that is available for other technologies.*

In addition to articulating counteraction theory and technology-specific regulatory inefficacy as theoretical possibilities, this Article examines the actual restrictions on patent-eligibility in two intangible technologies that are on the front lines of the ongoing battles over patent-eligible subject matter: diagnostic inferences and software. The Supreme Court has recently announced restrictions on the patent-eligibility of both technologies, and both restrictions are highly controversial under discrimination theory. However, the restrictions have a reasonable, although concededly imperfect, fit with the restrictions that can be justified under counteraction theory. In each technology, patent protection is unusually strong because certain non-eligibility doctrines fail to provide their expected validity-limiting regulation, and the Court's restriction on patent-eligibility works to counteract that strength.

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INTRODUCTION

From 2010 to 2014, the Supreme Court addressed the Section 101 doctrine of patent-ineligibility in an unprecedented four cases. Confronted with patents on technologies ranging from business methods[1] and software[2] to diagnostic inferences[3] and human genetics,[4] the Court invalidated the patents at issue in all four cases. Collectively, these opinions clearly signal the Court's intent to curtail the reach of patent-eligible subject matter.

A voluminous scholarly debate addresses the conditions under which restrictions on patent-eligibility like those announced by the Supreme Court have viable consequentialist justifications.[5] To date, what this Article calls the *discrimination theory* of patent-ineligibility has structured this debate: the goal of a restriction on patent-eligibility is to make the patent regime as a whole discriminate against the affected technology and provide relatively weak protection for it.[6] Discrimination theory focuses the normative debate

1. Bilski v. Kappos, 561 U.S. 593 (2010).
2. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).
3. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).
4. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).
5. This Article focuses solely on consequentialist justifications. It does not address moral justifications. *Cf.* Tun-Jen Chiang, *Competing Visions of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1858 (2014) (arguing that some disagreements over patent-eligibility reduce to different moral commitments). Nor does it address statutory interpretation. *Cf. In re* Bergy, 596 F.2d 952 (C.C.P.A. 1979) (arguing that the Supreme Court's articulation of patent-ineligibility conflicts with the structure of the Patent Act). Statutory interpretation is relevant to the project, but only in an indirect way: the lack of an explicit textual grounding for the doctrine of patent-eligibility in the Patent Act increases the salience of consequentialist reasoning in patent-eligibility analyses.
6. *See, e.g.*, Bernard Chao, *Moderating* Mayo, 107 NW. U. L. REV. 423 (2012); Tun-Jen Chiang, *The Rules and Standards of Patentable Subject Matter*, 2010 WIS. L. REV. 1353 (2010); John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609 (2009); 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 (2012) [hereinafter *Wisdom*]; Rebecca S. Eisenberg, Prometheus *Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J. ONLINE 341 (2013) [hereinafter Prometheus *Rebound*]; John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041 (2011); Anna B. Laakmann, *An Explicit Policy Lever for Patent Scope*, 19 MICH. TELECOMM. & TECH. L. REV. 43 (2012); Mark A. Lemley, Michael Risch, Ted Sichelman, & R. Polk Wagner, *Life After* Bilski, 63 STAN. L. REV. 1315 (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 (2011); David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 195 (2009); Lisa Larrimore Ouellette, *Patentable Subject Matter and Nonpatent Innovation Incentives*, 5 U.C. IRVINE L. REV. 1115 (2015); Arti Rai, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 STAN. L. REV. ONLINE 111 (2013); Pamela Samuelson & Jason Schultz, "*Clues" for Determining Whether Business and Service Innovations Are Unpatentable Abstract Ideas*, 15 LEWIS & CLARK L. REV. 109 (2011); Jacob S. Sherkow, *The Natural Complexity of Patent Eligibility*, 99 IOWA L. REV. 1137 (2014); Katherine J. Strandburg, *Much Ado About Preemption*, 50 HOUS. L. REV. 563 (2012) [hereinafter *Preemption*]; Katherine J. Strandburg, *An Institutional Approach to Patentable Subject Matter* (unpublished

on whether the affected technology merits a smaller quantum of protection than other technologies merit. Is the technology unusually likely to be a basic tool, meaning that patent protection would significantly retard future innovation? Is there less of a need for incentives to discover, commercialize, and disclose the technology, meaning that significant innovation and disclosure would persist absent patent protection? Although one focuses on the possibility of patent protection having large costs and the other on the possibility of patent protection having small benefits, both of these questions seek to justify restrictions on patent-eligibility by demonstrating that the net impact of ordinary, full-strength patents would be detrimental to overall social welfare and that weaker patents are therefore preferable.

This Article proposes and explores a different theory of the role that a restriction on patent-eligibility can play to shape optimal patent protection.[7] Patent-ineligibility is not the only doctrine that can implement a "substantive screen" regulating the outer limits of what constitutes a permissible patent interest (i.e., that reduces overall patent strength by selectively invalidating the most socially costly patents).[8] In fact, patent law's "patentability conditions"—that is, its validity doctrines other than patent-eligibility, including novelty, inherency, nonobviousness, overbreadth, and the rules of means-plus-function claiming—do the bulk of this regulatory work. One key, unrecognized fact about the patentability conditions is that they are sometimes unable to do the regulatory work that we expect them to do when they are brought to bear on certain technologies, leading to an inherent bias in favor of strong, socially costly patent protection in those technologies.[9] The *counteraction theory* of patent-ineligibility proposes that restrictions on patent-eligibility are sometimes the most effective means of offsetting such technology-specific biases in the patentability conditions and helping to equalize the strength of patent protection for all technologies.[10]

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manuscript) (on file with author) [hereinafter *Institutional Approach*]. A significant thread in the discrimination-theory debate addresses a second-order question about doctrinal means: When discrimination is merited, are the patentability conditions or restrictions on patent-eligibility the better tools for achieving that discrimination? *See infra* note 276 and accompanying text.

7. The argument here is not that discrimination theory is conceptually unsound. The goal is only to add another justification to the list of viable justifications for restrictions on patent-eligibility.

8. Jonathan S. Masur, *Costly Screens and Patent Examination*, 2 J. LEGAL ANALYSIS 687 (2010) (distinguishing substantive and costly screens).

9. This observation undermines what is perhaps the most commonly deployed argument against restrictions on patent-eligibility, namely, that anything that patent-eligibility can do to regulate patent validity, the patentability conditions can do better. *See infra* note 276 and accompanying text (discussing this "Annie Oakley" argument against restrictions on patent-eligibility). The dominance of this argument has likely contributed to the inherent biases in the patentability conditions going unnoticed for so long.

10. The goal of roughly equal patent protection for all technologies is, of course, only a default.

A focus on counteraction theory tees up questions about the condition precedent that creates the need for counteraction. Why are there technology-specific biases in the patentability conditions? That is, why are certain patentability conditions in certain technologies unable to do the work of invalidating costly patents that we expect them to do? Although there may be more than one answer to these questions, the answer on which this Article focuses is a doctrinal phenomenon that this Article terms *technology-specific regulatory inefficacy*.[11] A simple metaphor is helpful here to introduce the concept. The patentability conditions are legal tools for regulating patent validity. The physical tools in our basement toolboxes are only able to do the work that we expect them to be able to do when the technologies on which they are brought to bear have certain properties. For example, a crescent wrench can only do its work of tightening or loosening something when the something on which it is brought to bear is shaped like a nut. The central insight behind technology-specific regulatory inefficacy is that many of the patentability conditions are like conventional tools in that they, too, can only do their regulatory work when the claimed technologies have certain fundamental properties. They can only latch onto the claimed technologies and achieve the leverage required to regulate patent validity when the claimed technologies have certain fundamental properties. When technologies lack these fundamental properties, the patentability conditions are ineffective regulators, making the validity regulation for patents on those technologies lax and the resulting protection unusually strong. This is technology-specific regulatory inefficacy in a nutshell, and its action (making patents stronger on an arbitrary basis) is one reason why counteraction with a restriction on patent-eligibility (reducing patent strength) sometimes makes sense. When certain patentability conditions cannot regulate what constitutes a permissible patent interest or invalidate costly patents when they are brought to bear on certain technologies, patent-eligibility can step into the regulatory gap and do the needed work.

Technology-specific regulatory inefficacy rests on an argument about technological specificity in patent law, but it is a very different type of argument than the argument that is conventionally made about

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Conventional arguments about technological specificity in patent law suggest that different industries may have different innovation profiles that are best incentivized with different types of patent protection. *See infra* notes 281–282 and accompanying text. However, absent any reason for protecting different technologies with patents of different strengths, the default position should remain equal treatment for all technologies.

11. *See infra* note 80 (discussing other sources of biases in the patentability conditions that may give rise to a need for counteraction with a restriction on patent-eligibility).

technological specificity in patent law. The conventional argument posits that patent law is neutral on its face, both textually and in action in the courts, and that technology specificity arises only when judges use patent law in different ways in response to the different innovation profiles of different industries, whether consciously or not.[12] In contrast, technology-specific regulatory inefficacy posits that technological specificity is baked into the patentability conditions.[13] The belief that patent doctrine is technologically neutral absent judicial inflection is mistaken, but it is also understandable. The regulatory efficacy of the patentability conditions is contingent on properties of a technology that are so fundamental that, at first glance, it may seem like all technologies possess them. In fact, when the modern patentability conditions evolved in the industrial era of the nineteenth and early twentieth centuries, all patentable technologies did possess them. Over the course of the last half-century, however, the intrinsic nature of socially valuable technology underwent a radical change: it dematerialized.[14] In today's knowledge-age economy, information-processing technology with only a light footprint in the material world of extension is now commonplace. Intangibility lies at the root of the regulatory inefficacy identified in this Article: dematerialization altered the fundamental properties of technology on which the patentability conditions depend to achieve regulatory leverage. A rigorous examination of both the intrinsic nature of contemporary, dematerialized technology and the mechanisms through which the patentability conditions operate is required to reveal the technological specificity that is hard-wired into contemporary patent law.

As proof of concept of both the counteraction theory of patent-ineligibility and the technology-specific regulatory inefficacy that creates the need for counteraction, this Article focuses on two dematerialized technologies that are on the front lines of the contemporary battles over patent-ineligibility: diagnostic inferences, the technology at issue in the Supreme Court's opinion in *Mayo Collaborative Services v. Prometheus Laboratories*,[15] and software, the technology at issue in the Court's opinion in *Alice Corp. v. CLS Bank International*.[16] The intangibility of each

12. DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2009); John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. CHI. L. REV. 1073, 1078 (2015).

13. Judges would need to actively craft any technology-specific restrictions on patent-eligibility adopted to counteract the baked-in technological specificity of regulatory inefficacy.

14. *See infra* note 85 and accompanying text.

15. 132 S. Ct. 1289 (2012).

16. 134 S. Ct. 2347 (2014).

technology undermines the validity regulation normally imposed by certain patentability conditions. In turn, each technology is a good candidate for a restriction on patent-eligibility under counteraction theory to normalize the net strength of the validity regulation imposed.

Diagnostic inferences are highly unusual technologies. A diagnostic inference is an act of mental cognition in which a doctor logically reasons from two factual premises to reach a conclusion about a patient's health.[17] More specifically, the premises are, first, a general correlation—say, in general, patients with fevers are likely ill—and, second, a bit of knowledge about a particular patient—say, Sally has a fever. Based on these two premises, the doctor can reason to a diagnostic conclusion—namely, Sally is likely ill. Diagnostic inferences are unusual because, while most technologies exist in the extra-mental world, diagnostic inferences are built out of meaningful mental states within a thinker's mind. When patented technologies are built from meaningful mental states rather than extra-mental entities, neither inherency nor overbreadth, two of patent law's most important patentability conditions, can do the cost-reducing, regulatory work that we routinely expect them to do.

Inherency normally regulates patent validity and reduces costly patent density by enforcing the categorical rule that discovering new knowledge about how a product or process works, without also generating a new product or process that embodies the knowledge in a way that puts it to work, does not amount to a patentable invention. This rule may initially seem like it can be used in all technologies. However, upon closer inspection, it becomes clear that it only works under certain conditions. Inherency can only do its cost-reducing, regulatory work when there is a clear distinction between a product or process that puts knowledge to work in a useful manner, on the one hand, and the knowledge itself, on the other hand. This distinction is self-evident when the patented products and processes exist in the extra-mental world. Such products and processes are clearly different from knowledge in thinkers' minds. However, the distinction collapses when patents claim the use of meaningful mental states in human minds, as diagnostic-inference patents do, because both the both the products/processes and the knowledge are constructed from meaningful mental states. Under these circumstances, inherency loses its regulatory efficacy and is unable to reduce costly patent density.[18]

Overbreadth, too, normally does important cost-reducing work as a

17. *See infra* Section II.A.
18. *See infra* Section II.B.

regulator of patent validity: it invalidates highly general, and thus costly, patent claims. Judges and examiners detect overbreadth by querying whether the set of claimed technologies is disproportionately large with respect to the set of technologies that an inventor invents and discloses in the patent specification. Thus, overbreadth only works as a regulator of patent validity when generality is a set-theoretical construct. That is, it only works when greater generality is caused by a larger number of distinct technologies being grouped together in a single collection. However, the generality of a meaningful mental state in a thinker's mind is not a set-theoretical construct. A mental state that embodies highly general knowledge is a singular mental state that is intrinsically general, not a large collection of distinct mental states. When inventors seek patents on diagnostic inferences, they can therefore draft claims that are highly general yet that are "picture claims" encompassing only a single embodiment. So long as the claimed embodiment is disclosed, picture claims are never overbroad, meaning that inventors can easily obtain a general claim by inventing and disclosing a single embodiment of a diagnostic inference that is intrinsically general. The ability to enable and demonstrate possession of a general claim through disclosure of a single embodiment makes overbreadth an ineffective regulator of patent validity, even when it is brought to bear on the most general, and thus the most costly, of diagnostic-inference claims.[19]

Software is also an unusual technology, although in an entirely different way. It is a purely functional technology in the sense that it has been engineered so that a programmer need not know what is happening on a structural, material level within a computer in order to conceive a program or reduce it to practice.[20] In other words, software is aspatial: its arrangement in space is irrelevant to the definition of what constitutes an invention. Several patentability conditions, including the written description and the rules of means-plus-function claiming, depend on some aspects of the physical structure of a technology being relevant to the definition of a patentable invention in order to do their cost-reducing work of curtailing permissible patent generality. These patentability conditions simply cannot work like they usually do when they are brought to bear on purely functional technologies like software, meaning that they suffer from technology-specific regulatory inefficacy.[21]

19. *See infra* Section II.C.

20. *See infra* Section III.A.

21. *See infra* Section III.B. The Federal Circuit's adoption of algorithms as the metaphorical structures of software inventions mitigates this regulatory inefficacy, but it falls far short of eliminating

As demonstrated in these three examples, certain of the patentability conditions cannot do the cost-reducing work that we expect them to do when patents claim diagnostic inferences and software. The patentability conditions impose lax validity regulation in these technologies and create unintended biases in favor of strong patent protection. Counteraction theory suggests that restrictions on patent-eligibility can offset the biases and bring the patent protection for these technologies into closer alignment with the patent protection that is available for other technologies.

Of course, a counteracting restriction on patent-eligibility should ideally be tailored to the regulatory inefficacy at issue in a particular technology/patentability-condition pairing.[22] To test the explanatory power of counteraction theory in contemporary patent law, this Article maps the restrictions on the patent-eligibility of diagnostic inferences and software that can be justified under counteraction theory onto the restrictions that the Supreme Court announced in its *Mayo* and *Alice* opinions, respectively.[23] In some respects, the fit between counteraction theory and the Court's restrictions on patent-eligibility is remarkably good. Counteraction theory does a better job of justifying the *Mayo* opinion and its oft-criticized inventive-concept approach to the patent-ineligibility than discrimination theory does, at least under a mind-centered, rather than nature-centered, interpretation of *Mayo*.[24] It also provides a reasonable justification for *Alice*, although discrimination theory does, too, and the superiority of the inventive-concept approach is not as clear cut.[25]

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it. *See infra* notes 251–255 and accompanying text.

22. Counteraction theory works best when restrictions on patent-eligibility are closer to thinning provisions, like the restrictions announced in the Supreme Court's recent cases, than categorical exclusions of entire innovative endeavors. *See infra* notes 71–72 and accompanying text. If the restrictions were broad categorical exclusions, then patent-ineligibility would be more likely to overcompensate for whatever pro-patentee, technology-specific biases inhere in the patentability conditions.

23. The step from an identified instance of technology-specific regulatory inefficacy to a free-standing justification for all of the details of a specific restriction on patent-eligibility is admittedly a big one. *See infra* notes 75–79. A more modest, yet still important, deliverable lies in recognizing that technology-specific regulatory inefficacy allows some applicants to prosecute downhill and requires the patent examiners who are protecting the public interest to examine uphill. Even if the playing field is not returned to a perfectly level position, restrictions on patent-eligibility are more justifiable in technologies where there is a pre-existing slope to counteract than in technologies where the field starts out level.

24. *See infra* Section II.D.

25. *See infra* Section III.C. Counteraction theory cannot conveniently justify all of the Supreme Court's recent cases on patent-eligibility. For example, it cannot defend *Association for Molecular Pathology v. Myriad Genetics*, the Court's recent patent-ineligibility opinion addressing the products of nature exclusion. 133 S. Ct. 2107 (2013) (holding that genomic DNA, but not complementary DNA, is patent-ineligible); Dan L. Burk, *The Curious Incident of the Supreme Court in* Myriad Genetics, 90 NOTRE DAME L. REV. 505 (2014). More broadly, counteraction theory cannot justify any restriction on

Together, the concepts of counteraction and technology-specific regulatory inefficacy push patent law scholarship in new directions on several dimensions. They turn the role that the patentability conditions have to date played in arguments over patent-ineligibility on its head,[26] they counsel against a one-size-fits-all doctrine of patent-ineligibility,[27] and they add a focus on the intrinsic nature of technology to the ongoing discussion about technological specificity in patent law.[28] Finally, they offer an otherwise absent explanation of why and how intangibility should continue to limit patent-eligible subject matter, even in today's knowledge economy.[29]

This Article proceeds in four substantive parts. Part I introduces counteraction theory and technology-specific regulatory inefficacy. The following two parts offer proof of concept, with Part II focusing on diagnostic inferences and Part III addressing software. Part IV briefly notes how counteraction theory takes patent scholarship in new directions.

I. THEORY: COUNTERACTION TO REGULATORY INEFFICACY

Counteraction theory provides an original, consequentialist justification for restrictions on patent-eligibility. Section I.A explains how the patentability conditions selectively screen costly claims out of the patent regime. Section I.B summarizes the Supreme Court's recent patent-ineligibility opinions and the conventional arguments structured by discrimination theory that animate the debate over whether these opinions have viable consequentialist justifications. Section I.C then introduces the two concepts that lie at the heart of this Article: counteraction theory and technology-specific regulatory inefficacy.

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patent-eligibility tasked with ensuring that the realm of the natural remains beyond the reach of patent law, including the restriction that results from a nature-centered reading of *Mayo*. *See infra* note 275 and accompanying text.

26. *See infra* Section IV.A.
27. *See infra* Section IV.B.
28. *See infra* Section IV.C.
29. *See infra* Section IV.D.

A. The Patentability Conditions

Patent law's principal goal is to speed up technological innovation.[30] The basic story is a familiar, simple one: absent patent rights, rational individuals will not incur the sunk costs of innovation because they will not expect to recoup them in a competitive market for the innovation that they produce.[31] Patent rights mitigate this problem. Patent law grants innovators temporally limited, exclusive rights to their innovations, creating an expectation that successful innovators can internalize some fraction of the social welfare that their innovations generate and, hopefully, recoup their sunk costs.[32]

Yet, if the goal is to promote technological progress, patent law clearly cannot allow an inventor to claim anything that he holds out as an invention. Too much patent protection can be just as harmful as too little.[33] Patent law therefore employs a set of validity doctrines that regulate what constitutes a permissible patent interest. Rather than randomly invalidating some fixed fraction of patent claims, these doctrines function as a substantive screen. They selectively invalidate only the most costly of tranches of patents.[34] These validity doctrines are commonly sorted into two categories: the patentability conditions, addressed below, and patent-ineligibility, addressed in the following section.

