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THE COMPLETENESS REQUIREMENT IN PATENT LAW

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Abstract: This Article argues that courts have created a de facto extra-statutory condition of patentability, herein termed the "completeness" requirement. This requirement bars patents on certain inventions whose chief value lies in their function as inputs into downstream research. The Article contends that the notion of completeness explains doctrinal innovations that are difficult to rationalize any other way. Although it reflects an important policy of limiting unduly preemptive patent claims on foundational, building-block inventions, the completeness requirement in its current form fails to implement this policy in a way that is coherent and consistent with patent law's utilitarian goals. In addition, courts' attempts to develop the completeness requirement based on existing statutory provisions have resulted in controversial interpretations of the Patent Act, generating legitimacy costs. The Article argues that these problems are best addressed by explicitly recognizing completeness as a separate requirement of patentability and modifying the doctrinal tools used to enforce this requirement. To determine whether a patent claim passes completeness, the Article proposes a new test that focuses on the generality and unpredictability of a claimed invention's applications. Further, it argues that an amendment to the Patent Act codifying the requirement of completeness is the most effective way to implement the proposal. Finally, the Article explores the possibility of awarding a limited patent right, which it terms "Research Patent," to claims that satisfy existing requirements of patentability, but fail completeness. This right would provide the intellectual property incentives that are likely needed to develop and commercialize foundational inventions, and also help decrease the potential for stifling downstream innovation created by granting full patent protection to such inventions.

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INTRODUCTION

Suppose that, after several years of laboratory work, a researcher discovers a novel way to make a certain type of chemical bond faster and with higher efficiency.[1] This invention adds to other chemists' toolkits and paves the way for making an entirely new class of molecules, opening up possibilities of discovery of new drugs, useful materials, and so on. The inventor assembles a kit based on the new method and commercializes the invention, making it available to other scientists who wish to take advantage of the method. Worried that potential infringers can easily design around patent claims directed merely to a specific kit, the inventor attempts to patent the general method of making the chemical bond.

Or, consider a case where biomedical investigators discover that interfering with the function of a certain receptor in the human body can reduce "inflammation associated with diseases such as arthritis."[2] In contrast to earlier work, which had proceeded without the knowledge of this receptor's role, this approach treats the inflammation while avoiding "undesirable side effects such as stomach upset [sic], irritation, ulcers, and bleeding."[3] The discovery is highly valuable; as one commentator noted, "there is little question that the pioneering . . . work paved the way for a new generation of painkillers that would be easy on the stomach," including Celebrex.[4] Realizing that a patent to a method of *finding* a drug might be of little value, the inventors attempt to claim a method of *treating* the inflammation based on the discovery of the receptor function and a roadmap for finding drugs that would interfere with it.

Finally, consider a discovery that enables doctors to optimize dosages of a certain drug based on the concentration of a particular chemical compound (called a "probe molecule") in a blood sample taken from a patient.[5] The inventors license the technology to a company, which designs and sells kits for optimizing the drug dosages.[6] Experts hail the invention as a signif-

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[1] This is a stylized example describing an invention that would be held unpatentable in view of the U.S. Supreme Court's holding in *Brenner v. Manson*. *See* 383 U.S. 519, 534 (1966).

[2] *See* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 917, 929 (Fed. Cir. 2004).

[3] *See id.* at 918.

[4] *See* Seth Shulman, *A Painful IP Ruling*, MIT TECH. REV., June 2003, at 75, 75 ("[W]e need a patent system that distinguishes between those who would 'preempt' the future and those who actually help create it.").

[5] *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012).

[6] *See Prometheus Thiopurine Metabolites*, PROMETHEUS THERAPEUTICS & DIAGNOSTICS, http://www.prometheuslabs.com/Resources/PTM/Thiopurine_Metabolites_Product_Detail.pdf, *archived at* http://perma.cc/P85C-F5KF (last visited Mar. 27, 2015).

icant development in the treatment of inflammatory bowel disease,[7] and researchers and doctors use the kit to make further discoveries.[8] Again, unsatisfied to claim merely a kit, the inventors attempt to claim a general method of optimizing drug dosage based on the measured concentration of the probe molecule.

Because all of these inventions required significant investments, constituted important scientific advances, and promoted further research and development, it is difficult to fault the inventors for seeking valuable patent claims to protect them.[9] But courts held that none of them could be patented in view of what the inventors claimed and what they disclosed (or, rather, failed to disclose) in their patent applications.[10] As to the first invention, the patent applicant did not show that the chemicals made with the novel process would be useful to ordinary consumers (as drugs, for example) rather than to other researchers.[11] The Supreme Court therefore ruled that the process was not "useful" within the meaning of Section 101 of the Patent Act.[12] As to the second, because the inventors did not yet know what specific drugs would reduce the inflammation, the U.S. Court of Appeals for the Federal Circuit held that the patent failed to provide adequate "written description" under Section 112.[13] And as to the third, the Supreme Court de-

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[7] *See Can We Personalize Therapy for IBD?*, CANADIAN ASS'N OF GASTROENTEROLOGY (Feb. 27, 2011), http://www.cag-acg.org/uploads/syllabus_ibd_symposium.pdf, *archived at* http://perma.cc/GMS3-BUQQ.

[8] *See* Troy D. Jaskowski et al., *Analysis of Serum Antibodies in Patients Suspected of Having Inflammatory Bowel Disease*, 13 CLINICAL & VACCINE IMMUNOLOGY 655, 656 (2006).