The patentability conditions are grounded in different passages in the Patent Act, and they have little in common (except for their ability to invalidate costly patents, of course). With allowances for simplification, they fall into three groups based on the kind of work that they do. An initial group of patentability conditions, including novelty and nonobviousness, invalidates patents on technologies that are too close to the prior art.[35] These patentability conditions further two distinct policy goals. First, they

30. U.S. CONST. art. 1, § 8, cl. 8. Patent law promotes other goals, as well. It incentivizes the disclosure of inventions that might otherwise be kept secret. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480–81 (1974). It may facilitate the coordinated development of innovative products, reducing the wasteful duplication of effort that inheres in competitive development. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977).

31. *See, e.g.*, STAFF OF SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 1, 21 (Comm. Print 1958) (prepared by Fritz Matchlup).

32. *Id.*

33. Lab. Corp. of Am. Holdings v. Metabolite Labs., 548 U.S. 124, 124–26 (2006) (Breyer, J., dissenting from dismissal of the writ of certiorari as improvidently granted).

34. Masur, *supra* note 8, at 716 (noting that substantive examination can "defang" costly patents).

35. 35 U.S.C. § 102 (2012) (novelty); *id.* § 103 (nonobviousness). The "prior art" is a term of art for the technological status quo at the time of the application. It is the baseline used to determine whether a claim describes the kind of progress that merits patent protection.

invalidate costly patents on the low-hanging fruit of technological progress. If the claimed technology was already available to the public (not novel), or would have been made available to society in a timely manner even absent patent protection (obvious), patents provide little incentive benefit but still impose significant costs.[36] Second, by denying patent protection to minor (or non-existent) advances, they reduce costly patent density.[37] Another group of patentability conditions denies patent protection when inventors seek patent protection too early in a multi-step innovation process. Utility deems claims to many research intermediates to be useless,[38] and enablement and written description invalidate claims to early-stage innovations due to lack of sufficient support in the disclosure.[39] Here, the excluded claims are costly because they would, if valid, issue before much of the hard work needed to produce a downstream technology that has value to an end-user has been done, reducing the patent incentives available for that downstream work.[40] The final group of patentability conditions removes costly claims from the patent regime by capping the permissible claim generality.[41] These final doctrines operate through two related mechanisms. First, the overbreadth doctrines, also enforced through enablement and written description, tether permissible claim scope to the contribution to progress that an inventor publicly discloses in her patent specification.[42] Second, the rules of means-plus-function claiming focus on the problematic nature of functional claims in particular, requiring claims drafted with purely functional language to be limited in scope to the structures for performing the function disclosed in the specification, as well as those structures' equivalents.[43]

B. Patent-Eligibility and Discrimination Theory

The text of Section 101 of the Patent Act stating that only a "process, machine, manufacture, or composition of matter" can be patented is the

36. Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590 (2011).

37. *See infra* notes 114–123 and accompanying text.

38. 35 U.S.C. § 101 (2012); Brenner v. Manson, 383 U.S. 519, 532–36 (1966); *In re* Glass, 492 F.2d 1228, 1232–33 (1974).

39. 35 U.S.C. § 102(a) (2012); Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

40. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003).

41. *See infra* notes 149–152 and accompanying text.

42. 35 U.S.C. § 112(a) (2012).

43. *Id.* § 112(f).

statutory basis for patent-eligibility.[44] But contemporary debates over patent-ineligibility rarely parse the plain meanings of those terms.[45] They focus instead on a set of judicial exclusions from patent-eligibility that are not expressly codified in the statute: laws of nature, products of nature, and abstract ideas are not eligible for patent protection, even if a patent applicant is the first to discover or invent them.[46]

The importance of these judicial restrictions on patent-eligibility has risen and fallen in wave-like fashion over the last half century. The Supreme Court's first batch of cases in the 1970s and early 1980s sent mixed messages,[47] but they could easily be interpreted so as to give the restrictions some teeth. However, during the nearly thirty years of Supreme Court silence on patent-eligibility that ensued,[48] the lower courts gradually rendered these restrictions toothless. Patent-eligible subject matter became an always-present formality.[49] Most recently, in four opinions spanning only five years, the Court invalidated claims for lack of patent-eligibility, sending a strong signal that the doctrine should be reinvigorated so that it has significant bite.[50] In *Bilski v. Kappos*,[51] the Court held that a claim to a method of hedging financial risk is a patent-ineligible abstract idea.[52] In *Mayo Collaborative Services v. Prometheus Laboratories*,[53] it labeled a method of medical diagnosis as a patent-ineligible law of nature.[54] In *Association for Molecular Pathology v. Myriad Genetics*,[55] the Court held that genomic DNA isolated from the surrounding genome is a patent-

44. 35 U.S.C. § 101 (2012).

45. *But see In re* Nuijten, 500 F.3d 1346 (Fed. Cir. 2007) (holding that a signal claim did not describe a "manufacture").

46. The Supreme Court's precise labels for these categories have varied over time. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); Bilski v. Kappos, 561 U.S. 593 (2010); Diamond v. Diehr, 450 U.S. 175 (1981); Diamond v. Chakrabarty, 447 U.S. 303 (1980); Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63 (1972).

47. *See infra* note 62.

48. *But see* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001) (holding that the Plant Patent Act did not implicitly remove sexually reproducing plants from the subject matter of the utility patent regime).

49. The decline of restrictions on patent-eligibility culminated in the useful, concrete, and tangible results test of *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).

50. The Court's interest in patent-ineligibility was first signaled in its grant of certiorari in *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 548 U.S. 124 (2006) (dismissing certiorari as improvidently granted).

51. 561 U.S. 593 (2010).

52. *Id.*

53. 132 S. Ct. 1289 (2012).

54. *Id*.

55. 133 S. Ct. 2107 (2013).

ineligible product of nature.[56] Most recently, in *Alice v. CLS Bank*,[57] it extended *Bilski* to hold that a claim to a method of reducing the financial risk of a transaction remains a patent-ineligible abstract idea even if it is limited in scope to computer execution.[58]

These cases articulate a two-stage methodology for determining whether a claim recites patent-ineligible subject matter.[59] First, examiners and judges must locate any patent-ineligible subject matter—that is, laws of nature, products of nature, and abstract ideas—to which the claim is directed. Second, they must determine whether the claim describes this patent-ineligible subject matter in an impermissibly abstract manner or, alternatively, whether the claim contains limitations[60] that describe a patent-eligible application of the patent-ineligible subject matter. The proper way to perform each of these steps is contested, but the instructions for undertaking the second step—that is, distinguishing patent-ineligible claims to laws of nature and the like from claims to patent-eligible applications thereof—has proven to be extremely controversial.[61] Surprising many in the patent community, the Court's *Mayo* and *Alice* opinions revived the controversial inventive-concept approach to the methodology's second stage.[62] This approach incorporates a comparison to the prior art into the patent-eligibility analysis that resembles the comparison required by the novelty and nonobviousness doctrines. The limitations describing patent-ineligible subject matter cannot be the only limitations that differentiate a claim from the prior art. Inversely stated, a claim is patent-eligible only if it has an inventive concept that is separate from any patent-ineligible subject

56. *Id*.

57. 134 S. Ct. 2347 (2014).

58. *Id*.

59. The PTO has provided a crisp distillation of this two-stage methodology. 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618, 74,621 (Dec. 16, 2014) [hereinafter PTO Eligibility Guidelines].

60. Contemporary patent law employs claims, or descriptive texts, to delineate an inventor's patent interest. Each phrase or clause in the descriptive text is called a "limitation" because it limits claim scope.

61. The controversy dates back to the difficult-to-reconcile reasoning employed in two Supreme Court opinions from the late 1970s and early 1980s. *Compare* Diamond v. Diehr, 450 U.S. 175, 188–89 (1981) (rejecting any consideration of the novelty of certain features of the claimed invention in patent-eligibility) *with* Parker v. Flook, 437 U.S. 584, 591–95 (1978) (employing an inventive-concept approach in patent-eligibility). Before *Mayo*, the Federal Circuit had resolved this conflict by presuming that *Diehr* had implicitly overruled *Flook*. Arrhythmia Research Tech. v. Corazonix Corp., 958 F.2d 1053, 1057 n.4 (Fed. Cir. 1992). *Mayo*, the first of the Court's recent cases to adopt the inventive-concept approach, elevates *Flook* over *Diehr* and papers over the conflict by simply ignoring the contrary language in *Diehr*. *Mayo*, 132 S. Ct. at 1299.

62. *See Alice*, 134 S. Ct. at 2357–60; *Mayo*, 132 S. Ct. at 1297–302; PTO Eligibility Guidelines, *supra* note 59, at 74,624.

matter implicated in the claim. If someone discovers a previously unknown law or product of nature, or if someone develops a new abstract idea, this contribution to progress, standing alone, is not the type of contribution that amounts to a patent-eligible invention under the inventive-concept approach. Claiming the patent-ineligible subject matter in combination with prior-art, patent-eligible technology does not magically yield patent-eligible subject matter. To create a patent-eligible invention, an inventor must demonstrate inventiveness—again, something akin to novelty and nonobviousness—in the way in which the law of nature, product of nature, or abstract idea is put to practical use, or applied to solve a problem, in the claim.

The Supreme Court's re-establishment of patent-ineligibility as a robust limit on what can be patented has prompted a voluminous debate over the doctrine's consequentialist justifications.[63] While this debate unquestionably contains diversity of opinions, its arguments overwhelmingly employ a *discrimination theory* of patent-ineligibility: they support (or undermine) restrictions on patent-eligibility by producing evidence that the patent regime should (or should not) discriminate against the affected technology and provide weak protection for it. Discrimination theory focuses the debate on a single question: Does the affected technology merit patent protection that is weaker than the norm of the protection given to other technologies?[64]

Proponents of restrictions on patent-eligibility usually defend an affirmative answer to this question in two different ways. First, they adopt the Supreme Court's statements that patent-ineligibility prevents the patenting of "the basic tools of scientific and technological work"[65] or "building-block" technologies.[66] Basic-tool patents would privatize the inputs into future innovation, doing more harm (by retarding future innovation) than good (by speeding up the development of the basic tools).[67] Second, proponents of restrictions on patent-eligible subject matter also argue that patent-ineligibility may be focused on technologies for which

63. *See supra* note 6.

64. In addition, some commentators debate a second-order question about doctrinal means: When discrimination is merited, are the patentability conditions or restrictions on patent-eligibility the better tools for achieving the discrimination? *See infra* note 276 and accompanying text.

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

66. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012).

67. *See* Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 276 (2000); Golden, *supra* note 6, at 1065–74; Lemley et al., *supra* note 6, at 1328–29. *But see* Strandburg, *Preemption*, *supra* note 6, at 568, 586–614 (arguing that patent-ineligibility has not historically targeted basic-tool claims that are likely to cause downstream preemption).

patent law's innovation incentives are not needed.[68] Both of these arguments sound in discrimination theory. The first focuses on the possibility of protection having large gross costs and the second on the possibility of it having small gross benefits, but both raise questions about whether the affected technology merits patent protection that is weaker than the norm given to other technologies.

Discrimination theory often layers an efficient-gatekeeper argument on top of discrimination theory to support restrictions on patent-eligibility. A restriction may be an overbroad proxy for a set of costly patents, but the costs of its overbreadth may be outweighed by benefits of its administrability.[69] The gatekeeper variant of discrimination theory carried a lot of weight in earlier eras when the restrictions on patent-eligibility being debated were categorical exclusions of entire fields of endeavor, such as barring business methods or software from the patent regime in their entirety.[70] However, the import of the gatekeeper variant of discrimination theory is somewhat diminished today. The two-stage methodology in the Supreme Court's recent patent-ineligibility cases creates restrictions that are best conceived as closer to the thinning provision end of the spectrum rather than the categorical exclusion end.[71] They reduce the quantity of innovative

68. The lack of a need for patent incentives may be due to innovation being inexpensive to produce. Samuelson & Schultz, *supra* note 6, at 124–25. *But see* Lab. Corp. of Am. Holdings v. Metabolite Labs., 548 U.S. 124, 126 (2006) (Breyer, J., dissenting) (arguing that the cost of generating technologies is not relevant to patent-eligibility). Or, it may be due to non-patent institutions and business practices providing significant incentives. Dreyfuss, *supra* note 67, at 275; Ouellette, *supra* note 6, at 1129–31; Samuelson & Schultz, *supra* note 6, at 121–24; Strandburg, *Institutional Approach*, *supra* note 6; Katherine J. Strandburg, *Users as Innovators: Implications for Patent Doctrine*, 79 U. COLO. L. REV. 467, 492–94 (2008). For broader discussion of how sufficient innovation and creativity may exist absent intellectual-property incentives, see KAL RAUSTIALA & CHRISTOPHER SPRIGMAN, THE KNOCKOFF ECONOMY: HOW IMITATION SPARKS INNOVATION (2012); Rochelle Cooper Dreyfuss, *Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm*, 31 CARDOZO L. REV. 1437 (2010); Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303 (2013).

69. *See, e.g.*, Chiang, *supra* note 6, at 1360–63; Eisenberg, *Wisdom*, *supra* note 6, at 43–47; Golden, *supra* note 6, at 1055–74; Lemley et al., *supra* note 6, at 1326–27; Olson, *supra* note 6, at 184. *Cf.* Menell, *supra* note 6, at 1312 (advocating for a technological arts test); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139 (1999) (same). *See generally* FREDERICK SCHAUER, PLAYING BY THE RULES: A PHILOSOPHICAL EXAMINATION OF RULE-BASED DECISION-MAKING IN LAW AND IN LIFE (1991) (articulating an economic defense of rules, despite their over- and under-inclusiveness). One strain of the efficient-gatekeeper argument is built not on discrimination theory but on a broad conception of counteraction theory. *See infra* note 80.

70. Duffy, *supra* note 6, at 613; Eisenberg, *Wisdom*, *supra* note 6, at 45. Historical restrictions on patent-eligibility have taken the form of both rule-like categorical exclusions and standard-like thinning provisions. Chiang, *supra* note 6, at 1360–63; Duffy, *supra* note 6, at 623–38; Strandburg, *Preemption*, *supra* note 6, at 569–86.

71. Gatekeeper theory is also less important because the Court's two-stage methodology is difficult to classify as very rule-like or inexpensive to administer. Eisenberg, *Wisdom*, *supra* note 6, at 46–47;

business methods, medical diagnostics, and software that can be patented without preventing them from being patented altogether.[72]

C. Counteraction Theory and Regulatory Inefficacy

The contemporary debate over the existence of a consequentialist justification for the Supreme Court's recent patent-ineligibility cases has overlooked one reason why restrictions on patent-eligibility can help to craft optimal patent protection. If there are unplanned biases toward expansive protection for particular technologies that inhere in the patentability conditions, patent-ineligibility holds that patent-ineligibility can offset those biases. This is the core tenet of *counteraction theory*. Given restriction on patent-eligibility can bring the patent protection that is available for a technology into closer alignment with the protection that is available for other technologies and promote the default goal of sanctioning a roughly equal, although not exactly identical, quantum of patent protection for all technologies at the end of the day.[73]

To be clear, counteraction theory recognizes that a restriction on patent-eligibility itself, examined in isolation, does weaken the patent protection that is available for the affected technology. The point of disagreement is only whether the sum of the regulation imposed by all of the validity doctrines is necessarily stricter in a technology subject to a restriction on patent-eligibility than in a technology not subject to such a restriction. Counteraction theory recognizes that there is technology-specific laxity in some of the patentability conditions and that a well-crafted restriction on patent-eligibility can mitigate that laxity with a technology-specific curb on

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Michael Risch, *Forward to the Past*, 2009-2010 CATO SUP. CT. REV. 333, 362–63 (2010). *But see* Samuelson & Schultz, *supra* note 6, at 129–30 (arguing that *Bilski* provides "clues" that create a predictable framework for patent-ineligibility). A restriction on patent-eligibility could be relatively rule-like when compared to novelty and nonobviousness if it did not require a prior art search. Michael J. Meurer, *Controlling Opportunistic and Anti-Competitive Intellectual Property Litigation*, 44 B.C. L. REV. 509, 541–43 (2003). However, given that the Supreme Court has adopted the inventive-concept approach for identifying patent-ineligible claims, *see supra* note 62 and accompanying text, a prior art search of some kind seems to be required.

72. Depending on how future cases are decided, medical diagnostics may prove to be the exception to this rule. Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256 (2015).

73. Technological neutrality is only a default. Under the conventional defense of technology-specific patent law, a shift away from the default makes sense when the innovation profile in a particular industry counsels for stronger or weaker protection. *See infra* notes 281–282 and accompanying text. If an unplanned bias were to coincidentally grant stronger protection to an industry meriting strong protection, counteracting the bias could be counterproductive. *See infra* note 75 and accompanying text. However, absent a reason for protecting different technologies with patents of different strengths, the default position should be equal treatment for all technologies. Economically random departures from technological neutrality are difficult to defend.

patent-eligibility. Restrictions on patent-eligibility can trim back the unusually expansive nature of the patent protection sanctioned by the patentability conditions doctrines in certain technologies, furthering comparable validity regulation in all technologies.[74]

Even assuming that there is technology-specific laxity in a patentability condition, there are several caveats on counteraction theory as a consequentialist justification for restrictions on patent-eligibility. The presumption that different technologies merit the same strength of patent protection is only a default, and it can be rebutted. The economic profile of a particular industry might call for strong patent protection,[75] and this unusual strength could be achieved through embracing, rather than offsetting, any coincidental, lax validity regulation by the patentability conditions.[76] Alternatively, even if strong patent protection for the technology cannot be justified, the counteracting patent-eligibility restriction could do more harm than good. A very strong rule of patent-ineligibility might lead to a patent-curtailing departure from the norm that is greater in magnitude than the patent-permitting departure caused by the permissiveness of the patentability conditions.[77] Counteracting restrictions on patent-eligibility should therefore be tailored to the bias that inheres in the patentability condition, at least to the extent that such tailoring is possible.[78] Finally, counteraction can, in theory, come either from a restriction on patent-eligibility or a modification of a different patentability condition, but this Article only addresses counteraction through patent-ineligibility.[79]

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74. As a side note, counteraction theory's aspiration to equal treatment for all technologies means that technology-specific restrictions on patent-eligibility are likely to be TRIPS-compliant. TRIPS mandates technological neutrality. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27, Apr. 15, 1994, 1869 U.N.T.S. 299. If a restriction counteracts technology-specific laxity in a patentability condition, then it furthers, rather than undermines, technological neutrality.

75. For example, stronger protection may be a good idea because a technology has significant social value and the sunk costs of innovation are high. This is an example of the reasoning at the core of conventional discussions of technology-specific patent law: the economic innovation profile of a particular technology industry may differ from the norm in a way that recommends a departure from the norm in patent protection. *See infra* notes 281–282 and accompanying text.

76. *See, e.g.*, *infra* notes 192–194 and accompanying text.

77. For example, the patent-ineligibility rule could be a categorical exclusion of an entire innovative endeavor. *See supra* note 71 and accompanying text.

78. The tailoring need not be perfect. The protection after counteraction must only be closer to the norm than it was before, so some over- or under-compensation in the counteraction can be tolerated. In fact, some over- or under-compensation may be preferable if the justification for a restriction on patent-eligibility layers counteraction theory on top of discrimination theory.

79. In large part, this narrow focus follows directly from the task at hand, namely, exploring the ability of counteraction theory to provide a justification for the Supreme Court's recent opinions on patent-ineligibility that are otherwise difficult to justify. *See infra* Sections II.D, III.C. Yet it also follows

To be more than a theoretical possibility, counteraction theory requires technology-specific biases in the patentability conditions in need of counteraction. It therefore calls for an explanation of when and why the patentability conditions are unable in a particular technology to do the regulatory work that we expect them to do. To provide that explanation, this Article introduces the concept of *technology-specific regulatory inefficacy*: the intrinsic properties of certain technologies undermine the ability of the patentability conditions to regulate patent validity.[80]

A simple metaphor is useful here. Imagine that each of the validity doctrines is a unique tool for regulating what constitutes a permissible patent interest. When we think about three-dimensional, physical tools such as wrenches and screwdrivers, it is clear that a tool can only do the work that we expect it to do if the technology on which it is brought to bear has certain intrinsic properties. A crescent wrench can only do its intended work of tightening when there is a nut, or something with a similar shape, for the wrench to latch onto. If you try to use a crescent wrench to tighten a round-headed screw, the normally effective tool is ineffective. The wrench suffers from technology-specific inefficacy: its ability to do the job that we expect it to do is contingent on the technology on which it is brought to bear possessing certain properties.[81]

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in part from a belief that discussions about which existing patent doctrine should effectuate the counteraction can easily devolve into a shell game—a meaningless and confusing passing of the "ball" (the substantive restriction on what can be patented) from one "shell" (statutory validity doctrine) to another. Technology-specific regulatory inefficacy means that the patentability condition that is the most intuitive home for a doctrine doing a particular type of regulatory work usually cannot do that work. *But cf. infra* note 273 and accompanying text (discussing algorithms as a software-specific patch for the regulatory inefficacy of means-plus-function claiming and written description). The counteraction therefore needs to be housed in either a patentability condition that normally does an entirely different type of work or in patent-ineligibility, and there is no clear reason to choose one over the other.

80. Interpreted broadly, technology-specific regulatory inefficacy can account for lapses in the patentability conditions that do not follow from a mismatch between the intrinsic nature of a technology and a patentability condition. For example, one argument offered to support restrictions on the patent-eligibility of software and business methods is that the prior art in these fields is unusually difficult to identify. Dreyfuss, *supra* note 67, at 269. The difficulty of identifying prior art led to lax validity regulation which, in turn, supported a counteracting restriction on patent-eligibility. Here, the argument addresses technology-specific regulatory inefficacy in the novelty and nonobviousness doctrines, but it does not suggest that it is software's intrinsic, technological properties that cause the inefficacy. Rather, novelty and nonobviousness are ineffective regulators because the cost of identifying prior art in the software arts is excessive.

81. The notion that the patentability conditions provide a set of "policy levers" for fine-tuning patent protection can readily be co-opted to reinforce the wrench metaphor. *See* BURK & LEMLEY, *supra* note 12, at 95. A lever is a simple technology, usually in the form of a straight, rigid bar, that is fixed at a point in the middle and that exerts force on an object at one end due to a force applied at the other end. THE AMERICAN HERITAGE COLLEGE DICTIONARY 780 (3d ed. 1993). As simple as a lever is, it only works if there is a point of resistance—the fixed point—that creates a pivot. Absent a pivot, the application of a force on one end of the bar does not exert the anticipated force at the other end. Many

Many of the patentability conditions are like physical tools in the sense that they can only do the regulatory work of invalidating costly patents when the claimed technologies possess certain fundamental properties. Some patentability conditions can only get leverage, traction, or grip when the claimed technologies have certain basic features onto which the patentability conditions can latch. When a technology lacks these basic features, technology-specific regulatory inefficacy ensues. The validity regulation imposed by the patentability conditions is lax, and, absent counteraction, applicants seeking to patent the technology receive preferential treatment in relation to applicants seeking to patent other technologies.

Discussing the mismatch between doctrinal tools (patentability conditions) and claimed technologies that gives rise to technology-specific regulatory inefficacy in general terms is difficult because there is no single mismatch at issue. Different technologies resist the regulation of different patentability conditions, and different patentability conditions latch onto different intrinsic properties of the claimed technology. This Article therefore proceeds on the assumption that the best proof is in the pudding: the best way to understand technology-specific regulatory inefficacy is through deep-dive examples that illustrate how and why the intrinsic nature of a particular technology undermines the ability of a particular patentability condition to regulate patent validity. The following two Parts explore the technology-specific regulatory inefficacy that arises when patents claim diagnostic inferences and software.[82]

Nonetheless, despite the difficulty of discussing technology-specific regulatory inefficacy in general, there is one overarching observation that helps to explain not only what technology-specific regulatory inefficacy is but also why it exists. While the wrench metaphor provides a useful trope,[83] it should not be taken literally. A patentability condition will never become ineffective simply because it is brought to bear on round, rather than hexagonal, widgets. A far deeper change in the nature of technology is at issue: to the extent that diagnostic inferences and software are reliable guides, intangibility plays a critical role in triggering regulatory inefficacy.

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patentability conditions are legal technologies that, like metaphorical levers, only work if the claimed technologies possess certain fundamental properties. Bringing a patentability condition to bear on a technology that lacks those properties is like trying to use a lever without a pivot point: the tool simply cannot do the work that we expect it to do.

82. Each Part also examines the fit between the restrictions on patent-eligibility justified by counteraction theory and the restrictions announced in the Supreme Court's recent patent-ineligibility opinions. *See infra* Sections II.D and III.C.

83. *See supra* note 81 and accompanying text.

The patentability conditions work as we expect them to in tangible, industrial-era technologies like the mechanical and chemical arts. However, when brought to bear on more recently developed information-processing technologies like software and diagnostic inferences that have very light footprints in the material world of extension,[84] the patentability conditions sometimes falter. It is nothing less than the well-documented dematerialization of technology over the last half century that has altered technology at the fundamental level needed to trigger regulatory inefficacy in the patentability conditions.[85]

The correlation between intangibility and regulatory inefficacy points to a path-dependence origin story for the technology-specific nature of regulatory inefficacy. The actors who crafted patent law did not intentionally bake technology specificity into the law. Rather, they crafted doctrine that treated the then-extant technology in a technologically neutral manner, and the technological specificity arose later as byproduct of the unforeseen evolution of technology over time. When modern patent law was created in the late nineteenth and early twentieth centuries,[86] the technology for which patents were sought was synonymous with tangible, industrial-era technology. The tangible nature of technology was taken for granted as part and parcel of all technology. As Robert Merges colorfully notes, everyone assumed that "if you put technology in a bag and shook it, it would make some noise" in the early years of the patent regime.[87] Thus, although the legal actors who iteratively refined the patentability conditions likely intended to create technologically neutral law, their bounded imagination

84. Both technologies have been implicated in machine-or-transformation test cases in which the Federal Circuit attempted to reinvigorate intangibility as a limit on patent-eligibility. Ass'n for Molecular Pathology v. U.S. Patent &Trademark Office, 689 F.3d 1303, 1333–37 (Fed. Cir. 2012) (diagnostic inferences); Ultramercial, Inc. v. Hulu, Inc., 657 F.3d 1323, 1326–27 (Fed. Cir. 2011) (software).

85. Taken literally, dematerialization means achieving the same, or greater, functionality with less physical matter. Robert Herman, Siamak A. Ardekani & Jesse H. Ausubel, *Dematerialization*, 38 TECHNOLOGICAL FORECASTING AND SOCIAL CHANGE 333, 333 (1990). Some manifestations of dematerialization do not cause regulatory inefficacy in the patentability conditions. New materials and molecules, better designs, and smaller tolerances in manufacturing mean that today's mechanical gizmos can be smaller and lighter than yesterday's. Even the sharing economy can be framed as a cause of dematerialization to the extent that one car or bike can satisfy the needs of many consumers. JOHN THACKARA, IN THE BUBBLE: DESIGNING IN A COMPLEX WORLD 18–19 (2005). The aspect of technological dematerialization that gives rise to technology-specific regulatory inefficacy is more specifically the development of new technologies that are based on information processing, whether done within the human mind (diagnostic inferences) or outside of it (software).

86. The 1952 Patent Act, which remains the core of contemporary patent law, largely codified the doctrine developed in the courts over the prior century. *See* 35 U.S.C. §§ 101–376 (2012).

87. 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, 585 (1999).

prevented them from being able to do so. They were only able to craft patentability conditions that were technology-neutral with respect to what they conceived patentable technology to be, (i.e., with respect to tangible technologies). Without the ability to conceive of dematerialization and how it would change the fundamental properties of patentable technology, they could not craft patentability conditions that would effectively regulate dematerialized technologies such as software and diagnostic inferences.

II. PROOF OF CONCEPT: DIAGNOSTIC INFERENCES AND *MAYO*

In *Mayo Collaborative Services v. Prometheus Laboratories*,[88] the Supreme Court held that a diagnostic-inference claim was patent-ineligible because it described a law of nature in the abstract.[89] The majority of commentators who have addressed *Mayo* have argued that it has no viable consequentialist defense, and they have implicitly structured their arguments around discrimination theory.[90] The argument below shifts from discrimination theory to counteraction theory, and, by doing so, it is able to offer reasonable, although concededly imperfect, support for the Court's restriction on patent-eligibility articulated in *Mayo*.

Section II.A explains that, while most patent limitations read on extra-mental activity, diagnostic-inference claims have limitations that describe the manipulation of meaningful mental states in thinkers' minds. The following two sections demonstrate that two core patentability conditions cannot do their usual regulatory work when patents claim the manipulation of meaningful mental states as an invention. Section II.B details why inherency cannot reduce patent density, and Section II.C explains why overbreadth cannot curtail patent generality. Given this technology-specific regulatory inefficacy in the patentability conditions, Section II.D then examines the fit between the restriction on the patent-eligibility of diagnostic inferences that can be justified under counteraction theory and the restriction announced in *Mayo*.

A. Diagnostic Inferences Manipulate Meaningful Mental States

The *Mayo* claim is a method of optimizing a patient's dosage of a thiopurine drug to treat an autoimmune disorder.[91] Patients metabolize

88. 132 S. Ct. 1289 (2012).
89. *Id*.
90. *See infra* notes 172–175 and accompanying text.
91. *Mayo Collaborative Servs.*, 132 S. Ct. at 1295.

thiopurine drugs into metabolites. Prior to the *Mayo* researchers' work, the amount of the metabolites in patients' bloodstreams was already known to be medically significant in a general way. Too little metabolite was known to correlate with a significant risk of inefficacy, and too much with a significant risk of toxicity. But the precise upper and lower limits of the optimal window of metabolite concentration were unknown.[92] The *Mayo* researchers identified these limits, quantifying the correlations between metabolite levels and the points at which each type of medical risk grows to be too great. Based on this work, they obtained a patent on the following representative claim:

> A method of optimizing therapeutic efficacy for treatment of an [autoimmune] disorder, comprising:
>
> (a) administering a [thiopurine] drug . . . to a subject . . . and
>
> (b) determining the level of [a particular metabolite] in said subject . . .
>
> wherein the level of [the metabolite] less than [a lower threshold] indicates a need to increase the amount of said drug subsequently administered to said subject and
>
> wherein the level of [the metabolite] greater than [an upper threshold] indicates a need to decrease the amount of said drug subsequently administered to said subject.[93]

Although the claim is drafted with only two lettered steps, the Supreme Court parsed it into three limitations.[94] To infringe, a doctor must, first, administer the drug to a patient and, second, determine the patient's metabolite level. Third, as specified in the wherein clauses, the doctor must diagnose her patient by inferring a need to adjust the drug dosage up or down if the metabolite level is below or above the optimal window, respectively.[95] Importantly, the wherein clauses contain the method's sole advance over the prior art. Doctors had been performing the administering and determining steps prior to the *Mayo* researchers' work.[96] What they

92. *Id.*
93. *Id.*
94. *Id.* at 1297.
95. *Id.* at 1296. No post-diagnosis, extra-mental action is required for infringement. The wherein clause is satisfied "if the doctor believes" that an adjustment "is the proper procedure." Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04cv1200 JAH (RBB), slip op. at 17–18 (S.D. Cal. Nov. 22, 2005).
96. *Mayo Collaborative Servs.*, 132 S. Ct. at 1295.

hadn't been doing is using particular upper or lower thresholds in the metabolite levels to diagnose a need to decrease or increase drug dosage.

The third step of the wherein clauses is a *diagnostic inference*. In its generic form, a diagnostic inference is an act of logical reasoning involving two factual premises and a factual conclusion:

Premise 1:	An individual patient has attribute X.
Premise 2:	In general, patients who have attribute X are likely to have attribute Y.
Conclusion:	Said individual patient is likely to have attribute Y.[97]

Of course, a claim to this generic diagnostic inference in which X and Y are meaningless variables lacks novelty. Researchers therefore only claim species of diagnostic inferences. They do this by reciting the meanings of variables X and Y as claim limitations. More specifically, researchers usually discover a previously unknown, empirically valid correlation, and they draft a claim to a diagnostic inference that employs this correlation as Premise 2.[98] For example, the wherein clauses of the *Mayo* claim describe the following diagnostic-inference species:

Premise 1:	My individual patient has a metabolite level above [a specified upper threshold].
Premise 2:	In general, patients who have metabolite levels above [a specified upper threshold] are likely to benefit from a reduction in drug dosage.
Conclusion:	My individual patient is likely to benefit from a reduction in drug dosage.[99]

The need to establish novelty means that the diagnostic inferences for which inventors seek patent protection manipulate meaningful mental states or what are commonly called *mental representations* in cognitive science

97. More generally, a diagnostic inference is an example of a statistical syllogism. K. CODELL CARTER, A FIRST COURSE IN LOGIC 136 (2004).

98. Although the correlation exists before a researcher discovers it, the mental state that embodies human thought about the correlation comes into being at the moment of the correlation's discovery, and it is thus a novel mental state. *See infra* notes 128–129 and accompanying text.

99. The wherein clauses also describe a diagnostic inference premised on the correlation between low metabolite levels and a need to increase drug dosage.

and cognitive psychology.[100] Mental representations are "physical-biological states [that] have representational content—they are *about* things, inside or outside of an organism, and *represent them as being such and such*" within the mind.[101] Mental representations thus exist inside the mind, but they have states of affairs that exist in the material world of extension outside the mind as their representational content. Mental representations are central to how our minds work. They are nothing less than the locus of factual knowledge itself: "[i]t is because we have mental states with the capacity to represent that we can have knowledge."[102] Under a standard, cognitive-science account of rational human thought, the brain is a biological system that stores and recalls mental representations, much like a computer stores and manipulates meaningful variables when it processes information.[103] "To infer a proposition *q* from the propositions *p* and *if p then q* is … to have a sequence of [mental representations] of the form *p*, *if p then q*, *q*."[104]

Diagnostic inferences are exceptional technologies when compared to run-of-the-mill patentable subject matters. The vast majority of patented technologies are things or processes that exist in the extra-mental world of extension, but diagnostic inferences involve the logical processing of mental representations in thinkers' minds.[105] To be clear about the nature of diagnostic-inference patents, two points need to be highlighted. First, claims to diagnostic inferences do not privatize mental representations themselves in the abstract. That is, a doctor does not infringe the *Mayo* claim by simply understanding that Premise 1 or Premise 2 above is true. Rather, claims to diagnostic inferences describe the use of meaningful mental states functioning as premises and conclusion in an act of logical reasoning.[106] Second, only the representational content of the manipulated mental states can usually differentiate a claimed inference from prior art inferences. The correlations that researchers discover are usually phenomena or states of

100. JAEGWON KIM, PHILOSOPHY OF MIND 240 (2d ed. 2006).

101. *Id.*

102. *Id.* at 24–25. Technically, we only have knowledge when we have "mental representations with true contents—that is, representations that correctly represent" the world outside the mind. *Id.* at 25.

103. ANDY CLARK, MINDWARE: AN INTRODUCTION TO THE PHILOSOPHY OF COGNITIVE SCIENCE 28–33 (2001); David Pitt, *Mental Representation* § 8, STAN. ENCYCLOPEDIA OF PHIL., http://plato.stanford.edu/entries/mental-representation/ (last visited June 16, 2015).

104. Pitt, *supra* note 103, at § 1.

105. Although mental reasoning is almost always a critical input and/or output of the innovation process, Kevin Emerson Collins, *The Knowledge/Embodiment Dichotomy*, 47 U.C. DAVIS L. REV. 1279, 1293–94 (2014), very few inventors hold out a newly created mental act of reasoning as the novel aspect of the claimed invention.

106. Pitt, *supra* note 103, at § 1.

affairs in the world that pre-date the researchers' work.[107] Metabolite levels above the specified upper threshold were causing medically problematic toxicity problems before the *Mayo* researchers made their discovery. However, logical thought that employs the correlation as a premise is a novel "invention" created by the researcher. Prior to the discovery of the correlation between elevated metabolite levels and toxicity risks, nobody had a mental representation of the correlation, and nobody could perform a diagnostic inference using the correlation as a premise. The act of reasoning encompassed by the wherein limitations of the *Mayo* claim is therefore novel. In fact, the sole locus of the advance over the prior art in the *Mayo* claim is the content of the representation that functions as Premise 2, namely the newly quantified correlation between metabolite levels and ill-advised medical risk.

B. Inherency and Patent Density

The inherency doctrine is a branch of the novelty doctrine that denies patent protection to inventors who generate new knowledge about an existing product or process without generating a new product or process.[108] That is, inherency makes "the categorical judgment that an invention already being used by the public shouldn't be patentable because someone discovers information [i.e., knowledge] about how it works."[109]

When patents claim extra-mental technologies, inherency is an effective regulator of patent validity. It screens costly claims out of the patent regime by invalidating claims that are likely to create excessive patent density. However, when patents claim diagnostic inferences, inherency cannot do this work. Inherency is only an effective regulator when there is a clean distinction between newly created bits of knowledge (not protectable) and newly created inventions (protectable). This distinction breaks down when an invention is nothing more than the manipulation of newly created mental representations in thinkers' minds because mental representations are nothing but newly created knowledge.

1. Inherency Usually Reduces Density

Inherency is a well-accepted limit on patentability, and it plays a critical

107. Whether the correlations are *natural* phenomena is a much more difficult question that, thankfully, is irrelevant if *Mayo* is given a mind-centered interpretation. *See infra* text accompanying note 177.

108. 35 U.S.C. § 101 (2012).

109. Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 383–84 (2005).

role in shaping patent protection as we know it today.[110] For example, assume that there are three metal alloys in the prior art commonly used under highly corrosive conditions and that a researcher discovers the fact that one of them has vastly superior corrosion-resistance properties. The researcher has made a real contribution to technological progress. He has generated previously unknown, useful knowledge that will change how products are made. Nonetheless, inherency denies him patent protection.[111] He could attempt to use his newly discovered knowledge to draft a claim that describes the already-existing, high-performing alloy in a new way. For example, he could attempt to seek a claim to a process of using an alloy with vastly superior anti-corrosive properties under highly corrosive conditions. However, this claim is invalid under the inherency doctrine. The later-discovered property of the alloy (its superior anti-corrosive property) was an inherent property of the prior-art technology, so the claim lacks novelty.[112] Similarly, a researcher who discovers that eating a lot of broccoli helps to prevent cancer cannot patent a method of reducing the risk of cancer by eating a lot of broccoli because people have been ignorantly performing that method for many years.[113]

Inherency screens costly claims out of the patent regime because it reduces patent density.[114] Excessive patent density follows from the efficient scale for using a resource being significantly larger than the scale at which the property regime doles out privately owned parcels.[115] By

110. Some issues at the periphery of inherency are controversial. *See, e.g.*, Tilghman v. Proctor, 102 U.S. 707, 711–12 (1880) (finding no inherency when prior-art technology came about "accidentally and unwittingly"); *In re* Montgomery, 677 F.3d 1375 (Fed. Cir. 2012) (addressing inherency when the prior art is a text that describes a thing, not a material embodiment of the thing). The aspect of inherency addressed below, however, lies at the doctrine's uncontroversial core.

111. Provided, that is, that the researcher does not claim a mental process that manipulates a mental representation that has the newly discovered fact as its content. *See infra* Section II.B.2.

112. *Cf.* Titanium Metals Corp. v. Banner, 778 F.2d 775 (Fed. Cir. 1985) (holding that a claim to a metal alloy lacks novelty when the inventor discovered a previously unknown property of the alloy).

113. *In re* Cruciferous Sprout Litig., 301 F.3d 1343 (Fed. Cir. 2002). *See also* King Pharms., Inc. v. Eon Labs, Inc., 616 F.3d 1267, 1270–71 (Fed. Cir. 2010) (holding that a researcher who discovered that the bioavailability of a prior-art drug increases when it is consumed with food could not patent consuming the drug with food).