[9] *See* Elizabeth A. Doherty, *Biomarker and Personalized Medicine Patent Claims One Year After* Mayo v. Prometheus, FULL DISCLOSURE (Finnegan, Henderson, Farabow, Garrett, & Dunner, LLP, Washington, D.C.), June 2013, at 3, 4, *available at* http://www.finnegan.com/files/upload/Newsletters/Full_Disclosure/2013/June/FullDisclosure_Jun13_Print.pdf, *archived at* http://perma.cc/MWB6-JPQ2 ("From [a patent] applicant's point of view . . . narrower claims may be very easy for a competitor to design around and thus of little commercial value."); *see also* Peter W. Huber, *Who Owns the Code of Life?*, CITY J., Autumn 2013, at 10, 13 ("[P]atents that cover biological know-how only insofar as it is incorporated into an innovative drug or a diagnostic device provide little, if any, practical protection for what is often a large component of the ingenuity and cost of the invention. . . . [T]he pioneer can easily be the only player that fails to profit from its own pathbreaking work.").

[10] *See Mayo*, 132 S. Ct. at 1305; *Brenner*, 383 U.S. at 534; *Univ. of Rochester*, 358 F.3d at 929. In *Mayo*, although it is probable that no amount of disclosure would have rescued the asserted claims, the statements in the specification still mattered in that they counted against the validity of the claims. *See* 132 S. Ct. at 1297–98 (taking note of the patent's statements indicating that "methods for determining [probe molecule] levels were well known in the art" and using these statements against the patentability of the claims).

[11] *See Brenner*, 383 U.S. at 534.

[12] *See* 35 U.S.C. § 101 (2012); *Brenner*, 383 U.S. at 534.

[13] *See* 35 U.S.C. § 112(a); *Univ. of Rochester*, 358 F.3d at 929. The Federal Circuit is a federal appellate court charged with exclusive jurisdiction over appeals in patent cases. *See* 28 U.S.C. § 1295(a)(1) (2012).

termined that the patent claims did not "confine their reach to particular applications of" the correlation that the inventors discovered.[14] Thus, the Court concluded, the claims could not be patented because they were directed to a law of nature—one of the judicially recognized exceptions to patent eligibility.[15]

This Article posits that the doctrines represented by these three cases are best understood as products of courts' attempts to test the patent claims at issue against the same unwritten requirement of patentability, herein termed "completeness."[16] In general, the completeness requirement is concerned with whether, given the scope of the claim at issue and the disclosures in the patent's specification,[17] the invention is too foundational to qualify for a patent. Completeness is critically important because patents on artifacts of basic research are thought to disserve utilitarian goals of patent law.[18] Commentators contend that the need to avoid the harmful effects of such patents on downstream innovation outweighs the need to incentivize creation and commercialization of basic research and induce its disclosure using patent-based mechanisms.[19] The unwritten completeness requirement

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[14] *See Mayo*, 132 S. Ct. at 1302.

[15] *See id.* at 1305.

[16] The label "completeness" as used in this Article is not to be confused with the notion of a completely conceived invention for the purpose of the on-sale bar. *See* Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 66 (1998) ("The word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.'"). In contrast, "completeness" as used here connotes inventions that are artifacts of basic research. I thank Janice Mueller for pointing out this area of potential confusion.

[17] The term "specification" encompasses everything but the patent's claims. The claims define the scope of the patent right, and the specification provides the supporting disclosure. Although the proper term for this part of the patent is "written description," I use "specification" to be consistent with common usage.

[18] *See infra* notes 96–125 and accompanying text. As we will see throughout the Article, however, the outcomes of completeness cases sometimes belie courts' utilitarian rhetoric. *See, e.g.*, *infra* note 20 and accompanying text. This disjunction is probably due in part to the difficulty of defining "basic research," an issue that is addressed extensively in the Article. *See infra* notes 273–282 and accompanying text.

[19] *See, e.g.*, WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 306–08 (2003); STEVEN SHAVELL, FOUNDATIONS OF THE ECONOMIC ANALYSIS OF LAW 165 (2004) (arguing against property rights in basic research because grants and other forms of "[s]tate support" create a "reward system"); Alan Devlin, *Patent Law's Parsimony Principle*, 25 BERKELEY TECH. L.J. 1693, 1717 (2010) (arguing that laws of nature, physical phenomena, and abstract ideas are excluded from patentability because "[t]hese fields of discovery bear unique potential for overcompensation, given their upstream nature and the concomitant proclivity for ubiquitous downstream application"); *see also* Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195, 1220–21 (discussing patent law's "bias against basic science," and the justifications for that bias, in the context of the utility and patentable subject matter requirements). *See generally* David Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181 (2009) (arguing that

accordingly aims to bar patents on these so-called "upstream" inventions because such patents would likely become "bottlenecks" capable of chilling further inventive activity.[20] Specifically, some courts and scholars highlight, as a policy concern, the need to prevent "undue preemption" of downstream research through upstream patenting.[21] But because it is sometimes difficult to measure preemption directly and determine how much preemption is due, courts apply three doctrines—utility, written description, and patentable subject matter[22]—to eliminate classes of upstream patents that appear to be particularly likely to raise problems of undue preemption.[23]

This Article argues that conceiving of the three separate doctrines as facets of an unwritten, underlying requirement of patentability might aid in the development of a framework of patent rights and remedies that is more rational than that which patent law currently offers. The concept of completeness would help bring into sharp focus the policy goal of limiting patents on early-stage inventions that serve as foundational research inputs, and would direct decisionmakers to examine whether the outcomes of certain utility, written description, and patentable subject matter cases actually

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"the sensible basis for determining patentable subject matter is to determine whether innovation is unlikely in the absence of patents").