114. Inherency is commonly also justified with the argument that a *per se* rule preventing inventors from claiming prior art technologies ensures that inventors are not over-rewarded in relation to their contributions to progress. Burk & Lemley, *supra* note 109, at 383–84. However, there are many situations in which we allow inventors to reach beyond their contributions to amass sufficient incentives. For example, patents routinely reach into after-arising technology produced by later innovators. Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1083 (2009). Inherency should be understood as a means of limiting patent density, not solely as a means of achieving proportionality of contribution and reward.

115. This fragmentation problem is not specific to patent law: the efficient geographical scale for using land can be significantly larger than the geographical scale of the parcels of private property.

denying patent protection to innovators who generate new knowledge about how technology works but who do not produce new, extra-mental things or processes, inherency eliminates one way in which patent applicants can add another layer of patent rights on top of the patent rights already governing extant technologies. If inherency were not enforced, a researcher could obtain a patent every time he created new knowledge about a useful property of a known product or process. The resulting increase in patent density would be significant. By definition, any product or process has an enormous number of distinct properties,[116] and technological knowledge pertaining to how a thing or system works is usually generated in a slow, dripping fashion rather than all at once.[117]

Enforcing inherency has social costs: researchers today have no direct, patent-induced incentives to generate welfare-enhancing technological knowledge about existing products and processes.[118] Yet, the cost of the absent incentives is presumed to be smaller than the benefit of the reduction in patent density. Inherency's curb on patent density provides socially valuable validity regulation because excessive density creates two problems. First, there is what has alternatively been styled an anticommons,[119] thicket,[120] or disaggregation[121] problem. Higher patent density places a larger number of parties at the table in the negotiations that must occur to assemble the rights needed to authorize the large-scale use. The larger number of parties, in turn, increases the likelihood that transaction costs or strategic behavior will undermine any single party's

Robert C. Ellickson, *Property in Land*, 102 YALE L.J. 1315, 1333 (1993); Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998); Frank I. Michelman, *Ethics, Economics, and the Law of Property*, *in* 24 NOMOS: ETHICS, ECONOMICS, AND THE LAW 3, 11–19 (J. Roland Pennock & John W. Chapman eds., 1982), *reprinted in* 39 TULSA L. REV. 663 (2004).

116. Chris Daly, *Properties*, *in* 7 ROUTLEDGE ENCYCLOPEDIA OF PHILOSOPHY 757 (Edward Craig ed., 1998) ("A property is . . . an entity that things . . . have.").

117. Scientific, factual knowledge about the properties of any given system grows in a slow, dripping fashion even if scientific progress writ large is sometimes discontinuous. *See* THOMAS KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (1962) (contrasting paradigm shifts with normal science).

118. Patent law does create some incentives by protecting complementary inventions. Someone who discovers that eating broccoli reduces the risk of cancer, *see supra* note 113 and accompanying text, could patent methods of growing broccoli that increase the concentration of its cancer-fighting chemicals.

119. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

120. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POL'Y & ECON. 119 (2000).

121. Mark A. Lemley & A. Douglas Melamed, *Missing the Forest for the Trolls*, 113 COLUM. L. REV. 2117 (2013).

acquisition of the fragmented rights. High patent density may therefore cause the development or commercialization of a useful technology to be inefficiently overpriced (even for a rational monopolist), delayed, or stymied.[122] Second, patent density reduces incentives for innovators to produce significant inventions. A new technology generates a given welfare increase, and denser patenting spreads this surplus over a larger group of inventors. If some inventors' contributions are more important and costly than others, then giving minor contributors some of the surplus leaves less for the major contributors.[123]

2. Technology-Specific Regulatory Inefficacy

When patents claim diagnostic inferences, inherency is an ineffective regulator. It cannot do the work of reducing patent density that it can do when patents claim extra-mental technologies. For a simple illustration of inherency's inefficacy, consider a three-researcher scenario that extends the facts of *Mayo*. The first researchers are the actual *Mayo* researchers. They discover a correlation between the concentration of a thiopurine metabolite in a patient's blood being over a specified threshold and the patient being more likely to suffer toxicity-related adverse side effects. They receive roughly the representative *Mayo* claim:

> (a) determining whether a patient has a metabolite level above the specified threshold and, if he does,
>
> (b) inferring that the patient is in need of a decrease in his dosage of the thiopurine drug.[124]

Now assume that two subsequent researchers perform follow-on experiments that reveal different events in the biochemical pathway through which the body metabolizes thiopurine drugs. The second researcher discovers that the metabolite only exists in the body as a complex of the metabolite and chemical X. The second researcher obtains a diagnostic-inference patent on:

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122. Heller & Eisenberg, *supra* note 119, at 700–01; Lemley & Melamed, *supra* note 121, at 2158–59; Shapiro, *supra* note 120, at 122–26.

123. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 609 (6th ed. 2013).

124. *See supra* note 93 and accompanying text. The first, administering step of the actual claim is excised for the sake of brevity, but this simplification does not affect the analysis. In fact, the *Mayo* patent contained a similar two-step claim whose patent-eligibility rose and fell with the validity of the three-step claim. Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1357 (Fed. Cir. 2010).

> (a) determining whether a patient has a level of the metabolite-and-chemical-X complex above the specified threshold and, if he does,
>
> (b) inferring that the patient is in need of a decrease in his dosage of the thiopurine drug.

The third researcher discovers that a high metabolite level causes a buildup of protein Y that, in turn, leads to the adverse side effect. The third researcher obtains a diagnostic-inference patent on:

> (a) determining whether a patient has a level of the metabolite above the specified threshold and, if he does,
>
> (b) inferring that the patient has an unhealthy buildup of protein Y that should be remedied by a decrease in the dosage of the thiopurine drug.

If all three claims were valid, patent density would clearly be significant. Three claims, owned by different entities, would all govern what is the same diagnostic test, at least when what constitutes a single diagnostic test is defined from the perspective of a clinical doctor who treats patients. But the density is not capped at three patents. The three-researcher scenario only scratches the surface of the diagnostic-inference patents that future researchers could obtain. It employs only two reactions in the metabolic pathway through which thiopurine drugs affect the body, and most pathways chain together far more than two reactions. Each reaction in the pathway presents an opportunity for the discovery of yet another correlation and the creation of yet another diagnostic inference that is ripe for patenting. More broadly, the density concern raised by the three-researcher *Mayo* hypothetical exists in the routine, real-world scenario in which technological progress reveals knowledge about the properties of how a system works in a slow, dripping fashion rather than all at once.[125] The particulars of the hypothetical employ naïve science, but they realistically illustrate how scientific knowledge usually grows.[126]

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125. *See supra* notes 116–117 and accompanying text.

126. No high-profile cases resembling the three-researcher scenario have yet been litigated, but this fact alone does not undermine the reality of the costs of inherency's inefficacy. The patents that inventors seek are largely determined by the conventions and expectations of patent attorneys who draft patent claims. If *Mayo* had upheld the validity of diagnostic-inference claims, patent drafters would soon have recognized that all three claims in the three-researcher *Mayo* scenario are valid, the conventions of claim drafting would have shifted, and patent drafters would have regularly sought such claims. Patent drafters are known to be a wily bunch, *see* Parker v. Flook, 437 U.S. 584, 593 (1978) (discussing how patent-ineligibility must be sufficiently robust to avoid evasion through "the draftsman's art"), and they rarely leave value for their clients on the table over the long term.

At first glance, inherency might seem like it would invalidate the latter two patents and stave off the problem of excessive patent density. Inherency routinely invalidates claims that use newly discovered properties of old processes to describe the old things and processes in a new way,[127] and the second and third claims in the three-researcher scenario seem to do exactly this. They use newly created knowledge to describe the diagnostic inference invented by the first researcher in a new way in the claim. That is, they attempt to leverage a new description of an old technology into a novel claim. However, inherency cannot invalidate either of the two latter claims. Each of the three researchers' claims describes a mental process that did not exist in the prior art. The acts of thinking about a metabolite, a metabolite-and-chemical-X complex, and a build-up of protein Y are three separate acts of thinking, even if all three distinct acts of thinking are clinically interchangeable acts of thinking about the same metabolic system. Nobody can think about a discovery before the discovery has been made; nobody can use a bit of knowledge in an act of mental reasoning until that bit of knowledge is known. Therefore, the researchers' claims are all novel, and they are not inherent in the prior art.

The underlying general point is that inherency only works when there is a distinction between a novel product or process, on the one hand, and newly created knowledge about that product or process, on the other. When patents claim extra-mental technologies, this distinction exists. But it does not exist when patents claim processes that manipulate novel mental representations. Every bit of newly created knowledge is nothing but a novel mental representation in thinkers' minds,[128] so every newly discovered property of a product or process generates a novel mental state.[129] In turn, every mental process that employs a novel mental representation is also by definition novel. When patents claim mental processes that manipulate meaningful mental states, inherency doctrine never prevents an inventor from obtaining patent protection: the discovery of new knowledge entails the creation of a novel mental state and thus a novel mental process that manipulates that novel mental state.

In sum, inherency suffers from technology-specific regulatory inefficacy when it is brought to bear on diagnostic-inference patents. It cannot do the work of thinning out patent density that it does for other types of patents. It

127. *See supra* Section II.B.1.

128. *See supra* notes 100–104 and accompanying text.

129. Mental representations that have newly discovered facts as their content are not pre-existing mental states; they are not inherent in our minds prior to the discovery. If they were, then no diagnostic inference claim would ever be novel.

cannot prevent a novel diagnostic-inference "already being used by the public" from being subject to a new layer of patent rights every time "someone discovers information about how it works."[130] By describing the use of newly created mental representations in thinkers' minds, diagnostic-inference patents launder newly discovered properties of metabolic systems into novel patents, even when other diagnostic inferences with identical clinical utilities already exist in the prior art.[131] Inherency cannot prevent a dense accumulation of patents on what a doctor views as a single diagnostic inference with a single clinical utility when researchers repeatedly discover new properties of the body's metabolic processes.[132]

The practical consequences of this patent density could take either one of two different forms, depending on how the courts deal with another unique attribute of mental technology, namely, its nonvolitional nature. The conduct that infringes a patent on an extra-mental technology is always a volitional act, so the infringer at least intends to perform the act that constitutes infringement even if he does not know that he is committing infringement. In contrast, the conduct that satisfies a patent's diagnostic-inference limitation is almost always a nonvolitional or reflexive act once

130. Burk & Lemley, *supra* note 109, at 383–84. Dan Burk and Mark Lemley argue for a "public benefit" theory to determine inherency's limits: if a researcher discovers a new property of an old process, the researcher should be able to claim the old process without an inherency bar if the public had not been receiving the benefit of the newly discovered property. *Id.* at 375–89. Inherency's inefficacy when confronted with diagnostic-inference claims is consistent with, but not required by, Burk and Lemley's vision of inherency. It addresses the inverse situation: it demonstrates that there is no inherency bar if a claim describes a truly novel process, even if the old and new processes are perfect economic substitutes and the public had been receiving all the benefit of the new process from its use of the old process.

131. Addressing genetic diagnostics in particular, some commentators raise concerns about patent density when patents are granted on a gene-by-gene basis and diagnostics examine multiple genes or even the full genome. SECY'S ADVISORY COMM. ON GENETICS, HEALTH & SOC'Y, GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS at 3, 41, 49–52 (2010) [hereinafter SACGHS REPORT]; Rochelle C. Dreyfuss, *The Patentability of Genetic Diagnostics in U.S. Law and Policy*, *in* PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW: A TRILATERAL PERSPECTIVE, 7, 7–8 (Josef Drexl & Nari Lee eds., 2013). The fragmentation concern raised by inherency's inefficacy is conceptually distinct. What is commonly viewed as a single correlation between a gene and a clinical condition is in fact a bundle of distinct correlations, each of which can give rise to a novel diagnostic-inference patent. Inherency's inefficacy therefore compounds the density created by the multiple-gene problem.

132. Nor can other patentability conditions step in to do the work that inherency usually does. Utility cannot do the needed work. Although the three diagnostics considered in the text have identical clinical utilities, an invention does not have to work better than the prior art to be statutorily useful. Lowell v. Lewis, 15 F. Cas. 1018, 1019 (D. Mass. 1817) (No. 8568). Utility sanctions patents on perfect economic substitutes. Nor can nonobviousness do the needed work. Each of the diagnostic inferences is likely to be nonobvious so long as the newly discovered fact that enables the inference is unexpected. United States v. Adams, 383 U.S. 39, 48–52 (1966) (establishing that unexpected results weigh strongly in favor of nonobviousness).

the thinker has knowledge of the requisite factual premises.[133] When we say that a thinker jumps to a conclusion, we don't mean that the thinker makes a volitional decision to jump. The jump just happens. The reflexive nature of a diagnostic inference means that a doctor who has tested metabolite levels and is aware of the relevant medical literature will inevitably perform all three claims in the three-researcher scenario.[134]

The nonvolitional nature of a diagnostic inference raises an open issue of patent law: Should nonvolitional conduct trigger strict liability for patent infringement?[135] How courts answer this question determines the nature of the costs of the patent density in the three-researcher *Mayo* hypothetical. On the one hand, if courts were to hold that any performance of the claimed diagnostic inference, whether volitional or not, amounts to infringement, then inherency's inefficacy would produce a classic thicket or anticommons problem.[136] On the other hand, courts could hold that patent owners must demonstrate intent to perform a diagnostic inference to prove infringement.[137] If courts were to take this route, inherency's inefficacy would lead to a different cost: the cost of unenforceability. Each of the patent owners in the three-researcher hypothetical would find it extremely difficult to prove that a doctor had the intent to perform his claimed inference in particular. A doctor can always assert that she intended to perform an inference other than the one described in the claim being litigated. Given that mental states are not directly accessible to anyone other than the thinker,[138] proving that a doctor intended to make one inference rather than another is a nearly impossible task. In this situation, inherency's inefficacy produces a form of fragmentation in which the problem is not the overlapping rights of a thicket but rather the porous rights of an *archipelago*:

133. Kevin Emerson Collins, *Constructive Nonvolition in Patent Law and the Problem of Insufficient Thought Control*, 2007 WIS. L. REV. 759, 794–96.

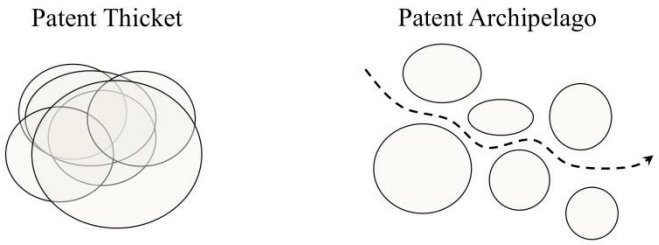
134. In *Metabolite Laboratories, Inc. v. Laboratory Corp.*, the Federal Circuit assumed that any doctor who knew the factual inferences proceeded to perform the diagnostic inference, reasoning that it would be malpractice for a doctor not to do so. Metabolite Labs. v. Lab. Corp., 370 F.3d 1354, 1364 (Fed. Cir. 2004).

135. Patent infringement is a strict liability offense: even someone who lacks knowledge of his legal status as an infringer can be held liable. Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 645 (1999).

136. *See supra* notes 115–123 and accompanying text.

137. Collins, *supra* note 133, at 782–87 (discussing the intent that could be required). An intent requirement makes sense because strict liability for nonvolitional conduct would over-reward inventors. *Id.* at 804–12.

138. KIM, *supra* note 100, at 19.



If intent must be shown in order to prove infringement, the rights of the owners of diagnostic-inference patents exist as scattered islands through which doctors can easily sail without running aground. It is not because the alleged infringer doesn't use any patented technology (he likely does), but rather because the patent owner cannot prove infringement. If researchers know this result in advance, then diagnostic-inference patents will not create much of any incentive to innovate in the first place.

C. Overbreadth and Patent Generality

When patents claim extra-mental technologies, overbreadth screens costly claims out of the patent regime by capping permissible claim generality. When patents claim diagnostic inferences, however, overbreadth cannot do this regulatory work. Overbreadth only curbs generality when generality is a set-theoretical construct, and the generality of a mental representation is not a set-theoretical construct. To the contrary, individual mental representations can be intrinsically general.

1. Overbreadth Usually Curbs Generality

When patent claims describe extra-mental technologies, claim generality is a set-theoretical construct: the metric for determining claim generality is the size of the set of distinct technologies that fit the claim's description.[139] For example, consider a trip up a simple ladder of claim generality: a claim can describe a Phillips screwdriver, a screwdriver, a hand tool, or a tool.

139. PETER D. ROSENBERG, PATENT LAW FUNDAMENTALS 42–44 (1975); Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1145 (2008). While the generality of the claimed technology is a set-theoretical construct, the language used to delineate claim scope can have something resembling intrinsic generality. For example, the word "rhomboid" is intrinsically more general than the word "square." Descriptive language and mental representations can both have intrinsic generality because they are representations that can have general content. *See infra* note 161.

The tool claim is more general than a hand-tool claim because there are things that are tools but not hand tools (e.g., table saws and drill presses). Similarly, a hand-tool claim is more general than a screwdriver claim because some hand tools are not screwdrivers (e.g., hammers and wrenches). Critically, the set-theoretical nature of claim generality means that generality is a characteristic of the claim, not any individual embodiment of technology.[140] There is no such thing as an intrinsically general, real-world embodiment of a technology that can infringe a patent claim. For example, there is no thing-in-the-world that itself embodies the generality of the description "hand tool." Any device that falls within a general hand-tool claim also falls within some more specific claim such as a screwdriver, wrench, or hammer claim. The description "hand tool" has generality because it aggregates a large number of distinct technologies into a single category. When claim generality is a set-theoretical construct, generality is only a property of a description in a claim, and it is not a property of an infringing device or method in the world. Generality without specificity is impossible in concrete embodiments of a technology.

Patent law's overbreadth doctrines latch onto the set-theoretical nature of claim generality to curb permissible claim generality. They compare two sets of technologies: the set that an inventor contributes to technological progress in his specification or disclosure and the set described by the claim. They invalidate any claim for which the claimed set is excessively large in relation to the disclosed set. Highly general claims are more likely to be overbroad in relation to a patent's disclosure because general claims encompass larger sets of distinct technologies, and these larger sets are more likely to be too large in relation to the set of disclosed technologies. For example, if an inventor discloses a set of Phillips screwdrivers, his Phillips-screwdriver claim would likely be valid, but his hand-tool claim would likely be invalid.

There are two patent doctrines that both employ the principle of overbreadth to cap permissible claim generality. Each one imposes a different requirement on what it means for an inventor to have contributed an embodiment of a technology to technological progress. First, enablement focuses on the disclosure of information about how to make and use a technology: claim scope must remain commensurate with the set of technologies that the disclosure teaches the person having ordinary skill in the art to make and use without undue experimentation at the time of

140. That is, generality is a characteristic of types, not tokens, or of collections, not individuals.

filing.[141] Written description, in contrast, focuses on the disclosure of information about the physical structure of a technology, mandating that claim scope must remain commensurate with the set of technologies that a person of ordinary skill who has read the disclosure recognizes that an inventor "possessed" or "invented" at the time of filing.[142] Thus, although each looks at a different type of information, both examine the commensurability of the disclosure and the claim.

To risk repetition, overbreadth limits claim generality only because generality is a set-theoretical construct. When claim generality is a set-theoretical construct, inventors never invent, or thus disclose, an individual embodiment of a technology with intrinsic generality matching the generality of the claim. There is no single embodiment of a tool that an inventor can disclose that, by itself, matches the generality of the description "hand tool." Rather, inventors always invent and disclose sets of concrete embodiments. As claim generality grows, the claimed set will grow to be outsized in relation to the disclosed set unless the disclosed set, too, grows. Overcoming overbreadth's limit on claim generality by providing a more robust disclosure of a larger set of technologies becomes impossible at some point because it requires an inventor to disclose additional embodiments that the inventor cannot yet make or conceive. The inventor of the first hand tool must invent a specific tool such as a screwdriver. This inventor likely does not have the knowledge of hammers and wrenches that must be disclosed to support a general hand-tool claim.[143]

For an example of how the set-theoretical nature of claim generality allows overbreadth to curb permissible claim generality, consider the Supreme Court's analysis of Samuel Morse's claims to a telegraph machine.[144] Morse, like most patent applicants, sought and obtained multiple claims at several nested levels of generality.[145] His more specific claims were limited to machines that possessed various structural features of the telegraph machine that Morse actually invented.[146] His most general claim encompassed all telegraph machines, regardless of their structural

141. *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).

142. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Possession and invention, in turn, are legal code for an inventor disclosing the technology's defining structural properties. Kevin Emerson Collins, *Patent Law's Functionality Malfunction and the Problem of Overbroad, Functional Software Patents*, 90 WASH U. L. REV. 1399, 1430–33 (2013).

143. However, overbreadth's rule of commensurability breaks down when claims encompass certain types of after-arising technology. *See* Collins, *supra* note 114, at 1093–124.

144. O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853).

145. *Cf.* Tun-Jen Chiang, *The Levels of Abstraction Problem in Patent Law*, 105 NW. U. L. REV. 1097 (2011).

146. *O'Reilly*, 56 U.S. (15 How.) at 85–86.

configurations, that employed "the motive power of … electro-magnetism, however developed for marking or printing intelligible characters … at any distances."[147] The Court upheld Morse's specific claims because the claimed set of technologies was proportional in size to the disclosed set, but it invalidated the general claim for overbreadth. The general claim encompassed too many undisclosed embodiments. It encompassed too many "mode[s] of writing or printing at a distance" that did not "us[e] any part of the process or combination set forth in [Morse]'s specification."[148] Morse was not entitled to the general claim because he invented a small set of embodiments and he was unable to disclose a set of embodiments commensurate in size with the set encompassed by the general claim.

Highly general claims have large social costs. Generality increases the static and dynamic costs of patent protection.[149] It increases static costs because it allows the patent owner to increase price and reduce use,[150] and it increases dynamic costs because it slows down the subsequent progress that improves on or experiments with a patented invention.[151] Highly general patents are more difficult to design around, so they are more likely to give the owners of earlier-issued patents control over later-developed innovations.[152]

2. Technology-Specific Regulatory Inefficacy

When patents claim diagnostic inferences, overbreadth cannot do the work of reducing patent generality that we expect it to do. For simple illustrations of overbreadth's inefficacy, consider two hypotheticals in which the inventors of diagnostic inferences can obtain extremely general

147. *Id.* at 112.

148. *Id.* at 113. It is unclear whether *O'Reilly* is most analogous to an enablement case, a written description case, or even a patent-eligibility case. What is clear, however, is that the Supreme Court invalidated the claim because of overbreadth.

149. Claim generality usually also increases the gross benefits of patent protection because it augments incentives to innovate, but, as generality increases, the costs of additional increments of generality eventually outweigh the benefits. Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257 (2007).

150. SUZANNE SCOTCHMER, INNOVATIONS AND INCENTIVES 103–07 (2004); Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1699–700 (2008).

151. F. M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 450–53 (2d ed. 1980); Stiglitz, *supra* note 150, at 1710–12.

152. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990). The correlation between patent generality and the difficulty of design-around is not perfect. For example, narrow, specific claims to bottleneck technologies can generate significant dynamic costs because there are no economic substitutes for the few technologies encompassed by the specific claim. John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 440 (2004) (discussing bottleneck technologies).

claims without triggering any overbreadth concerns. The key observations to note here are that an inventor can invent and disclose a single embodiment of a diagnostic inference that is intrinsically general and that the disclosure of a single, intrinsically general embodiment can enable and demonstrate possession of a highly general claim.

First, consider a hypothetical patent on a diagnostic inference for identifying cancer. Early in the scientific process of understanding cancer, a researcher discovers the highly general, factual correlation between the presence of unregulated cell growth in a tumor and a cell being cancerous.[153] This researcher has discovered a previously unknown, statistically valid correlation, and he has invented a novel diagnostic inference that employs this correlation as its second premise:

Premise 1:	An individual patient has a cell that is undergoing unregulated growth.
Premise 2:	In general, patients who have cells undergoing unregulated growth are likely to have cancer.
Conclusion:	Said individual patient is likely to have cancer.[154]

This diagnostic inference is akin to a "tool" claim considered above[155] in that it is high up on the ladder of generality of the possible diagnostic inferences that can be used to identify cancer.[156] Yet, disclosure of the empirically true fact that functions as Premise 2 in the inference satisfies the enablement and written description requirements with respect to this claim,

153. Cancer is a tumor that "is capable of progressive growth, unrestrained by the capsule of the parent organ." BLACK'S MEDICAL DICTIONARY 111 (41st ed. 2005).

154. No historical inventor sought to patent this inference, but this historical contingency does not undermine the immediacy of the concerns raised. Assuming that someone at some time discovered this law of nature, only the then-prevalent norms of claim drafting prevented the claim from becoming a reality. *See supra* note 126. Either patent prosecutors had not yet thought up the template of the diagnostic-inference patent, or they presumed that it was invalid. For an example of a litigated, highly general diagnostic-inference claim that was partially upheld, see Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011).

155. *See supra* note 143 and accompanying text.

156. There are many more specific diagnostic inferences that can also be employed to diagnose particular types of cancer. Although Premise 2 remains empirically valid, scientists question whether it is more obfuscating than helpful to think of cancer as a single disease. *See* Gina Kolata, *Cancers Share Gene Patterns, Studies Affirm*, N.Y. TIMES (May 1, 2013), http://www.nytimes.com/2013/05/02/health/dna-research-points-to-new-insight-into-cancers.html. However, the assumption in the hypothetical is that the more specific correlations are not yet known, so the diagnostic being patented is the general correlation between cancer and unregulated cell growth.

and this claim is therefore not invalid for overbreadth so long as the patent discloses that fact. The researcher discovered a single, highly general fact, created a single "piece" of highly general knowledge, and claimed a diagnostic inference using that "piece" of knowledge as a premise.[157] The researcher has invented and disclosed a diagnostic method that is intrinsically general because it employs newly created, general knowledge as a premise.

Second, consider a hypothetical based on the historical researchers who discovered the virus now called HIV.[158] These researchers discovered a statistically valid correlation between the presence of HIV in a patient's blood and the patient's likely future development of AIDS. They could have claimed the following diagnostic inference:

Premise 1:	An individual patient has the HIV virus in his blood.
Premise 2:	In general, patients who have the HIV virus in their blood are unusually likely to develop AIDS in the future.
Conclusion:	Said individual patient is unusually likely to develop AIDS in the future.

This, too, is a highly general diagnostic-inference claim. Had it been sought, AIDS testing and even AIDS research could have been centralized under the purview of a single patent owner.[159] Yet, so long as the newly discovered correlation is statistically valid, the diagnostic-inference patent is not invalid for overbreadth. Again, the researcher's disclosure of the single, highly general fact demonstrates both enablement and possession of the highly general diagnostic-inference claim.

Overbreadth is ineffective in these hypotheticals because the generality of a diagnostic-inference claim is not a set-theoretical construct. The generality of a mental representation in a thinker's mind derives from the generality of the state of affairs in the extra-mental world that it represents.

157. *See supra* notes 100–104 and accompanying text.

158. STEVE CONNOR & SHARON KINGMAN, THE SEARCH FOR THE VIRUS: THE SCIENTIFIC DISCOVERY OF AIDS AND THE QUEST FOR A CURE 24–63 (1988).

159. The historical antibody patents that were actually issued in the 1980s based on the discovery of the HIV virus were not broad enough to centralize AIDS testing or research under the purview of a single entity. CONNOR & KINGMAN, *supra* note 158, at 24–63. Again, only the norms of patent prosecutors in the early 1980s prevented the researchers from seeking a diagnostic-inference patent. *See supra* note 154.

For example, knowledge that a fever correlates with illness is more general than the knowledge that a high fever correlates with the flu because "fever" describes a larger set of conditions than "high fever" does and "illness" describes a larger set of conditions than "flu" does. The generality of the state of affairs to which a mental representation refers is a set-theoretical construct. However, a bit of generalized knowledge in a thinker's mind that represents that state of affairs is not. A bit of generalized knowledge is not simply a set of bits of specific embodiments of knowledge. Rather, a mental representation is an intrinsically general mental state:[160] it can be its own, distinct mental representation that has a more broadly applicable state of affairs as its content.[161] In turn, diagnostic inferences can have intrinsic generality, too, because their generality derives from the generality of the mental representations that they manipulate.

When patents claim extra-mental technologies, the set-theoretical nature of generality means that generality is a quality of a description, not an individual embodiment of the technology. However, generality is not merely a quality of a description of a diagnostic inference. It is also a property of the individual instance or token of the claimed diagnostic inference itself.[162]

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160. Describing the generality of a representation as an "intrinsic" property of the representation is awkward. The very nature of a representation is something that points to or means something other than the thing itself. *See* DANIEL CHANDLER, SEMIOTICS: THE BASICS 13 (2007) ("[A] sign … *stand[s] for* something other than itself."). Nonetheless, this Article adopts the "intrinsic" label to highlight the way in which the generality of a mental representation, unlike the generality of an extra-mental thing or process, is not a set-theoretical construct.

161. To reiterate, the generality of the state of affairs in the world that is the content of the representation remains a set-theoretical construct. The correlation between fever and sickness is more general than high fever and the flu because the terms "sickness" and "fever" refer to larger sets of conditions than the terms "high fever" and "flu" do. However, the generality of knowledge in a thinker's mind—i.e., of a thinker's knowledge-bearing mental state—is not a set-theoretical construct; a bit of general knowledge is not merely a collection of a larger set of bits of more specific knowledge.
Mental representations can have intrinsic generality not because they are mental but rather because they are representations. They have intrinsic generality in the same way that the descriptive language of a patent claim, another type of representation, can have intrinsic generality. *See supra* note 139. *Cf.* KIM, *supra* note 100, at 25 (noting that the representational capacity of extra-mental representations derives from the original representational capacity of mental states).

162. Another way of framing the important difference between extra-mental technology and diagnostic inferences builds on the distinction between categories and concepts. Categories are set-theoretical constructs: they are classes of distinct things, properties, or processes. E. BRUCE GOLDSTEIN, COGNITIVE PSYCHOLOGY 240 (3d ed. 2008); Douglas L. Medin & Lance J. Rips, *Concepts and Categories: Memory, Meaning, and Metaphysics*, *in* THE CAMBRIDGE HANDBOOK OF THINKING & REASONING 37, 37 (Keith J. Holyoak & Robert G. Morrison eds., 2005); GREGORY L. MURPHY, THE BIG BOOK OF CONCEPTS 5–6 (2002). For example, the category "hand tool" is the set of things in the world that are tools that one can hold in one's hands. In contrast, concepts are entities within our minds that stand for, mean, refer to, or represent extra-mental categories. GOLDSTEIN, *supra*, at 240; Medin & Rips, *supra*, at 37; MURPHY, *supra*, at 5–6. The concept *hand tool* is what a thinker uses to identify and

The fact that the generality of a diagnostic inference is not a set-theoretical construct can be proven by demonstrating that there can be generality without specificity in an embodiment of a mental representation. When generality is a set-theoretical construct, this is impossible.[163] However, in contrast, it is entirely possible for a researcher to possess a mental representation of fever correlating with illness without, at the same time, possessing a mental representation of a high fever correlating with flu (or any other more specific type of fever correlating with any more specific type of illness). Similarly, the cancer and HIV researchers have created diagnostics that cannot be described in any more specific way than the highly general way in which they are claimed. Thus, unlike an embodiment of an extra-mental technology, an embodiment of a mental representation can have generality without specificity, and a highly general picture claim to a diagnostic method is not a logical contradiction. The impossible extra-mental analog would be a claim that reads on only a single tool yet that embodies the full generality of the "hand tool" description. Such a claim is impossible because, when generality is a set-theoretical construct, there is no such thing as a hand tool that is not also a saw, hammer, screwdriver, or any other specific type of hand tool.

The fact that the generality of a diagnostic-inference claim is an intrinsic property of an individual embodiment, not a set-theoretical construct that inheres only to collections and descriptions, gums up the mechanism that overbreadth employs to regulate claim generality. The intrinsic generality of a diagnostic inference means that moving up or down a ladder of generality does not aggregate larger or smaller sets of inferences within a single description. To the contrary, movement in either direction means shifting to different inferences that employ different mental representations as premises. The inferences on the higher rungs are intrinsically more general than the inferences on the lower rungs. When inventors can invent and disclose a single embodiment of a technology that is intrinsically

reason about tangible things that are members of the category "hand tool." Concepts are not set-theoretical constructs. They may stand for or represent categories, but they themselves are not categories. They are singular mental entities in human minds that represent the collections of entities that constitute categories. When patents claim extra-mental technologies, they use concepts as a means to the end of referring to categories of technology. JOHN LYONS, LINGUISTIC SEMANTICS: AN INTRODUCTION 75–79 (1995) (explaining that descriptive texts have meaning that is separate from the things or processes to which they refer only because they invoke concepts in readers' minds). They do not refer to concepts themselves. However, when patents claim diagnostic inferences, they do refer to, and thus privatize, the manipulation of concepts in thinkers' minds. The mental representations manipulated in a diagnostic inference are made up of constellations of concepts placed in logical relationships with one another. *See* Pitt, *supra* note 103, at § 3.

163. *See supra* note 143 and accompanying text.

general, a general claim will frequently be commensurate, rather than overbroad, with respect to the disclosure. (Imagine how easy it would be to obtain broad claims if an inventor could disclose a single embodiment of a technology that enables and demonstrates possession of the full breadth of a general hand-tool claim.) Greater generality does not mean a larger set of distinct technologies within claim scope, so greater generality cannot threaten to make the claimed set of technologies too large in respect to the disclosed set of technologies. The generality of the claimed inference can move in lock step with the intrinsic generality of the disclosed correlation that functions as Premise 2, so researchers who discover highly general facts about the world can routinely enable and possess intrinsically general diagnostic inferences. They do not encounter overbreadth problems.[164]

In sum, overbreadth is an ineffective regulator of permissible claim generality when patents claim diagnostic inferences or other technologies that manipulate meaningful mental states. The lack of effective generality regulation will raise the social cost of patent protection for diagnostics inferences. When patents claim extra-mental technology, and generality is a set-theoretical construct, overbreadth ensures that the costly, general claims are given out only infrequently. Only the rare inventors who make significant contributions to progress and disclose many distinct embodiments of a technology can satisfy the written description and enablement doctrines when they seek general claims. To receive a hand-tool claim, an inventor must likely disclose hammers, screwdrivers, and pliers, among other technologies. However, when patents claim diagnostic inferences, overbreadth's inefficacy means that highly general claims can routinely be given to inventors who do not make unusually significant contributions to technological progress. In fact, more costly, general claims are easier to obtain than less costly, specific claims are. An early pioneer in the medical sciences usually generates knowledge of a general correlation before generating any knowledge of more specific correlations. For example, researchers are likely to understand the easy-to-discover, general correlation between fever and illness before they understand the difficult-to-discover, specific correlation between high fever and flu. Absent counteraction, the general diagnostic-inference claims that impose the greatest costs on society will often be the easiest diagnostic inferences for patent applicants to acquire.[165]

164. Greater generality in a diagnostic inference can lead to validity problems other than overbreadth. For example, a disclosed correlation can become so general that it is no longer empirically true, and a diagnostic inference based on a false correlation lacks utility.

165. Patents on general diagnostic inferences only lead to generality costs if performing a specific

D. Reconceptualizing Mayo

In *Mayo*, the Supreme Court held the claimed diagnostic method to be a patent-ineligible law of nature.[166] Employing its two-stage methodology for assessing patent-eligibility,[167] the Court initially identified the newly discovered correlations between metabolite levels and medically ill-advised risks as laws of nature and then concluded that the claim did not describe a patent-eligible application of those laws.[168] More specifically, the Court used the inventive-concept approach in the second stage,[169] reasoning that the claim was patent-ineligible because its advance over the prior art resided solely in the correlations themselves. Inversely stated, the claim limitations other than the wherein clause—namely the administering and determining steps—"consist[ed] of well-understood, routine, conventional activity already engaged in by the scientific community."[170] Had either of these steps, or even their combination, embodied an inventive contribution, the claim may have been patent-eligible.[171]

Patent commentary has roundly criticized *Mayo* and its inventive-concept approach with two arguments, both of which are based on discrimination theory. First, focusing on diagnostic inferences in particular, commentators assert that there is no good reason to believe that diagnostic inferences deserve weaker patent protection than other technologies deserve.[172] Second, expanding their analysis beyond diagnostic inferences,

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diagnostic inference infringes a claim to a general diagnostic inference. However, given that the mental representations at different rungs of the ladder of generality are distinct mental states, this legal outcome is not preordained. If performing a specific diagnostic inference does not infringe a claim to a general diagnostic inference, and there is no strict liability for nonvolitional conduct, *see supra* notes 135–138 and accompanying text, then general diagnostic-inference patents will not create high generality costs. Rather, they will create an archipelago problem as infringement can be easily avoided, regardless of the generality of the patented inferences. *See supra* notes 136–138 and accompanying text.

166. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012). For an overview of the invention and claims at issue, see *supra* notes 91–93 and accompanying text.

167. *See supra* notes 59–62 and accompanying text.

168. *Mayo Collaborative Servs.*, 132 S. Ct. at 1296–98.

169. *See supra* note 62 and accompanying text.

170. *Mayo Collaborative Servs.*, 132 S. Ct. at 1298. *See also id.* at 1303–04.

171. *Id.* at 1302.

172. Eisenberg, *Wisdom*, *supra* note 6, at 27–31; Jeffrey L. Fox, *Industry Reels as Prometheus Falls and Myriad Faces Further Reviews*, 30 NATURE BIOTECHNOLOGY 373, 373 (2012); Christopher M. Holman, Mayo, Myriad, *and the Future of Innovation in Molecular Diagnostics and Personalized Medicine*, 15 N.C. J.L. & TECH. 639, 666–77 (2014) [hereinafter *Future of Innovation*]; Christopher M. Holman, *Patent Eligibility as a Policy Lever to Regulate the Patenting of Personalized Medicine*, *in* PERSPECTIVES ON PATENTABLE SUBJECT MATTER 114 (Michael B. Abramowicz, James E. Daily, & F. Scott Kieff eds., 2014) [hereinafter *Policy Lever*]; Rai, *supra* note 6, at 113. *But see* SACGHS REPORT, *supra* note 131 (reviewing evidence that patent incentives were not needed to develop a number of simple genetic diagnostic inferences).

commentators convincingly argue that the Court's inventive-concept approach to patent-eligibility would invalidate an unexpectedly large swath of patents if its nature-oriented reasoning were taken at face value.[173] Many claims that we unquestioningly treat as patent-eligible subject matter—and that should remain patent-eligible subject matter, provided the patent regime exists at all—would be invalid if newly discovered laws of nature could not be the claims' inventive concept.[174] In light of these criticisms, proposals for cabining *Mayo* usually suggest that *Mayo* should not be taken at face value. More specifically, they suggest that *Mayo* should be cabined by either redefining laws of nature in a narrow fashion or abandoning the inventive-concept approach altogether.[175]

Counteraction theory, however, offers a different way of cabining *Mayo*: *Mayo* should be interpreted in a mind-centered, not nature-centered, manner. Under the conventional nature-centered interpretation, the purported naturalness of the correlations in patients' bodies is the crux of the patentability problem.[176] In contrast, under a mind-centered interpretation, what is natural and what is man-made artifice is irrelevant. Rather, it is the mental status of the diagnostic inference that employs the correlation as a premise that is the crux of the patentability problem. Diagnostic-inference patents are likely to have a pro-patentee bias because the patentability conditions cannot effectively regulate technologies that manipulate meaningful mental states.[177] So, *Mayo* should be reconceptualized to require an inventive concept in the claim separate from limitations describing any such mental technologies.[178]

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173. Chao, *supra* note 6, at 427–33; Rai, *supra* note 6, at 112; Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 623–31 (2015); Michael Risch, *Nothing Is Patentable*, 67 FLA. L. REV. F. 45, 47–53 (2015); Ted Sichelman, Funk *Forward*, *in* INTELLECTUAL PROPERTY AT THE EDGE: THE CONTESTED CONTOURS OF IP 361, 375–77 (Rochelle Dreyfuss & Jane Ginsburg eds., 2014).