[20] *But see* Tun-Jen Chiang, *Competing Visions of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1858, 1873–85 (2014) (suggesting that there is a strong non-utilitarian streak behind patentable subject matter exclusions, which manifests itself with particular salience in recent Supreme Court cases). To the extent courts have begun to depart from patent law's utilitarian moorings in completeness cases, this Article proposes a path for correcting this trend.

[21] *See, e.g.*, *Brenner*, 383 U.S. at 534 (reasoning that patents on upstream inventions "may confer power to block off whole areas of scientific development"); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 124 (1999) (warning that upstream patents are "likely to inhibit creativity and thus progress"); Richard H. Stern, *Scope-of-Protection Problems with Patents and Copyrights on Methods of Doing Business*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 105, 145 (1999) ("[E]very claim 'preempts' whatever is the subject matter of that claim. The task of applying a doctrine against undue preemption is to limit the preemptiveness of allowed claims to an extent as will allow others to operate within the applicable business genre . . . .").

[22] The utility test asks whether an invention is "useful." *See Brenner*, 383 U.S. at 528–29. The written description test asks whether the inventor "actually invented" (or "possessed") the claimed subject matter. *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351, 1355 (Fed. Cir. 2010) (en banc). And patentable subject matter tests ask whether the invention is "markedly different" from a natural product, or "an inventive application" of a law of nature or abstract idea. *See* Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2358 (2014) (explaining the "inventive application" test); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013) (outlining the "markedly different" test).

[23] For examples of cases where courts made this policy reasoning clear, see *Mayo*, 132 S. Ct. at 1294 ("[Precedent] warn[s] us against upholding patents that claim processes that too broadly preempt the use of a natural law."); *Brenner*, 383 U.S. at 535 ("[T]here is insufficient justification for permitting an applicant to engross what may prove to be a broad field."); *Ariad*, 598 F.3d at 1353 ("[C]laims to research plans . . . impose costs on downstream research, discouraging later invention.").

reflect this policy.[24] If the ultimate goal of barring unduly preemptive patents is kept firmly in mind, courts and patent examiners could identify other problematic patents of this sort that decisionmakers have nonetheless allowed, and also determine which patents they have invalidated in error. Indeed, the completeness lens might help address the concern that, although courts sometimes reject patent claims to certain early-stage biotechnological and chemical inventions, they routinely permit claims to other types of foundational inventions that might preempt many research and development applications in various areas of technology.[25] For example, applying the concept of completeness may help decisionmakers deal in a coherent way with the problem of broad, functionally drafted software and business method claims that are thought to threaten downstream development pathways.[26] Such claims have generally escaped judicial scrutiny,[27] although this appears to be changing as courts have begun to apply the patentable subject matter requirement against software and business method patents with increasing rigor.[28]

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[24] Recent developments in patent law suggest that courts in patentable subject matter cases, in particular, may have strayed from this policy. *See* Chiang, *supra* note 20, at 1873–85; *infra* notes 371–372 and accompanying text; *see also infra* notes 320–350 and accompanying text (analyzing the outcomes courts would likely have reached had those courts applied the completeness test proposed in this Article to patents at issue in various utility, written description, and patentable subject matter cases).

[25] *See, e.g.*, Dan L. Burk, *The Problem of Process in Biotechnology*, 43 HOUS. L. REV. 561, 581 (2006) (arguing that the Federal Circuit's attempts to distinguish unpatentable biochemical research tools from other, patentable research tools, such as scientific instruments, are not persuasive); *see also infra* notes 201–227 and accompanying text (addressing related arguments in greater detail).

[26] *See* Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905, 908 (explaining that "broad functional claiming of software inventions" has enabled patentees to "effectively capture[] ownership not of what they built, but of anything that achieves the same goal, no matter how different it is"). To be sure, courts have also allowed some upstream patents in the biomedical fields. *See infra* notes 253, 341 and accompanying text.

[27] In particular, it has been argued that courts have not applied the written description requirement in a rigorous way to software-type inventions. *See, e.g.*, Lemley, *supra* note 26, at 925 n.86.

[28] *See, e.g.*, *Alice*, 134 S. Ct. at 2351–52 (holding unpatentable "a computer-implemented scheme" for managing financial risk); Ultramercial, Inc. v. Hulu, LLC, 772 F.3d 709, 712 (Fed. Cir. 2014) (holding unpatentable "a method for distributing copyrighted media products over the Internet"); Digitech Image Techs., LLC v. Elecs. for Imaging, Inc., 758 F.3d 1344, 1347 (Fed. Cir. 2014) (holding unpatentable "a method for creating a device profile within a digital image processing system"); Walker Digital, LLC v. Google, Inc., No. 11-318-LPS, 2014 WL 4365245, at *2, *11–12 (D. Del. Sept. 3, 2014) (holding unpatentable a software method and system for matching potential employees with employers). The fact that courts have invalidated functionally drafted biotechnology claims under the written description requirement, but have recently invalidated software and business method claims exhibiting similar flaws under a different requirement, further points to the ad hoc, siloed nature of the completeness case law. *Cf.* Kevin Emerson Collins, *An Initial Comment on* Ariad*: Written Description and the Baseline of Patent Protection for*