174. New uses of known chemicals, the mercury thermometer, and even Velcro would arguably be patent-ineligible. Collins, *supra* note 105, at 1335–36.

175. Eisenberg, Prometheus *Rebound*, *supra* note 6, at 342–44; Holman, *Future of Innovation*, *supra* note 172, at 667–69; Sichelman, *supra* note 173, at 377–80. The Federal Circuit has also expressed concern about taking the inventive-concept approach in *Mayo* at face value. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1286 (Fed. Cir. 2015) (Lourie, J., concurring in the denial of rehearing en banc) (stating that *Mayo* means that the Federal Circuit is "unfortunately obliged" to employ an inventive-concept approach in the second stage of the patent-ineligibility analysis).

176. The laws of nature branch of patent-ineligibility prevent patent applicants from gaining ownership over nature. Nature is viewed as something that "has always existed" and that the applicants did not invent. Parker v. Flook, 437 U.S. 584, 593 n.15 (1978); *see also* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 129 (1948).

177. *See supra* Sections II.B, II.C.

178. The Supreme Court has repeatedly and explicitly identified mental processes as patent-ineligible subject matter, including in *Mayo*. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012); Gottschalk v. Benson, 409 U.S. 63, 67 (1972). The Federal Circuit sometimes

A mind-centered interpretation of *Mayo* does cut against the grain of the opinion's "laws of nature" rhetoric.[179] However, this is the price to be paid for a consequential justification of *Mayo* under counteraction theory. Counteraction theory provides a sound justification for a mind-centered interpretation of *Mayo* that defuses the *Mayo* critics' two principal arguments.[180] It undermines the first argument by identifying a good reason to restrict the patent-eligibility of diagnostic-inference patents even if diagnostic inferences do not deserve weak patent protection: a restriction on patent-eligibility can counteract the regulatory inefficacy of inherency and overbreadth. It undermines the second argument because the curb on patent-eligibility created by a mind-centered interpretation of *Mayo* is far narrower in its impact than the curb created by a nature-centered interpretation. Most patented inventions are wound up with laws of nature in some way and are vulnerable to invalidation under a nature-centered interpretation of *Mayo*.[181] In contrast, very few patent claims recite the manipulation of meaningful mental states as claim limitations, and fewer yet rely entirely on such limitations to establish distinction from the prior art.[182] In fact, a mind-centered interpretation would come close to limiting *Mayo*'s patent-invalidating impact to a subset of diagnostic technologies.[183] Although most, if not all, patentable inventions are accompanied by the discovery of

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makes mental processes patent-ineligible by labeling them as abstract ideas. CyberSource Corp. v. Retail Decisions, Inc. 654 F.3d 1366, 1371 (Fed. Cir. 2011). However, the Court did not frame its *Mayo* analysis in terms of either the mental-process or abstract-ideas exclusion. *But cf. infra* note 179 (noting that there is often slippage between the different categories of excluded subject matter).

179. Nonetheless, a mind-centered interpretation of *Mayo* is a reasonable interpretation. Collins, *supra* note 105, at 1315–21 (arguing that both the reasoning in the *Mayo* opinion and the structure of the Patent Act support a mind-centered interpretation). The Supreme Court's earlier cases establishing the patent-ineligibility of algorithms had significant slippage between the abstract ideas and laws of nature exclusions. *Compare Benson*, 409 U.S. at 71–72 (ideas), *with Flook*, 437 U.S. at 590–91 (laws of nature). Some slippage between laws of nature and mental processes should therefore not be shocking. Furthermore, a mind-centered interpretation maps cleanly onto the reasoning and outcomes in most post-*Mayo* cases. Many of the Federal Circuit's post-*Mayo* cases involving diagnostic patents discuss the mental nature of inference steps and reach holdings that are consistent with a mind-centered interpretation of *Mayo*. *In re* BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation, 744 F.3d 755 (Fed. Cir. 2014); SmartGene, Inc. v. Advanced Biological Labs., 555 Fed. App'x. 950 (Fed. Cir. 2014); PerkinElmer, Inc. v. Intema Ltd., 496 Fed. App'x. 65 (Fed. Cir. 2012); Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303, 1333–35 (Fed. Cir. 2012). *See also* Eisenberg, *supra* note 72, at 271–76 (discussing the mental-steps trend in post-*Mayo* cases). *But see* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015); *Ass'n for Molecular Pathology*, 689 F.3d at 1335–37.

180. *See supra* notes 172–173 and accompanying text.

181. *See supra* note 173.

182. *See supra* note 105.

183. Importantly, however, a mind-centered interpretation would not invalidate all diagnostic technologies. *See infra* note 185.

new knowledge,[184] diagnostic inferences are the only type of invention for which inventors routinely seek patent protection where logical reasoning enabled by the mental representations that embody that knowledge is held out as the privatized technology itself. Additionally, not all newly invented medical diagnostics depend on the novelty of a diagnostic inference to establish an inventive contribution to the prior art, so many diagnostic patents remain patent eligible under a mind-centered interpretation of *Mayo*.[185]

The inventive-concept approach to the second stage of the patent-eligibility analysis has perhaps been the most criticized aspect of the Supreme Court's *Mayo* opinion.[186] However, under a mind-centered interpretation, the inventive-concept approach is a feature, not a flaw, of the analysis. It minimizes the reach of the restriction on patent-eligibility, tailoring the restriction to the problem created by the regulatory inefficacy of inherency and overbreadth. The inventive-concept approach means that claims are invalid only if the advance over the prior art resides entirely in the content of mental representations employed in the diagnostic inference, and it is only under this condition that inherency and overbreadth malfunction. Inherency is ineffective when claims rely on the content of a mental representation to establish a distinction from the prior art.[187] However, if the extra-mental steps embody an advance over the prior art, then the claim describes a novel set of extra-mental technologies, and inherency is perfectly capable of regulating patent density.[188] Similarly, the inefficacy of overbreadth is normatively problematic only when the particular limitation that is responsible for the overbreadth lies at the claim's point of novelty.[189] Inventors should be able to draft their claims broadly

184. *Cf.* WILLIAM C. ROBINSON, 2 THE LAW OF PATENTS FOR USEFUL INVENTIONS § 496 (1890) (discussing the mental component of an invention).

185. For an example of a medical-diagnostic patent that is patent-ineligible under a nature-centered interpretation of *Mayo* but patent-eligible under a mind-centered interpretation, see Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015).

186. *See supra* note 173 and accompanying text. *See also* Mark A. Lemley, *Point of Novelty*, 105 NW. U. L. REV. 1253, 1277–79 (2011) (discussing the impact of the point of novelty approach of *Parker v. Flook*). *But see* Chao, *supra* note 6, at 433–41 (seeking to rehabilitate the point of novelty approach to patent-eligibility after *Mayo*).

187. *See supra* Section II.B.2.

188. Many diagnostic-inference claims that rely on trivial advances in the extra-mental steps to establish novelty will likely be invalid for obviousness. 35 U.S.C. § 103 (2012). The obviousness doctrine does not suffer from regulatory inefficacy when patents claim diagnostic inferences. Newly discovered knowledge, whether recited as a mental-representation claim limitation or not, routinely supports nonobviousness under the guise of an invention's "unexpected consequences." United States v. Adams, 383 U.S. 39, 51–52 (1966).

189. Kevin Emerson Collins, *Getting into the "Spirit" of Innovative Things: Looking to Complementary and Substitute Properties to Shape Patent Protection for Improvements*, 26 BERKELEY

away from the point of novelty; the generality of a diagnostic-inference limitation should not be relevant in the overbreadth analysis if that limitation is not required to identify an invention that embodies a patentable advance over the prior art.[190] In sum, although the inventive-concept approach is conventionally viewed as the most problematic aspect of the Supreme Court's *Mayo* opinion, it is precisely this approach that tailors a mind-centered interpretation of *Mayo* to the subset of problematic claims that trigger regulatory inefficacy and that are likely to lead to excessive density and generality costs.

There are, of course, caveats on the ability of counteraction theory to justify a mind-centered interpretation of *Mayo*, even when regulatory inefficacy in the patentability conditions has been documented.[191] For example, the default principle that all technologies merit roughly the same quantum of patent protection may not apply. In fact, one could reasonably argue that optimal patent policy might grant diagnostic inferences unusually strong patent protection. Diagnostic inferences have significant social value because they give rise to personalized or precision medicine.[192] They are also becoming more expensive to produce, as the FDA is increasing the scope of its regulatory footprint in medical diagnostics.[193] Together, these features of the innovation profile in the medical-diagnostics industry suggest that, under the conventional argument about technology-specificity in patent law,[194] the pro-patentee bias created by regulatory inefficacy should not be counteracted because it is a welfare-enhancing bias.

TECH. L.J. 1217 (2011); Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905, 958–59 (2013).

190. Consider a claim that recites two limitations, one describing an extra-mental product or process and the other describing a diagnostic inference. If the extra-mental limitation constitutes a novel and nonobvious invention, then only the generality of the extra-mental limitations can lead to an overbreadth problem. The diagnostic-inference limitation is simply a restriction on the scope of an otherwise valid claim. It does no harm to the public, regardless of its overbreadth. If a claim reciting limitations A, B, and C is patentable, then a highly general limitation D in a claim reciting limitations A, B, C, and D does not over-reward an inventor, even if D's breadth is not fully supported by the specification. Note, however, that limitation D may inappropriately prevent future inventors from obtaining an improvement patent if limitation D is highly specific and added after the original application is filed. *In re* Ruschig, 379 F.2d 990, 995–96 (C.C.P.A. 1967).

191. *See supra* notes 75–79 and accompanying text.

192. Holman, *Policy Lever*, *supra* note 172, at 115–23. For a general discussion of personalized medicine, see Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, NEW ENGLAND J. MED., July 22, 2010, at 301; PRESIDENT'S COUNCIL OF ADVISORS ON SCI. AND TECH., PRIORITIES FOR PERSONALIZED MEDICINE (2008), http://www.whitehouse.gov/files/documents/ostp/PCAST/pcast_report_v2.pdf.

193. *See generally* Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. DAVIS L. REV. 1881 (2016).

194. *See infra* notes 281–282 and accompanying text.

Alternatively, even if the goal of inter-technology equality in patent protection is adopted, the counteraction provided by a mind-centered interpretation of *Mayo* may be poorly calibrated to the regulatory inefficacy that is present. The restriction on patent-eligibility may overshoot: it may create an anti-patentee bias that is stronger than the pro-patentee bias created by the inefficacy of inherency and overbreadth.[195] These two arguments can also be combined. Any overshooting may be unusually harmful because of the strong social need for innovation incentives, even if the overshooting yields an anti-patentee bias that is not greater in magnitude than the pro-patentee bias of regulatory inefficacy.

Another caveat is that there may be another possible restriction on the patent-eligibility of diagnostic inferences that is more closely tailored to the regulatory inefficacy of the patentability conditions than a mind-centered interpretation of *Mayo*. Regulation resistance creates fertile conditions for high density and generality costs, but it does not guarantee that every diagnostic-inference patent will actually yield such costs. Some diagnostic-inference patents will not contribute to excessive density.[196] Other diagnostic-inference patents will not impose large generality costs.[197] However, it is doubtful that there is a better-tailored, and yet still administrable, rule for selectively invalidating only the costly diagnostic-inference patents. The information that examiners and judges need to identify the patents that will actually create significant density and generality costs is impossible to obtain.[198]

To see the difficulty of a more targeted exclusion, consider commentators' proposals that the Supreme Court's recent patent-eligibility cases should be interpreted narrowly so that only the patents that are likely to foreclose significant amounts of future innovation (roughly, basic-tool patents) are held invalid.[199] In theory, such a foreclosure-of-innovation

195. Whether over-counteraction is acceptable depends in part on whether there is an administrable rule that provides more closely calibrated counteraction. *See infra* notes 196–211 and accompanying text.

196. For example, all relevant knowledge about a system may be discovered simultaneously. *See supra* text accompanying note 125.

197. For example, the claims may be premised on highly contingent and specific correlations. *See supra* note 161 and accompanying text.

198. The argument here is a variant of the classic debate that pits over- and under-inclusive rules against better-tailored standards. *See generally* FREDERICK SCHAUER, PLAYING BY THE RULES: A PHILOSOPHICAL EXAMINATION OF RULE-BASED DECISION-MAKING IN LAW AND IN LIFE (1991). Rules are preferable when the decision maker cannot easily obtain the information needed to administer the standard accurately.

199. 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, 1370–75 (2011); Lemley et al., *supra* note 6, at 1324–27; Sichelman, *supra* note 173, at 377–80; Allen K. Yu, *Within Subject Matter*

proposal offers a restriction on patent-eligibility that is more closely tailored to patents that will actually create large generality costs than a mind-centered interpretation of *Mayo*. (But note that it does not address the regulatory inefficacy of inherency and the corresponding density costs.) In practice, however, a foreclosure-of-innovation proposal fails to produce workable doctrine for drawing a line between patent-eligible and patent-ineligible diagnostic inferences.[200]

The proposal by Mark Lemley, Michael Risch, Ted Sichelman, and R. Polk Wagner for bringing patent-ineligibility to bear on diagnostic-inference patents illustrates this difficulty.[201] Lemley et al. identify a list of foreclosure-of-innovation factors—including both overbreadth and a number of *sui generis* factors, namely whether "the claimed invention [is] potentially generative of many kinds of new inventions," whether the technological field "rel[ies] heavily on cumulative invention," and whether the field is "fast-moving"[202]—and they conclude that the *Mayo* patent is patent-ineligible under these factors.[203] Lemley et al. rely on overbreadth to do the bulk of the heavy lifting in identifying foreclosure of future innovation.[204] They find none in *Mayo*, stating that *Mayo* "involves an application of the natural principles discovered by the patentee."[205] This result is not surprising, given that overbreadth is an ineffective regulator of diagnostic inferences. Diagnostic inferences are never overbroad with respect to the disclosure of a statistically valid correlation, so overbreadth will never arise in this context.[206]

With overbreadth eliminated as a factor that could weigh against patent eligibility, the fate of the foreclosure-of-innovation proposal hangs on the

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Eligibility—A Disease and a Cure, 84 S. CAL. L. REV. 387, 428–30 (2011).

200. In other words, a mind-centered interpretation of *Mayo* is more of a rule-like, categorical exclusion than the foreclosure-of-innovation proposals are: the cost of its over-exclusion is counterbalanced by the benefit of its administrability. *See supra* notes 69–72 and accompanying text (discussing the gatekeeper defenses of patent-ineligibility).

201. Lemley et al., *supra* note 6, at 1342–44. The proposal is designed for all types of patents, but, among other examples, they consider the *Mayo* patent.

202. *Id.* at 1341. Lemley et al. also state that courts should consider whether a patentee's contribution is "important … relative to the prior art." *Id.* This is not a measure of the foreclosure of future innovation but rather a measure of whether an inventor deserves a patent that forecloses future innovation. *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012) (reasoning that the *Mayo* claims are patent ineligible in part because the patentees only made a small contribution to progress).

203. Lemley et al., *supra* note 6, at 1344.

204. They even refer to their proposal as an "overclaiming" proposal. Lemley et al., *supra* note 6, at 1317; *see also* Sichelman, *supra* note 173, at 374 (arguing that patent-eligibility invalidates claims "when the scope of the claim is much greater than the practical application actually invented").

205. Lemley et al., *supra* note 6, at 1344.

206. *See supra* Section II.C.2.

remaining *sui generis* factors. Lemley et al. simply ignore the two economic factors that look to the nature of an industry or technological field as a proxy for dynamic costs.[207] The choice to overlook these factors is understandable given that the factors are extremely rough proxies for dynamic costs, but it reinforces how unhelpful the factors are in selectively screening out only the costly patents. The principal argument that Lemley et al. advance to support their conclusion is that the *Mayo* claim "is not generative" and that it will not "unduly bar future inventors."[208] To the extent that these assertions are factually correct, they make a strong case in favor of patent ineligibility. However, Lemley et al. provide no real evidence to back up this assertion.[209] The failure to provide evidence to demonstrate a lack of innovation foreclosure is not surprising. Measuring innovation foreclosure directly requires that an examiner or judge look past the technology that exists today and identify the viable routes to the technologies of tomorrow that will be non-infringing substitutes if they are ever developed.[210] Other commentators who articulate foreclosure-of-innovation proposals for tailoring restrictions on patent-ineligibility openly acknowledge the

207. These factors would likely have weighed in favor of patent-ineligibility because the biomedical sciences are widely considered to be fast moving and cumulative. Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 814 (2001).

208. Lemley et al., *supra* note 6, at 1344.

209. The only argument offered to support their assertion degenerates into a game of shift-the-baseline on a ladder of generality or an insoluble levels-of-abstraction problem. Lemley et al. argue that the *Mayo* patent is not a basic-tool patent because there are broader, more basic claims that could have been made. That is, the patentee could have "claimed *all* correlations of every drug in the body," and, in relation to this broad claim, the *Mayo* patent only correlates "very specific measurements of a particular drug" to changes in the likelihood of particular clinical outcomes. *Id.* This hypothetical is unhelpful for two reasons. First, the broad, hypothetical claim is invalid for lack of utility because it is based on a premise that is so general that it is not factually true. *See supra* note 164. Second, the up-the-ladder move can be readily countered with a down-the-ladder move. Consider a diagnostic-inference patent premised on a newly discovered correlation between a metabolite level being ten percent over the optimal upper threshold and a twenty percent increase in the likelihood of adverse side effects. The *Mayo* patent is extremely general in comparison to this hypothetical patent, and it would foreclose significantly more future innovation.

210. Determining the future commercial viability of a nascent technology has proven extremely difficult in the rare patent-misuse cases in which the analysis cannot be avoided. Princo Corp. v. Int'l Trade Comm'n, 616 F.3d 1318 (Fed. Cir. 2010). Even the overtly economic methodology of antitrust law shies away from the identification of innovation markets because the foreclosure of future innovation is so difficult to measure. Richard J. Gilbert & Steven C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 ANTITRUST L.J. 569, 596 (1995) ("In many market circumstances there is so much serendipity in research and development that it is impossible to predict the sources of innovation with reasonable certainty."); Herbert Hovenkamp, *Response: Markets in IP and Antitrust*, 100 GEO. L.J. 2133, 2135 (2012) ("[M]arket power assessment will probably never do a good job of taking innovation into account because innovation is so badly behaved ….").

difficulty of identifying undue foreclosure of future innovation.[211] Nor do the Supreme Court's repeated discussions of the basic-tools justification for patent-ineligibility provide guidance on how to selectively screen out basic-tool claims.[212] In sum, the factors in a foreclosure-of-innovation test are either measurable generalities that are not highly probative of a patent's effect on future innovation or highly probative economic conclusions that are next to impossible to measure.

The caveats on *Mayo*'s fit with counteraction theory discussed above are significant and should not be lightly dismissed. What is clear, however, is that technology-specific regulatory inefficacy makes protection for diagnostic inferences an "innovation-inefficient means of increasing the incentive to innovate" relative to patent protection on other technologies.[213] The innovation-inefficiency of patent protection for diagnostic inferences, in turn, suggests that an institution other than patent law might be the best means for providing additional innovation incentives in this field, if such incentives are needed.[214] For example, a mind-centered interpretation of *Mayo* that limits the patent protection available for medical diagnostics could be coupled with regulatory exclusivity administered by the FDA as part of the FDA's ongoing shift in its regulatory footprint in medical diagnostics.[215] An FDA-administered exclusivity regime could provide innovation incentives without employing peripheral claims and thus without laboring under the regulatory inefficacy that inheres in diagnostic inference patents. Even if the costs of regulatory inefficacy are smaller than the costs of a mind-centered interpretation of *Mayo*, the costs of providing incentives

211. For example, Rochelle Dreyfuss and James Evans acknowledge that their proposed foreclosure-of-innovation analysis "require[s] both a grasp of the field and an understanding of the patented invention's epistemic significance within it" and that "[t]hese are not easy tasks." Dreyfuss & Evans, *supra* note 199, at 1372. In fact, they implicitly concede that these determinations may be beyond the institutional competence of courts when they propose that the PTO should convene a panel of experts to address the matter. *Id.*

212. Strandburg, *Preemption*, *supra* note 6, at 568. In fact, the Supreme Court has expressly noted the absence of any such proxies. In *Mayo*, the Court invoked a lack of institutional competence to support its rejection of a foreclosure-of-innovation rule that draws a line between diagnostic inferences based on the generality of the correlation at issue. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012) ("[J]udges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature.").

213. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1612–14 (2006) (arguing against pay-for-delay settlements).

214. *See* Hemel & Ouellette, *supra* note 68, at 326–61 (developing a framework for choosing between patents, prizes, grants, and tax credits for providing innovation incentives).

215. Rai, *supra* note 6, at 113; Sachs, *supra* note 193, at 1889–99. For a discussion of FDA regulatory exclusivity in general, see Yaniv Heled, *Regulatory Competitive Shelters*, 76 OHIO ST. L. J. 299 (2015).

through another institution might well be yet lower than the costs of regulatory inefficacy.

III. PROOF OF CONCEPT: SOFTWARE AND *ALICE*

In *Alice v. CLS Bank*,[216] the Supreme Court held that a patent claim to a computer-executed method of reducing risk in a financial transaction describes a patent-ineligible "abstract idea."[217] Counteraction theory provides a reasonable, although concededly imperfect, explanation for the Court's reasoning in *Alice*. Section III.A demonstrates that a software invention is a purely functional technology in the sense that it can only be defined, and thus claimed, by its functional properties. Section III.B identifies the regulatory inefficacy that is specific to software (and other purely functional technologies). It explains that two of patent law's patentability conditions—means-plus-function claiming and written description—cannot do the work of invalidating costly patents that they usually do when confronted with claims to purely functional technologies like software.[218] Section III.C examines the fit between the restriction on the patent-eligibility of software that can be justified by counteraction theory and the rule of patent-ineligibility announced in *Alice*.

A. Software Is a Purely Functional Technology

All embodiments of technologies that can infringe a patent claim have two types of properties: structural and functional.[219] Structural properties include physical, spatial, and chemical properties. For example, *having a compressed spring* is a structural property of a mousetrap, and *having a particular molecular structure* is a structural property of a therapeutic drug. In contrast, functional properties are the tasks an invention can achieve, the behavioral capacities that it possesses, and the roles it can play in a larger system. For example, *being capable of releasing stored potential energy upon being jostled* is a functional property of a spring-loaded mousetrap, and *being capable of curing a particular disease* is a functional property of a drug. No token of a technological product or process is either purely

216. 134 S. Ct. 2347 (2014).

217. *Id*.

218. The Federal Circuit's cases identifying algorithms as the metaphorical structure of software inventions give means-plus-function claiming some regulatory grip, but they do not fix the regulatory inefficacy at issue. *See infra* notes 251–255 and accompanying text.

219. *In re* Swinehart, 439 F.2d 210, 212 (C.C.P.A. 1971) (distinguishing structural properties that describe what an invention "*is*" from functional properties that describe what an invention "*does*").

functional or purely structural; all such tokens possess both structural and functional properties.[220] Furthermore, structural and functional properties are interrelated: the predominant materialist worldview holds that a technology possesses the functional properties that it does only because it possesses its structural properties.[221] That is, there is a one-way dependence of causality from structure to function: the structural properties of a technology are what give rise to its functional properties.[222] What makes a mousetrap capable of catching mice or a drug capable of curing a disease? The answer resides in the structural properties of the mousetrap or drug.

In one way, the relationship between the structural and functional properties of software is no different from the relationship that exists in a mousetrap or drug. Programmed computers do not undermine materialism:[223] just like mousetraps and drugs, they are material, worldly entities that have physical, structural properties that allow them to perform the functions that they perform.[224]

Yet, in another way, software is exceptional. Unlike in a mousetrap or drug, the physical, structural properties of a software program are usually irrelevant to identifying, delineating, or defining what a programmer does when she invents a software program. Programmers certainly don't develop software by planning out the software's physical properties: "a programmer who modifies the physical structure of a computer by providing source code to the computer need not even know that the computer's memory is being physically modified at all, much less understand or appreciate the nature of those physical modifications."[225] Nor, after the program is created, does a structural description of the program turn into a reasonable way of identifying what the program is: "[t]he process of computer programming enables a programmer to create a machine that has a particular novel physical structure for performing a particular function without requiring the programmer to design the novel features of the machine in physical

220. Peter Kroes, *Technological Explanations: The Relation Between Structure and Function of Technological Objects*, 3 PHIL. & TECH. 18, 18 (1998) (discussing "two different modes of description, viz., a *structural* and a *functional* mode of description" for technological objects).

221. *See generally* MATERIALISM AND THE MIND-BODY PROBLEM (David M. Rosenthal ed., 2d ed. 2000) (collecting significant historical and contemporary essays on materialism).

222. For this reason, the structural properties of a technology are commonly viewed as an answer to the "how" question of technology: "how [a] system will be able to perform the required function" requires "*an explanation . . . in terms of the physical structure of that* [system]." Kroes, *supra* note 220, at 20–21.

223. Software is commonly and incorrectly labeled as exceptional because it is "non-physical." *See, e.g.*, *In re* Grams, 888 F.2d 835 (Fed. Cir. 1989).

224. Robert Plotkin, Computer Programming and the Automation of Invention: A Case for Software Patent Reform, 7 UCLA J.L. & TECH. 1, 38–39 (2003).

225. *Id.* at 44–45.

terms."[226] The exceptional, functional nature of software—i.e., the irrelevance of the physical, structural properties of a software embodiment to the definition of a software program—is not an accident. To the contrary, it has been engineered into the very nature of software itself at the most fundamental of levels. The core value of software lies in the fact that the task of programming need not involve any consideration of the physical properties of the hardware.[227] It is practically impossible to refer to a set of structural characteristics shared by the embodiments of a software invention. In contrast, it is entirely possible for a mechanical engineer who invents a mousetrap and a chemist who invents a small-molecule drug to conceive of their inventions in structural terms.

Software is thus exceptional not because it is literally immaterial, but rather because it is *aspatial*. A real-world embodiment of a software invention has physical, material properties, but these properties are not relevant to what constitutes a protectable software invention. A protectable software invention is a purely functional technology on all relevant levels of definition: it is function "all the way down."[228]

B. Structure, Function, and Patent Generality

The written description doctrine and the rules of means-plus-function claiming are usually effective regulators of patent validity insofar as they curb permissible patent generality and remove costly, general claims from the patent regime. However, when patents claim purely functional technologies like software, these patentability conditions cannot do the work that we expect them to do. Their efficacy as regulators of patent validity is contingent upon a technology having physical structure that is relevant to the definition of what an inventor has invented, and software has no such physical structure.

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226. *Id.* at 26.

227. *See* W. DANIEL HILLIS, THE PATTERN ON THE STONE, at ix (1998) ("Computers are understandable because you can focus on what is happening at one level of the hierarchy without worrying about the details of what goes on at the lower levels."). *See also* Plotkin, *supra* note 224, at 36; Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308, 2317 (1994).

228. STEPHEN HAWKING, A BRIEF HISTORY OF TIME 1 (updated and expanded 10th anniversary ed. 1998) (using an origin myth about a stack of turtles to raise the issue of infinite regress to find a ground).

1. Means-Plus-Function Claiming and Written Description Usually Curb Generality

Means-plus-function claiming and written description are patentability conditions that invalidate claims defined only by a functional description of a technology.[229] Inversely stated, both mandate that an inventor include some of the physical, structural properties of the technology that he invented as limitations on claim scope.

The rules of means-plus-function claiming were Congress's response to Supreme Court cases in the first half of the twentieth century that regularly invalidated patent claims relying solely on limitations reciting the functional properties of a newly invented technology to establish a claim's novelty over the prior art.[230] For example, in *Halliburton Oil Well Cementing Co. v. Walker*, an inventor claimed an improved machine for measuring the depth of an oil well.[231] The advance lay in the device's ability to measure sound waves reflected not only from the well's bottom but from its tubing joints as well.[232] In some of the inventor's claims, this advance was described in purely functional language as a means for tuning a resonator to sound waves reflected from tubing joints.[233] The Court invalidated these claims because they employed purely functional language to describe the advance over the prior art or, inversely stated, failed to specify any structural properties of the newly invented technology that differentiated the claimed invention from the prior art.[234] The Court reasoned that such claims should be invalid because the purely functional claim language would create excessive generality costs:

> In this age of technological development there may be many other devices beyond our present information or indeed our imagination which will perform that function and yet fit these claims. And unless frightened from the course of experimentation by broad functional claims like these, inventive genius may evolve many more devices to accomplish the same purpose.[235]

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229. *See supra* notes 41–43 and accompanying text.

230. *See, e.g.*, Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1 (1946); Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364 (1938); Holland Furniture Co. v. Perkins Glue Co., 277 U.S. 245 (1928).

231. *Halliburton Oil Well Cementing*, 329 U.S. at 5–7.

232. *Id.*

233. *Id.* at 8–9.

234. *Id.*

235. *Id.* at 12.

In the 1952 Patent Act, Congress overruled *Halliburton Oil Well Cementing* when it articulated the rules of means-plus-function that still exist today.[236] These rules are a compromise of sorts. They overturn the Court's holding in that they allow inventors to draft claims with purely functional limitations. However, if inventors use purely functional limitations, a special, scope-restricting rule of claim construction will limit the scope of their claims: the functional limitations can only read on devices for performing the recited function that have the physical, structural properties of the technologies disclosed in the specification or their equivalents.[237] In short, claim scope is limited to technologies that have the physical, structural properties of the inventor's disclosed embodiments.

The written description requirement is a more recently minted doctrine that extends the rules of means-plus-function claiming to the biomedical sciences, albeit with an invalidity rule rather than a scope-narrowing rule of claim construction.[238] Written description mandates that the set of claimed technologies must remain commensurate with the set of technologies that the inventor "invented" or "possessed" at the time of filing.[239] The technologies that the inventor "invented" or "possessed," in turn, is legalistic code for the technologies that have some core subset of the structural properties of the technologies that an inventor discloses in the specification.[240] Written description is thus a tool for invalidating claims that employ excessively functional limitations and capping the permissible claim generality of patent claims.[241]

For example, in *University of Rochester v. G.D. Searle & Co.*,[242] the

236. 35 U.S.C. § 112(f) (2012).

237. *Id.*

238. The written description doctrine is often assumed to impose an unusual, technology-specific burden on biotechnology inventors. This view of written description is misguided because it fails to account for the technology-specific benefit that biotechnology inventors receive from not being subject to the rules of means-plus function claiming. The rules of means-plus-function claiming were never imported into biotechnology, so the written description doctrine was invented to fill the gap and provide roughly the same scope-regulating role in the biotechnological arts that the rules of means-plus-function claiming play in other arts. In sum, written description does not tilt a level playing field but instead levels an already tilted one. Collins, *supra* note 142, at 1431 n.128.

239. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

240. Collins, *supra* note 142, at 1430–33.

241. The primary function of written description is commonly identified as a prohibition on claims that are filed too early in time, before an inventor understands the structure of any of the embodiments that he is claiming. *See, e.g.*, BURK & LEMLEY, *supra* note 12, at 118. However, the not-too-early concern is just a limit condition of the not-too-broad concern. If an inventor has not disclosed the structure of any embodiment within the scope of the claims, the set of claimed technologies is never commensurate with the set of technologies that the inventor invented or possessed at the time of filing because the set invented or possessed is a null set.

242. 358 F.3d 916 (Fed. Cir. 2004).

Federal Circuit invalidated a claim to a method of administering a non-steroidal compound that selectively inhibits the activity of a particular protein.[243] The claim recited only a functional property of the compound, and the patent did not disclose—let alone recite as a limitation on claim scope—the structural properties of any molecule capable of achieving the desired function.[244] Similarly, in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, the court invalidated claims to methods of reducing the binding of a transcription factor to a family of genes.[245] The claims were purely functional—they "encompass[ed] the use of all substances that achieve the desired result"—and they therefore were not limited by the structural properties of any molecule that could achieve that result.[246] Reinforcing that written description requires structural limitations on claim scope, the Federal Circuit noted that written description problems are "especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing [the structures of the] species that achieve that result."[247]

Claims that are drafted with purely functional language, and that are therefore invalid under means-plus-function claiming or written description, are likely to generate significant generality costs. Not only do purely functional claims reach beyond that which an inventor has invented, they reach toward the definition markets and thereby make design-around unusually difficult.[248] The requirement that valid claims include some physical-structure limitations serves as an administrable proxy for eliminating claims with excessive generality costs in most technologies.

2. Technology-Specific Regulatory Inefficacy

When patents claim purely functional technologies such as software, neither means-plus-function claiming nor written description is an effective regulator. Those patentability conditions can limit generality costs when the physical, structural properties of a technology are relevant to the definition of what an inventor has invented, but software is an unusual technology in which the physical, structural properties of an invention are not relevant in

243. *Id.* at 917.
244. *Id.* at 927.
245. *Ariad Pharm.*, 598 F.3d at 1340.
246. *Id.* at 1341, 1350.
247. *Id.* at 1349.
248. Collins, *supra* note 142, at 1411–24.

this way.[249] Means-plus-function claiming and written description thus malfunction in the software arts. They cannot get the grip needed to rein in the overbreadth of functional claims because there are no relevant physical, structural properties to grab onto and require as claim limitations.[250] Absent a *sui generis* restriction of some kind, technology-specific regulatory inefficacy means that functional software claims—that is, all software claims—should be expected, on average, to be unusually broad and generate unusually high generality costs.

The regulatory inefficacy of the patentability conditions in diagnostic inferences has, to date, gone unrecognized, but it has not gone unrecognized in the software arts. The Federal Circuit has already taken the first step needed to modify means-plus-function claiming in a *sui generis*, technology-specific manner and transform it into an effective regulator: it identified an "algorithm" as a metaphorical structure in the software arts.[251] Functional limitations in means-plus-function software claims are thus limited in scope to the algorithms for performing the claimed function disclosed in the specification and their equivalents.[252] While the Federal Circuit's algorithm-as-structure patch to means-plus-function claiming in the software arts moves the law in the right direction, it does not go nearly far enough to eliminate the technology-specific regulatory inefficacy of means-plus-function claiming and written description. The algorithm-as-structure rule has proven to be formalistic, inconsistently applied, and easily

249. *See supra* Section III.A.

250. Nor can enablement—patent law's other main patentability condition that curtails permissible claim scope—step in and do the needed work. Enablement is poorly equipped to curtail the reach of claim scope into after-arising technology that has not yet been conceived or visualized at the time of filing. Collins, *supra* note 142, at 1433–39; Collins, *supra* note 114, at 1098–105.

Antibody technology, too, was a purely functional technology as a practical matter in its early days. Unlike software, antibodies have not been purposely engineered to make structure irrelevant. Rather, it was our limited ability to characterize the two or three-dimensional structure of antibodies and understand how they bound to antigens that made them purely functional as a practical matter. Because antibodies were purely functional technologies, the written description doctrine suffered from regulatory inefficacy when brought to bear on antibodies, too, just as it does when it is brought to bear on software. Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004) (discussing the PTO's "antibody exception" to written description).

251. WMS Gaming Inc. v. Int'l Game Tech., 184 F.3d 1339, 1347–50 (Fed. Cir. 1999). The Federal Circuit has also suggested that algorithms are the metaphorical structure of software inventions under the written description doctrine. LizardTech, Inc. v. Earth Res. Mapping, 424 F.3d 1336, 1340–43 (Fed. Cir. 2005); Robert P. Merges, *Software and Patent Scope: A Report from the Middle Innings*, 85 TEX. L. REV. 1627, 1665 (2007).

252. If there is no disclosed algorithm, the claim is invalid. Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech., 521 F.3d 1328 (Fed. Cir. 2008). In computer science, an algorithm specifies a way of achieving a functionally defined task with a series of more specifically defined functions. DICTIONARY OF COMPUTER SCIENCE, ENGINEERING, AND TECHNOLOGY 13 (Phillip A. Laplante ed., 2000) ("step-by-step procedure … for solving certain kinds of problems or accomplishing a task").

evaded.[253] For example, method claims are never construed using the rules of means-plus-function claiming,[254] and the algorithm-as-structure patch does not establish the level of specificity at which a functional description of a software program qualifies as an algorithm.[255]

C. Reconceptualizing Alice

In *Alice*, the Supreme Court addressed a claim to a software invention for reducing settlement risk through the use of a trusted third-party intermediary.[256] The claim described a series of computer-implemented steps:

> (a) creating a shadow credit record and a shadow debit record for each stakeholder party …;
>
> (b) obtaining … a start-of-day balance for each shadow credit record and shadow debit record;
>
> (c) … adjusting each respective party's shadow credit record or shadow debit record [for every transaction resulting in an exchange obligation and] allowing only these transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time …[257]

Employing its two-stage methodology for evaluating patent-eligibility,[258] the Court concluded that this claim described a patent-ineligible abstract idea rather than a patent-eligible application of that idea. First, the Court identified "the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement risk" as an abstract idea.[259] Second, the Court

253. Collins, *supra* note 142, at 1461–63; Lemley, *supra* note 189, at 944–46. The Federal Circuit's recent opinion in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015) (en banc), did recently make the rules of means-plus-function claiming more difficult to evade. For proposals that pre-date *Williamson* to apply the algorithm-as-structure patch to means-plus-function claiming in a more systematic manner, see *infra* note 273.

254. Collins, *supra* note 142, at 1461–62.

255. *Id.* at 1463–65; Kevin Emerson Collins, *The* Williamson *Revolution in Software's Structure*, BERKELEY TECH. L.J. (forthcoming 2016).

256. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

257. *Id.* at 2352 n.2.

258. *See supra* notes 59–62 and accompanying text.

259. *Alice*, 134 S. Ct. at 2355–57. *Alice* offers little guidance on the criteria that courts should use to identify and define an abstract idea. It reasons that intermediated settlement is an abstract idea because it is similar to risk hedging, an activity that the Court had already labeled as an abstract idea in *Bilski*. *Id.* However, *Bilski* did not explain why the concept of hedging risk is an abstract idea, either. Bilski v. Kappos, 561 U.S. 593, 611–12 (2010).

held that the limitations that described how the method was to be performed on a computer—for example, "creating a shadow credit record" and "adjusting" those credit records—were too generic to transform the claim into a patent-eligible application of an abstract idea.[260] More specifically, the Court again used the inventive-concept approach to reach this conclusion,[261] reasoning that the claim limitations specifying the software implementation of the abstract idea on a computer were not an advance over the prior art but were rather "purely conventional."[262] Counterfactually, had the claim described an advance in computer science—that is, an advance showing how to "improve the functioning of the computer itself" with more efficient software—the Court implied that the claim could have been directed to a patent-eligible, inventive application of an abstract idea.[263]

The debate over a consequentialist justification for *Alice* has, to date, followed the template provided by discrimination theory: commentators have disagreed over whether there is a good reason for the patent regime to grant weaker protection to innovative, computer-implemented abstract ideas than it grants to run-of-the-mill innovative technologies. This debate commonly plays out under the assumption that most patent-ineligible abstract ideas in the software context are methods of conducting business.[264] *Alice* critics draw on scholarship suggesting that patent incentives for the development of innovative business methods are just as valuable as incentives for the development of other innovative technologies.[265] *Alice* supporters argue that the social benefits of business-method patents are low because there are adequate innovation incentives for business methods even absent patent protection and that their social costs are high because business methods are akin to the basic tools of our economy.[266]

260. *Alice*, 134 S. Ct. at 2359–60.

261. *See supra* note 62 and accompanying text.

262. *Alice*, 134 S. Ct. at 2357–58, 2359–60.

263. *Id.* at 2359. *Alice* also suggested that software claims could be patent-eligible if there are advances "in any other technology or technical field" besides computer science. *Id.* at 2359–60.

264. Post-*Alice* opinions have also made this association. DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245, 1256 (Fed. Cir. 2014) ("Although the Supreme Court did not "delimit the precise contours of the 'abstract ideas' category" in resolving *Alice* . . . [w]e know that some fundamental economic and conventional business practices are . . . abstract ideas."). *Gottschalk v. Benson*, 409 U.S. 63 (1972), identified mathematical algorithms as abstract ideas, but few post-*Alice* cases have followed *Benson*'s lead and addressed the patent-ineligibility of mathematical algorithms.