To be sure, technology-specific standards in patent law are sometimes justifiable.[29] And patents on research inputs may crop up with greater frequency, or may be particularly pernicious, in some areas of technology relative to others. It may also be the case that, in certain fields, it is easier to tell when a patent claim is directed to a "bottleneck" invention, and should therefore be a target for invalidation or rejection.[30] Nevertheless, utilitarian concerns about undue preemption of downstream research should apply to all foundational inventions,[31] no matter the field.[32] In line with this goal, the

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After-Arising Technology, 2010 PATENTLY-O PATENT L.J. 60, 62, *available at* http://patentlyo.com/media/docs/2010/04/collins.ariad.pdf, *archived at* http://perma.cc/5YV9-6DA5 ("[W]ritten description may impose restrictions on claims in biotechnology to which claims in other technological sectors are already subject under a different patent doctrine."). A further complicating factor in this area is that the *scope* (rather than validity) of functionally drafted software claims might be limited if they are treated as so-called means-plus-function claims. *See* Collins, *supra*, at 68–71; *see also* 35 U.S.C. § 112(f) (2012) (defining means-plus-function claims). In practice, however, courts rarely apply the means-plus-function doctrine. *See* Lemley, *supra* note 26, at 907–08 ("Both because of the nature of computer programming and because of the way the means-plus-function claim rules have been interpreted by the Federal Circuit, those patentees have been able to write those broad functional claims without being subject to the limitations of Section 112(f).").

[29] *See* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 95 (2009) (encouraging courts to "build industry-sensitive policy analysis into their decisions" and "take account of the technology-specific nature of the patent system"). *See generally* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002) (exploring how patent law is often technology-specific in application and proposing reforms to optimize rules for particular industries).

[30] The difference in the treatment of chemistry and biotechnology versus software inventions has sometimes been justified on the basis that the former are "unpredictable arts," but that doctrine seems to provide only a partial answer. *See infra* notes 156–157 and accompanying text; *cf.* Sean B. Seymore, *Foresight Bias in Patent Law*, 90 NOTRE DAME L. REV 1105, 1111–14 (2015) (arguing that decisionmakers sometimes deny patent protection to meritorious inventions in the chemical field based on false assumptions or generalizations).

[31] *See* LANDES & POSNER, *supra* note 19, at 306–08; SHAVELL, *supra* note 19, at 165; Devlin, *supra* note 19, at 1717; *see also* Dan L. Burk, *The Curious Incident of the Supreme Court in* Myriad Genetics, 90 NOTRE DAME L. REV. 505, 535 (2014) (discussing "the policy of maintaining fundamental access"). *But cf.* Chiang, *supra* note 20, at 1873–85 (maintaining that moral considerations play a significant role in patentable subject matter cases and challenging the view that courts in these cases focus exclusively on utilitarian concerns).

[32] *Cf.* Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1327 (Fed. Cir. 2004) (Dyk, J., concurring in the order denying rehearing en banc) ("In my view we have yet to articulate satisfactory standards [for enforcing the written description requirement] that can be applied to all technologies."); *id.* (Linn, J., dissenting from the order denying rehearing en banc) ("The burden of [the Federal Circuit's written description cases] has fallen on the biotech industry disproportionately . . . ."); Christopher M. Holman, *Is* Lilly *Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of* Eli Lilly *and Its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1, 4 (2007) (describing the written description requirement as "a 'super-enablement' requirement specifically targeting biotechnology and substantially restricting the patentability of biotechnology-related inventions"); Seymore, *supra* note 30, at 1112 (arguing that the utility requirement reflects a bias against chemical inventions).

completeness framework might encourage broad scrutiny of attempts to patent upstream inventions and, at the same time, help courts establish limiting principles to avoid sweeping into the bin of invalidity patents that pose no threat to downstream research.[33]

Additionally, recognizing that completeness concerns underlie three seemingly disparate lines of doctrine can pave the way to increased judicial legitimacy and transparency.[34] The cases that I have placed under the completeness rubric have all been quite controversial, and have drawn a firestorm of academic (and judicial) criticism.[35] Indeed, scholars have argued

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[33] Even Burk and Lemley, who support the idea of technology specificity, argue that courts have the tests wrong. *See* Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 735 (2004) (presented at Symposium, *The Past, Present and Future of the Federal Circuit*, 54 CASE W. RES. L. REV. 669 (2004)) (arguing that the Federal Circuit's approach is "not optimal from the perspective of economic policy"). *Cf. generally* R. Polk Wagner, *Exactly Backwards: Exceptionalism and the Federal Circuit*, 54 CASE W. RES. L. REV. 749 (2004) (criticizing the Burk-Lemley thesis); R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341 (2003) (same).

[34] *Cf.* Kevin Emerson Collins, *The Knowledge/Embodiment Dichotomy*, 47 U.C. DAVIS L. REV. 1279, 1348 (2014) (arguing that "conceptual coherence and doctrinal transparency—that is, having the PTO and the courts mean what they say and say what they mean—create social value").