265. Michael Abramowicz & John F. Duffy, *Intellectual Property for Market Experimentation*, 83 N.Y.U. L. REV. 337 (2008) (arguing that free riding undermines incentives to implement truly innovative business models).

266. Dreyfuss, *supra* note 67, at 275–76; Olsen, *supra* note 6, at 228–34; Samuelson & Schultz, *supra* note 6, at 121–25. The four concurring Justices in *Bilski v. Kappos* also endorsed the policy argument that software innovation does not benefit from patent protection. 561 U.S. 593, 648–56 (2010).

In contrast, counteraction theory changes the nature of the questions that we must ask to find a consequentialist justification for *Alice*. Does *Alice*'s restriction on patent-eligibility counteract the regulatory inefficacy of the means-plus-function and written description doctrines? Does it bring otherwise excessively strong patent protection for software back into better alignment with the norm of protection in all technologies? The answer, of course, depends on in part on what constitutes an abstract idea. For example, *Alice*'s justification under counteraction theory is stronger if a patent-ineligible claim to an abstract idea is a code phrase for a claim to a software program drafted at too high a level of generality, regardless of whether the software executes a business method. Inversely stated, *Alice* makes more sense if functional limitations specifying how to "improve the functioning of the computer itself"[267] amount to a functional description that is sufficiently specific that it does not generate undue generality costs. If an abstract idea were to be defined with reference to claim generality, then a restriction on the patent-eligibility of abstract ideas would not cause the patent regime as a whole to discriminate against software patents. Rather, it would call on patent-ineligibility to do roughly the same work in the software arts that the patentability conditions are already doing in other arts but cannot do in software because of technology-specific regulatory inefficacy.[268]

However, even if counteraction theory does justify a restriction on the patent-eligibility of software claims, the doctrinal fit between the precise restriction on patent-eligibility announced in *Alice* and the restriction needed to counteract regulatory inefficacy in the software arts may prove to be a bit awkward. There are two interconnected, open doctrinal questions that could undermine this fit. First, should the locus of the claim's inventive concept matter? *Alice* says it should,[269] and it thereby yields a relatively narrow set of patent-ineligible claims. So long as there is sufficient specificity in the limitations that embody the inventive concept, then the claim is patent-eligible, regardless of the level of generality of other

267. *Alice*, 134 S. Ct. at 2359.

268. The usual caveats on counteraction as a justification for a restriction on patent-eligibility also apply. *See supra* notes 75–78 and accompanying text. To be clear, defining an abstract idea solely with reference to claim generality raises significant administrability problems. Most notably, a direct assessment of the magnitude of a claim's generality costs may be beyond the competence of examiners and Article III judges. Collins, *supra* note 142, at 1466–67. In fact, the difficulty of directly assessing a claim's generality costs is one reason why patent law adopted the distinction between functional and structural claim limitations as a proxy for those costs in the first place. *Id.* at 1411–24.

269. *See supra* notes 260–263 and accompanying text.

functional limitations.[270] Yet, neither means-plus-function claiming nor the written description doctrine overtly requires any consideration of a claim's inventive concept.[271] Thus, it would seem that a restriction on patent-eligibility that simply counteracts the inefficacy of these doctrines in the software arts should not employ the inventive-concept approach.[272] Second, does there need to be metaphorical structure in each individual claim limitation? *Alice* requires sufficient specificity only in the limitations embodying a claim's inventive concept, so it does not seem to mandate sufficient specificity in each of the "creating," "obtaining," and "adjusting" limitations. Whether *Alice*'s approach provides the counteraction with the best fit to the regulatory inefficacy at issue, however, is unclear because the two doctrines whose inefficacy *Alice* seeks to counteract take different approaches on this issue. Means-plus-function claiming requires every functional limitation, considered individually, to recite some physical structure, whereas the written description doctrine has not been applied on a limitation-by-limitation basis. A full analysis of how these two questions should be answered, and thus a more definitive assessment of the fit between *Alice* and the restriction needed to counteract the regulatory inefficacy in the software arts, requires a more detailed analysis than can be undertaken here.[273] What can be said, however, is that, under counteraction theory, *Alice* pushes the *status quo* of patent law in the right direction as it

270. The inventive-concept approach leads to a relatively broad exclusion on another dimension. For example, imagine that each of the "creating," "obtaining," and "adjusting" steps in the *Alice* claim is limited to one of several conventional programming techniques for achieving the claimed method. Under an inventive-concept approach, the claim would remain patent-ineligible because the locus of the advance over the prior art still exists only at the level of an abstract idea. However, if one were only worried about generality costs, this claim would not be problematic because there are conventional, non-infringing techniques for implementing the abstract idea.

271. *See supra* notes 236–241 and accompanying text. *But cf.* Halliburton Oil Well Cementing Co. v. Walker, 329 U.S. 1, 8 (1946) (holding only that functional claiming at a claim's "point of novelty" was problematic) (quoting Gen. Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 371 (1938)).

272. *But cf. supra* notes 189–190 and accompanying text (suggesting that broad claiming away from the point of novelty is not problematic).

273. If one believes that the optimal counteraction ignores the inventive concept and demands specificity on a limitation-by-limitation basis, then the best approach to counteraction might not implicate the doctrine of patent-eligibility at all. Rather, the needed counteraction could come from a *sui generis*, technology-specific modification of the rules of means-plus-function claiming. Rather than simply calling whatever functional description exists in the specification an algorithm, courts could identify a level of specificity at which a functional description of a software program should be treated as a metaphorical structure. For example, functional limitations that map onto end-user preferences (tasks that consumers want the software to perform) could be invalid for overbreadth while functional limitations that describe programming techniques for satisfying those end-user preferences could be valid because they are limited to the metaphorical structure of a software invention. Collins, *supra* note 142, at 1421–23, 1466. *See also* Lemley, *supra* note 189, at 943–63 (suggesting limitations describing the "goal" or "function of the program" should be invalid as overbroad, whereas limitations describing "the way an inventor implements a function" should not).

offsets the regulatory inefficacy of certain patentability conditions in the software arts, even if it turns out to do so imperfectly.

IV. NEW DIRECTIONS

The value of counteraction theory lies, in part, in its explanatory power. Counteraction theory provides a reasonable, although concededly imperfect, consequentialist justification for the Supreme Court's recent opinions on the patent-ineligibility of diagnostic inferences in *Mayo* and software in *Alice*.[274] However, the explanatory power of counteraction theory should not be overstated. Counteraction theory cannot conveniently justify all of the Supreme Court's recent cases on patent-eligibility. To the contrary, it sheds little light on restrictions on patent-eligibility that, like the Court's recent opinion in *Association for Molecular Pathology v. Myriad Genetics*, are tasked with ensuring that the realm of the natural remains beyond the reach of patent law.[275]

Beyond its explanatory import, counteraction theory pushes back against conventional wisdom and moves patent scholarship in new directions on a number of dimensions. This part briefly notes four of them.

A. Patent-Ineligibility Versus the Patentability Conditions

Prior scholarship recognizes that patent-ineligibility and the patentability conditions are imperfect substitutes in the sense that both are capable of regulating what constitutes a permissible patent interest and doing the welfare-enhancing work of invalidating costly patents. However, to date, commentators have only used this insight to advocate against restrictions on patent-eligibility. One of the most frequently echoed arguments in debates over patent-eligibility is what should be called the Annie Oakley argument: anything patent-ineligibility can do to regulate patent validity, the patentability conditions can do better.[276] Counteraction

274. *See supra* Sections II.D, III.C.

275. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (holding that genomic DNA, but not complementary DNA, is patent-ineligible). Nor can counteraction theory justify a nature-centered interpretation of *Mayo*. *See supra* notes 176–178 and accompanying text.

276. Donald Chisum's assertion is typical of the Annie Oakley argument: "Used with appropriate vigor, the [patentability conditions] can effectively screen out virtually all claims . . . that are . . . only abstract ideas or natural phenomena …." 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, 14 (2011). Michael Risch's assertion is typical, too: "any invention that satisfies the [patentability conditions] is patentable." Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 591 (2008). For other uses of the Annie Oakley argument, see *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1073–74 (Fed. Cir. 2011); Duffy, *supra* note 6, at 622–23; Kristin Osenga,

theory turns the Annie Oakley argument on its head. The need for restrictions on patent-eligibility follows directly from the patentability conditions inability to do the needed work under certain circumstances. That is, it is the technology-specific regulatory inefficacy of the patentability conditions that gives rise to a need for restrictions on patent-eligibility.

B. A Grand Unified Doctrine of Patent-Ineligibility?

By stating in *Alice* that its two-stage methodology should guide the patent-ineligibility analysis for laws of nature, natural phenomenon, and abstract ideas, the Supreme Court articulated what amounts to a grand unified doctrine of patent-eligibility—a single doctrine that identifies the boundary of patent-eligible subject matter in all technologies.[277] Counteraction theory counsels against any such grand unified theory.[278] Counteraction theory and discrimination theory may justify restrictions on patent-eligibility in different contexts, and there is no *a priori* reason to expect the two different reasons for curtailing patent-eligibility to be optimally implemented through the same doctrine. Furthermore, even looking only at restrictions justified by counteraction theory, there is no reason to employ the same doctrine in different technological arts. Different patentability conditions become ineffective in different technologies for different reasons, and different patent-ineligibility rules are best for counteracting these divergent variants of regulatory inefficacy. For example, the inventive-concept approach to patent-eligibility is necessary to counteract regulatory inefficacy in diagnostic inferences,[279] but it may not be in software.[280]

Ants, Elephant Guns, and Statutory Subject Matter, 39 ARIZ. ST. L.J. 1087, 1115–18 (2007). *Cf.* Dennis Crouch & Robert P. Merges, *Operating Efficiently Post*-Bilski *by Ordering Patent Doctrine Decision-Making*, 25 BERKELEY TECH. L.J. 1673, 1674 (2010) (arguing that the patentability doctrines can do most of the needed work and that patent-eligibility decisions should be avoided by applying the patentability conditions first as a procedural matter). For commentary critiquing, or at least finding exceptions to, the Annie Oakley theory, see Eisenberg, *Wisdom*, *supra* note 6, at 50–64; Lemley et al., *supra* note 6, at 1329–32; Golden, *supra* note 6, at 1055–74; Olson, *supra* note 6, at 202.

277. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014). *See also* PTO Eligibility Guidelines, *supra* note 59, at 74,621–25 (interpreting *Myriad* to employ the same inventive-concept methodology articulated in *Alice* and *Mayo*). A grand unified theory of patent-ineligibility is also a common goal in patent scholarship. *See, e.g.*, Emily Michiko Morris, *What Is "Technology"?*, 20 B.U. J. SCI. & TECH. L. 24 (2014); Efthimios Parasidis, *A Uniform Framework for Patent Eligibility*, 85 TUL. L. REV. 323 (2010).

278. *Cf.* Kevin Emerson Collins, Bilski *and the Ambiguity of "An Unpatentable Abstract Idea"*, 15 LEWIS & CLARK L. REV. 37, 61–65 (2011) (arguing that patent-eligibility should have different doctrinal manifestations to address different types of costly claims).

279. *See supra* notes 187–190 and accompanying text.

280. *See supra* notes 269–272 and accompanying text.

C. Technology-Specific Patent Law

A rich vein of contemporary patent scholarship argues in favor of technological-specificity in patent law.[281] The dominant narrative is that patent law is facially neutral but that it is—and should be—applied in a technology-specific manner because the economic profile of innovation differs from industry to industry.[282] Stronger protection may be appropriate when innovation is costly, and weaker protection may be appropriate when innovation is cheap or non-patent incentives for innovation are present. Inversely, narrow protection may be appropriate when an industry develops through cumulative innovation, except perhaps when large incentives for pioneer innovations are beneficial because pioneer innovations are both expensive to produce and socially valuable. In all of these situations, the core argument in favor of technology-specific patent law is the same: different technological fields merit different types of patent protection because different industries have different economic profiles of innovation.

Counteraction theory, too, suggests that patent law is technology-specific, but the technological specificity arises for a different reason. Under counteraction theory, patent law is not technologically neutral by default. Differences in the intrinsic natures of technologies hardwire technology-specific regulatory inefficacy into the patentability conditions.[283] Technology-specific counteraction through patent-ineligibility simply responds to the hardwired technological specificity. This response is not designed to create different levels of patent protection in different industries

281. Dan Burk and Mark Lemley launched this argument. BURK & LEMLEY, *supra* note 12, at 37–48.

282. *Id.* A secondary argument is that courts, rather than Congress, should do the needed tailoring. *Id.* at 95–108.

283. To date, patent commentary has largely ignored or "black-boxed" the differences in the intrinsic natures of patented technologies that cause regulatory inefficacy. Michel Callon & Bruno Latour, *Unscrewing the Big Leviathan: How Actors Macro-Structure Reality and How Sociologists Help Them to Do So*, *in* ADVANCES IN SOCIAL THEORY AND METHODOLOGY: TOWARD AN INTEGRATION OF MICRO- AND MACRO-SOCIOLOGIES 277, 284–85 (Karin Knorr-Cetina & Aaron Victor Cicourel eds., 1981) ("A black box contains that which no longer needs to be reconsidered, those things whose contents have become a matter of indifference."). More generally, economically minded commentary often black-boxes the intrinsic properties of technology. Clive Lawson, *An Ontology of Technology: Artefacts, Relations and Functions*, 12 TECHNÉ 48, 49 (2008) (arguing that economists routinely reduce technology to a production function characterized by inputs and outputs). One notable exception is Jim Bessen and Mike Meurer's argument that software-specific patent law, whether in the form of a restriction on patent-eligibility or something else, is needed because software is intrinsically "abstract." JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 201–12 (2008). However, precisely what makes software abstract, and thus what makes the patentability conditions unable to regulate patents like they usually do, remains underspecified in Bessen and Meurer's argument. *Id.*

to accommodate the industry-specific economics of innovation. Rather, it is designed to offset technology-specific regulatory inefficacy and bring the strength of patent protection available in different industries into closer alignment.

D. Rethinking Intangibility as a Limit on Patent-Eligibility

Historically, intangible inventions could not be patented.[284] However, as economically valuable technology dematerialized over the last half century,[285] the bar on patenting intangible inventions gradually eroded. In the industrial age, the intangibility bar made sense: it was a reasonable proxy for a bar on patenting the knowledge about inventions that patentees are obligated to disclose and make available to the public as part of patent law's *quid pro quo*.[286] It ensured that machines, chemicals, and eventually processes of using the same were patent-eligible, but that newly discovered knowledge about those technologies was not. However, in the shift from the industrial era to today's knowledge of information economy, intangibility gradually ceased to be a viable litmus test for patent-ineligibility. A strict intangibility bar came to be seen as an irrational, technology-specific exclusion of the most cutting-edge of technologies—most notably software—from the patent regime.[287] Although there may be good reasons to exclude some inventions that happen to be intangible from the patent regime, the simple fact that an invention is intangible is not generally understood to be one of them.[288]

Yet, puzzling waves of resistance to the patentability of intangible inventions still come and go. In *Diamond v. Diehr*,[289] the Supreme Court described "a function which the patents laws were designed to protect" as "transforming or reducing an article to a different state or thing."[290] *Diehr*'s focus on tangibility reappeared in the *Freeman-Walter-Abele* test for patent-eligibility, which over time slowly faded away.[291] More recently, the Federal Circuit employed the machine-or-transformation test to assess

284. Cochrane v. Deener, 94 U.S. 780, 788 (1876) ("A process . . . is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing."); Richard S. Gruner, *Intangible Inventions: Patentable Subject Matter for an Information Age*, 35 LOY. L.A. L. REV. 355, 355–56 (2002).

285. *See supra* note 85.

286. Collins, *supra* note 105, at 1315–21.

287. *In re* Musgrave, 431 F.2d 882 (C.C.P.A. 1970); Gruner, *supra* note 284, at 359–61.

288. Gruner, *supra* note 284, at 356–67.

289. 450 U.S. 175 (1981).

290. *Id. at* 192.

291. *In re* Abele, 684 F.2d 902, 907 (C.C.P.A. 1982).

patent-eligibility and thereby positioned tangibility as the defining feature of patent-eligible subject matter.[292] Today, the machine-or-transformation test is in retreat, and the importance of intangibility as a limit on patent-eligibility again seems to be decreasing.[293]

To date, none of the periodic ascendancies of intangibility as a touchstone for patent-ineligibility has produced a convincing normative explanation of why intangibility should play this role for today's knowledge-age technologies. Counteraction theory and regulatory inefficacy therefore break new ground by offering an otherwise absent explanation of both why and how intangibility should remain wound up with the patent-eligibility analysis. Intangibility lies at the root of regulatory inefficacy. The dematerialization of industrial-era technologies that led to today's relatively intangible technologies is exactly what caused certain patentability conditions to become ineffective regulators.[294] Intangible subject matters merit a skeptical second look as part of the patent-eligibility analysis because they are likely to trigger regulatory inefficacy in the patentability conditions. The causal relationship from intangibility to regulatory inefficacy also identifies the types of intangibility that should be relevant in patent law—namely those that trigger regulatory inefficacy. The intangibility of meaningful mental states causes problems,[295] as does the intangibility of software.[296] To date, courts have been looking for intangibility in all the wrong places, and responding to it in all the wrong

292. *In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008), *aff'd on other grounds*, Bilski v. Kappos, 561 U.S. 593 (2010). In software, the machine-or-transformation test and its use of tangibility as a touchstone of patent-eligibility led some Federal Circuit judges to uphold apparatus claims and invalidate method claims to the same invention. CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1305–11 (Fed. Cir. 2013) (Rader, J., concurring-in-part and dissenting-in-part) (upholding apparatus claims and invalidating method claims to the same software invention). *Cf.* Lemley et al., *supra* note 6, at 1322–25 (raising unanswered questions about the patentability of software inventions under the machine-or-transformation test). In diagnostic inferences, the Federal Circuit came to see the tangibility of the determining step that precedes the inference step as dispositive of patent-eligibility. *Compare* Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347 (Fed. Cir. 2010), *rev'd*, *Mayo*, 132 S. Ct. 1289 (2012) (upholding a claim with a determining step that transformed matter into a different state or thing), *with* Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329, 1355 (Fed. Cir. 2011), *vacated sub nom.*, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) (invalidating a claim in which the determining step could be performed simply by reading).

293. The Supreme Court quickly demoted the machine-or-transformation test from the sole test for patent-eligibility to "a useful and important clue" for assessing patent-eligibility. Bilski v. Kappos, 561 U.S. 593, 604 (2010). The Supreme Court's silence on the subject of the machine-or-transformation test in subsequent cases has led the Federal Circuit to reduce its reliance on it.

294. *See supra* notes 83–86 and accompanying text.

295. *See supra* Part II.

296. *See supra* Part III.

ways, because they have not understood why the intangibility of a patented technology is normatively problematic.[297]

CONCLUSION

Over the last six years, the Supreme Court has issued an unprecedented four opinions restricting the reach of patent-eligibility under Section 101 of the Patent Act. These opinions have received a tepid reaction in patent commentary, at best. Sound consequentialist justifications for these opinions have proven difficult to identify.

This Article develops counteraction theory as a justification for restrictions on patent-eligibility, and it illustrates that counteraction theory provides a reasonable, although concededly imperfect, justification for some of the Court's recent patent-eligibility opinions. Counteraction theory has its greatest explanatory power in the Supreme Court's opinions in *Mayo* addressing diagnostic inferences, provided *Mayo* is interpreted in a mind-centered manner, and in *Alice* addressing software. However, it provides little insight into the Court's opinion in *Myriad* that draws a line between unpatentable nature and patentable, man-made artifice.

297. *See supra* section II.C.2. Intangibility still has a role to play in keeping the privatizing effects of patent claims out of the realm of the disclosure. *See supra* note 286 and accompanying text. However, this role is neither as important nor as straightforward as it is often assumed to be. Collins, *supra* note 105, at 1321–49 (detailing the limits on patentability that are needed to protect patent law's duality of claiming and disclosing).