[35] For some scholarly critiques of the utility requirement, see Seymore, *supra* note 30, at 1124–26; Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1077 (2014); Samantha A. Jameson, Note, *The Problems of the Utility Analysis in* Fisher *and Its Associated Policy Implications and Flaws*, 56 DUKE L.J. 311, 322–33 (2006); *see also* Joshua D. Sarnoff & Christopher M. Holman, *Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents*, 23 BERKELEY TECH. L.J. 1299, 1339–40 (2008) (describing the role of the utility standard). For some scholarly critiques of the written description requirement, see Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 161–63 (2006); Holman, *supra* note 32, at 17–20; Mark D. Janis, *On Courts Herding Cats: Contending with the "Written Description" Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH. U. J.L. & POL'Y 55, 62–88 (2000); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 633–49 (1998); Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209, 222–26 (1998). For some scholarly critiques of the patentable subject matter requirement, see Bernard Chao, *Moderating* Mayo, 107 NW. U. L. REV. 423, 426–27, 433–36 (2012); Joshua Kresh, *Patent Eligibility After* Mayo*: How Did We Get Here and Where Do We Go?*, 22 FED. CIR. B.J. 521, 522 (2013); Mark A. Lemley et al., *Life After* Bilski, 63 STAN. L. REV. 1315, 1322–25, 1338–39 (2011); Katherine J. Strandburg, *Much Ado About Preemption*, 50 HOUS. L. REV. 563, 566–67 (2012); Allen K. Yu, *Within Subject Matter Eligibility—A Disease and a Cure*, 84 S. CAL. L. REV. 387, 417–26 (2011). For judicial critiques of the utility requirement, see *In re* Fisher, 421 F.3d 1365, 1380 (Fed. Cir. 2005) (Rader, J., dissenting); *In re* Kirk, 376 F.2d 936, 957 (C.C.P.A. 1967) (Rich, J., dissenting). For written description, see *Ariad*, 598 F.3d at 1361 (Rader, J., dissenting); *Univ. of Rochester*, 375 F.3d at 1307, 1315–21 (Rader, J., dissenting from the order denying rehearing en banc) (criticizing the Federal Circuit's written description requirement and collecting articles critical of the requirement). For patentable subject matter, see CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1297, 1303–05 (Fed. Cir. 2013) (en banc) (Rader, C.J., concurring in part and dissenting in part), *aff'd*, 134 S. Ct. 2347 (2014); *In re* Bilski, 545 F.3d 943, 977–78 (Fed.

that some utility, written description, and patentable subject matter cases reflect judicial subjectivity[36]—or even bias.[37] Moreover, certain completeness cases have been described not merely as wrong—itself a serious charge given that the cases are intended to serve an important policy—but as unprincipled.[38] Understanding the rationales underlying these cases and, where necessary, adjusting the legal rules to better reflect the rationales might help answer these critiques and provide more satisfactory solutions to the problem of patenting of basic research.

Indeed, recognizing completeness as a unified requirement of patentability might point to needed reforms in patent law. For example, decisionmakers can codify the completeness requirement to help bring it into line with the core policy aim of limiting undue preemption of downstream research. Codification would replace and streamline the multiplicity of problematic tests that courts have developed under the completeness requirement's doctrinally siloed enforcement.[39] Although courts can, in principle, improve the functioning of the completeness requirement under the existing conditions of patentability, a statutory fix may be needed because

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Cir. 2008) (en banc) (Newman, J., dissenting), *aff'd on other grounds sub nom.* Bilski v. Kappos, 561 U.S. 593 (2010).

[36] *See, e.g.*, Kresh, *supra* note 35, at 540 ("Throughout the decades, courts have struggled with handling patent claims that they disliked. Many times they have looked to the exceptions to § 101, in particular 'abstract ideas' and 'products of nature,' to eliminate claims of which they disapproved."); Max Stul Oppenheimer, *Patents 101: Patentable Subject Matter and Separation of Powers*, 15 VAND. J. ENT. & TECH. L. 1, 5 (2012) (noting the "lack of a consistent judicial theory supporting [courts'] exceptions" to categories of patentable subject matter under § 101); Pitlick, *supra* note 35, at 222–26 (criticizing the Federal Circuit for taking written description "jurisprudence in an unjustifiably new and reckless direction"); Seymore, *supra* note 35, at 1077 (arguing that the utility requirement is arbitrary); Allen K. Yu, *The En Banc Federal Circuit's Written Description Requirement: Time for the Supreme Court to Reverse Again?*, 33 CARDOZO L. REV. 895, 913 (2012) (arguing that the written description doctrine allows courts "to strike down ad hoc, without standard, and as a matter of law claims [they] do not like").

[37] *See, e.g.*, Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959, 961 (1986) (arguing that the Supreme Court's holding "that mathematical algorithms could not be patented[] was poorly reasoned and stemmed from . . . judicial bias"); Seymore, *supra* note 30, at 1133 (arguing that foresight bias drives courts to apply heightened patentability requirements to chemical inventions).

[38] *See, e.g.*, Pitlick, *supra* note 35, at 223 (arguing that in its written description cases, the Federal Circuit took its "jurisprudence in an unjustifiably new and reckless direction, freed of any constraints of *stare decisis*"); *see also supra* notes 35–37 and accompanying text (observing that some critics have argued that completeness cases reflect judicial subjectivity or bias).

[39] *See infra* notes 197–266 and accompanying text (surveying the inconsistencies and other problems associated with the three disparate completeness doctrines); *cf.* Collins, *supra* note 28, at 71 (arguing that it is "clearly impossible to understand the written description doctrine without understanding the baseline of protection for after-arising technology provided by other patent doctrines"); Anna B. Laakmann, *An Explicit Policy Lever for Patent Scope*, 19 MICH. TELECOMM. & TECH. L. REV. 43, 60 (2012) (discussing the problems with "perceiv[ing] each of the statutory requirements as a distinct silo").

the historical and doctrinal baggage that comes with established provisions could make this difficult.[40] Much like the requirement of nonobviousness—initially a judge-made doctrine that underwent codification and a course correction in the Patent Act of 1952—completeness could benefit from codification and course correction today after years of judicial experimentation.[41] Although imminent congressional intervention of this sort might seem unlikely in today's political climate, the state of affairs might change if recent judicial developments in this area of patent law lead to widespread dissatisfaction.[42]

One possible statutory solution is a rule barring all patent claims directed to objects of basic research.[43] Although basic research has proven difficult to define, work in the field of science studies provides one possible framework.[44] For example, one scholar characterizes the generality of an invention's applications and the unpredictability associated with downstream research directions that an invention might open up as hallmarks of basic research.[45] Guided by these considerations, a test for implementing the completeness requirement might ask whether the claim at issue is directed primarily to an invention that sets the foundation for future research and development, and whether the claim has the potential to cover many unforeseeable, transformative applications. Although this test would add administrative costs associated with these factual inquiries, it would also yield significant benefits.[46]

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[40] *See infra* notes 351–378 and accompanying text. Scholars have proposed other improvements to some doctrines underlying completeness—particularly patentable subject matter—short of a statutory solution. *See, e.g.*, Lemley et al., *supra* note 35, at 1337–46; Yu, *supra* note 35, at 427–40.

[41] *See* Graham v. John Deere Co., 383 U.S. 1, 3–4, 12–13 (1966) (discussing the judicial origins of the nonobviousness requirement). For example, the language "[p]atentability shall not be negated by the manner in which the invention was made" contained in § 103—the nonobviousness requirement as codified in the 1952 Patent Act—was intended to abrogate "the flash of creative genius" (also known simply as "flash of genius") test set forth in *Cuno Engineering Corp. v. Automatic Devices Corp.* and other similar tests. *See* 35 U.S.C. § 103 (2012); 314 U.S. 84, 91 (1941); Giles S. Rich, *Why and How Section 103 Came to Be*, 14 FED. CIR. B.J. 181, 188 (2004). *But see Graham*, 383 U.S. at 15 n.7 (stating that the "flash of creative genius" statement was only "a rhetorical embellishment"). I thank Rochelle Dreyfuss for drawing this analogy to my attention.

[42] *See infra* notes 371–372 and accompanying text.

[43] *See infra* notes 375–378 and accompanying text (setting forth the proposed statutory framework).

[44] *See* Jane Calvert, *What's Special About Basic Research?*, 31 SCI. TECH. & HUMAN VALUES 199, 203–05 (2006).

[45] *See id.* at 204 ("The most common epistemological features [scientists and policymakers] associate[] with basic research [are] unpredictability . . . and generality.").

[46] These benefits include withholding patents only from inventions that harm downstream innovation, and improving transparency and legitimacy of the completeness requirement relative to its current implementation. *See supra* notes 24–38 and accompanying text; *cf.* Donald S. Chi-

Another, more ambitious proposal for reform stemming from the recognition of the completeness requirement involves the establishment of a partial or intermediate patent right for inventions that satisfy the extant requirements of patentability, but fail completeness.[47] Instead of barring intellectual property protection for such inventions entirely, this secondary proposal would provide for a narrower set of rights—for example, a limited patent that comes only with the remedy of a compulsory license. Indeed, if the concern is that owners of upstream patents wield an *undue* amount of preemption, then the logical solution is to weaken the available remedy until the patentee receives the preemption that is *due*—or, at the very least, obtains something less that the amount of preemption that comes with a full patent right.[48] Thus, even if utilitarian considerations suggest that upstream inventions should not be given full patent protection,[49] partial patent protection might be justifiable on these grounds.

The U.S. Patent and Trademark Office ("PTO"), however, currently lacks the power to grant patents that come with a limited remedy. For a given claim, the PTO has only two choices: grant the full patent right, or no right at all.[50] But a statutory fix could enable the PTO to confer an intermediate patent right on certain inventions. A partial patent solution to protect inventions that meet the standard conditions of patentability, but fail the requirement of completeness, would thus mitigate the patent system's "uniformity costs" with regard to upstream patents.[51] This Article explores pos-

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sum, *Weeds and Seeds in the Supreme Court's Business Method Patents Decision: New Directions for Regulating Patent Scope*, 15 LEWIS & CLARK L. REV. 11, 11–12, 14–15 (2011) (proposing that the Court replace its "Section 101 abstract idea preemption" test with two fact-intensive inquiries into patentable subject matter in order to achieve more consistent, predictable outcomes).

[47] *See infra* notes 418–436 and accompanying text (describing the features of the proposed limited patent right).

[48] Complete absence of patent protection for upstream inventions may deter investment in important technologies and reduce the volume of valuable disclosures. *See infra* notes 382–400 and accompanying text. In other words, the right amount of patent preemption for upstream inventions is unlikely to be zero in most circumstances.

[49] *See* Joshua D. Sarnoff, *Patent-Eligible Inventions After* Bilski*: History and Theory*, 63 HASTINGS L.J. 53, 106–24 (2011); *supra* note 19 and accompanying text.

[50] Although courts have the power to tailor *remedies* by granting or denying injunctions and by modulating the amount of damages, courts have less flexibility with respect to patent *validity* because they can only uphold or invalidate patent claims. *See* 35 U.S.C. § 282(b)(2) (2012) (providing that patent invalidity is a defense to a suit for patent infringement); *id.* §§ 283–284 (authorizing courts to award injunctions and damages in patent infringement cases). And the costs associated with a court determining the extent of the infringer's liability ex post are high. *See infra* notes 409–414 and accompanying text.

[51] The lack of intermediate solutions in patent law gives rise to so-called "uniformity costs." *See* Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845, 871–74 (2006). The uniformity costs this Article focuses on are the

sible forms that a limited patent right might take so as to provide the intellectual property incentives that are likely needed to develop and commercialize upstream inventions, while helping decrease the potential for stifling downstream innovation associated with full patent protection.

Part I of this Article defines upstream inventions and sets forth judicial and scholarly concerns with allowing patents on such inventions.[52] Part II then explains how the law currently deals with some of these inventions.[53] This Part shows that certain cases invoking utility, written description, and patentable subject matter requirements work together to create a de facto requirement of completeness. Part III canvasses critiques of the completeness cases and explains that these cases do not consistently implement the policy that motivates the requirement.[54] Part IV proposes and justifies a test that addresses these critiques, and discusses the mechanics of putting the proposed form of the completeness requirement into effect, including its possible codification.[55] This Part also puts the new form of the completeness requirement into practice, testing how actual and hypothetical patent claims might fare under the proposed test. Finally, Part V explores whether patent protection is needed to incentivize the creation of inventions that would be unpatentable for failure to comply with the proposed form of the completeness requirement.[56] This Part provides suggestions for the structure of a partial patent right to protect such inventions, and discusses advantages and disadvantages of the proposal.[57]

I. UPSTREAM INVENTIONS: WHAT THEY ARE AND WHY THEIR PATENTING IS PROBLEMATIC

Section A of this Part defines upstream inventions and categorizes them into three groups: research aids, so-called "research-plan" inventions, and inventions directed to laws of nature, natural phenomena, or abstract ideas.[58] Section B explains that allowing patents on all three types of inventions has the potential to impose intolerable costs on downstream researchers and stifle future innovation.[59] Abandoning existing doctrinal barriers

costs arising from the fact that patent law lacks ex ante mechanisms for modulating remedies for successful enforcement of a patent claim based on the nature of the underlying invention.

[52] *See infra* notes 58–125 and accompanying text.

[53] *See infra* notes 126–196 and accompanying text.

[54] *See infra* notes 197–266 and accompanying text.

[55] *See infra* notes 267–378 and accompanying text.

[56] *See infra* notes 379–400 and accompanying text.

[57] *See infra* notes 402–460 and accompanying text.

[58] *See infra* notes 60–95 and accompanying text.

[59] *See infra* notes 96–125 and accompanying text.

and replacing them with a unified completeness requirement would help bring into focus the policy aim of limiting potentially harmful upstream patents.

A. Categories of Upstream Inventions

"Upstreamness," for lack of a better word, has eluded a clear definition.[60] Nevertheless, several themes emerge from the cases and literature. The three examples discussed in the Introduction represent three forms of inventions that courts have held to be too upstream to be patentable.[61] They can be loosely categorized as research aids, research-plan inventions, and inventions belonging to the categories of laws of nature, natural phenomena, or abstract ideas. Patent claims to all three types of inventions have engendered undue preemption concerns because they threaten to block too many downstream research pathways. All three types of inventions are potential targets of the completeness requirement.

Inventions in the first category include materials, objects, and methods whose main function is to promote further research.[62] Courts and commentators have termed these inventions "research tools"[63] or "research interme-

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[60] *See* Chris Holman, *Clearing a Path Through the Patent Thicket*, 125 CELL 629, 629 (2006) (defining upstream patents as "patents that claim technologies associated with basic and early stage research and development, as opposed to patents covering 'downstream' commercial products"); David B. Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?*, 3 J. PHIL. SCI. & LAW, Jan. 2003, at n.22, *available at* http://jpsl.org/archives/biotechnology-patent-pool-idea-whose-time-has-come, *archived at* http://perma.cc/8UMR-2WY8 ("A patent is an upstream patent if it is vital to the development of many other inventions. For example, a type of miniaturized transistor would be an upstream invention and a computer chip would be a downstream product, if the transistor plays a vital role in the computer chip. However, the same computer chip might be an upstream invention relative to a device that uses the chip, such as cellular phone.").

[61] *See supra* notes 1–15 and accompanying text.

[62] *See* Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 123 ("[A] research tool is an invention the primary function of which is to facilitate scientific or technological progress.").

[63] *See* Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 10–17 (2001) (attempting to define "research tools"); Sarnoff & Holman, *supra* note 35, at 1302–03 (same); Strandburg, *supra* note 62, at 123 (same). *But see* F. Scott Kieff, *Coordination, Property, and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 EMORY L.J. 327, 409–10 (2006) ("[A]ll players in the market realize over time that terms like 'upstream' and 'downstream' are so relative that they simply may be synonyms for 'things to be bought' and 'things to be sold' by any private party able to gain the agency's attention."); Mueller, *supra*, at 10 ("'Research tools' is a phrase of many meanings depending on perspective."). Judges also disagree on the meaning of "research tools." *See, e.g.*, Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part) ("My colleagues on this panel appear to view the [patents-in-suit] as for a 're-

diates."[64] Chemical compounds not having a known consumer end use, and methods of making such compounds, fall into this general category.[65] Even though these chemicals have no use to the ordinary consumer, they often draw the interest of researchers—for example, as potential drug candidates or as building blocks for making larger molecules. Isolated human embryonic stem cells exemplify another research tool invention known for its broad applicability.[66]

Still another group of inventions commonly thought of as belonging to the research tool category relates to methods of manipulating genetic material.[67] One such technique, called the polymerase chain reaction ("PCR"), enables the preparation of a large quantity of DNA—a molecule that encodes genetic information—from a small sample.[68] This technique has numerous applications ranging from paternity testing to the diagnosis of cancers and detection of viruses.

It is important to note, however, that the universe of research tools and intermediates is not limited to biological and chemical materials and methods of making such materials. Consider, for example, the atomic force microscope, which is a device that enables the observation of very small objects at high resolutions.[69] The atomic force microscope is viewed as a building-block technology that can serve as an input into many areas of downstream research, such as nanotechnology.[70]

The second category of upstream inventions has been variously characterized as a "wish," a "research plan," or "a hypothesis."[71] Like research

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search tool.' That is a misdefinition. The [patented molecules] are not a 'tool' used in research, but simply new compositions having certain biological properties."), *vacated*, 545 U.S. 193 (2005).

[64] *See In re Fisher*, 421 F.3d at 1373 (classifying as "research intermediates" a group of chemical compounds made from the same building blocks as DNA); *see also infra* notes 209–217 and accompanying text (exploring the differences between research intermediates and research tools).

[65] *See supra* notes 1, 11–12 and accompanying text.

[66] *See* Peter Yun-hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on Biotechnology Research Tools*, 19 HARV. J.L. & TECH. 79, 82, 106–08 (2005); Mueller, *supra* note 63, at 13–14.

[67] *See* Mueller, *supra* note 63, at 13.

[68] *See id.* at 13 nn.56–57 (describing the PCR process and patents on PCR methods).

[69] *See* G. Binnig et al., *Atomic Force Microscope*, 56 PHYSICAL REV. LETTERS 930, 930–33 (1986).

[70] *See* Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 613–14 (2005) (describing atomic force microscopes as "basic building blocks in nanotechnology"); *cf. In re Fisher*, 421 F.3d at 1380 (Rader, J., dissenting) (arguing that microscopes generally are research tools that "take a researcher one step closer to identifying and understanding a previously unknown and invisible structure").

[71] *See* Michael P. Sandonato & Feng Xu, *Describing Written Description: The Implications of* Ariad, CHINA IP MAG., June 2010, at 73, 75 ("[T]he patent law is directed to the 'useful Arts,' not to research hypothesis, [sic] academic theories or scientific principles.").

tools and intermediates, research-plan inventions often fail to offer an end product from which a non-researcher end user can derive a direct benefit.[72] One upstream invention of this sort is a method of treating a health condition based on a newly identified biological target of drug action.[73] Although the discoverers of the target developed and described search methods for drugs that would treat the condition, they did not provide any examples of drugs having the capacity to do so.[74] Hence, it might be said that the inventors hypothesized a method of treatment, but never completed the invention.

Like research tools, research-plan inventions are not limited to the fields of chemistry and biochemistry because fundamental research must logically occur in some form in all areas of technology. Consider, for example, the Wright brothers' famous invention. The Wrights' key insight was that one could achieve controlled flight by modulating motion along all three axes of rotation about a flying machine's center of mass.[75] Had the Wrights not described how to build a plane, and instead only provided a roadmap for doing so using so-called "three-axis control," one could argue that they had at best come up with a research plan, or put forth a hypothesis,

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[72] *See* Joseph Jakas, Comment, *Encouraging Further Innovation:* Ariad v. Eli Lilly *and the Written Description Requirement*, 42 SETON HALL L. REV. 1287, 1325 (2012). In some cases, broad patent claims containing functional language can fail the written description requirement even when applicants disclose some (but not enough) examples of chemical structures. *See* Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1364–67 (Fed. Cir. 2011).

[73] *See supra* notes 2–4, 13 and accompanying text. Some courts and commentators argue that the subject matter covered by this claim should not even be considered an "invention" in view of the absence of disclosures of chemical structures in the specification. *See Univ. of Rochester*, 358 F.3d at 930 n.10; Oskar Liivak, *Rescuing the Invention from the Cult of the Claim*, 42 SETON HALL L. REV. 1, 5 (2012) (arguing that "the invention is not simply a shorthand reference for the claimed subject matter," but rather "the set of embodiments conceived and disclosed by the inventor in enough detail that they can be reduced to practice").

[74] *See Univ. of Rochester*, 358 F.3d at 929. Instead of patenting the method of treatment, the inventor could have patented only the search method for finding drugs that act on the target. But because researchers could easily design around that sort of a patent claim, it would likely not be valuable. Although the knowledge of the drug target *is* extremely important for future research, that invention is difficult to monetize unless the patent actually covers drug products. *See* Michael Delmas Plimier, Case Note, Genentech, Inc. v. Novo Nordisk *&* University of California v. Eli Lilly and Co., 13 BERKELEY TECH. L.J. 149, 161 (1998); *see also infra* note 387 and accompanying text (discussing why narrow patent claims often have little commercial value).

[75] *See What Did the Wright Brothers Invent?*, WRIGHT BROS. AEROPLANE CO. 2, http://www.wrightbrothers.org/Information_Desk/Help_with_Homework/Help_with_Homework_Intro/What%20did%20the%20Wright%20brothers%20invent.pdf, *archived at* http://perma.cc/VPP3-6Z95 (last visited Mar. 27, 2015) ("The Wrights never claimed to have invented the airplane, or even the first airplane to fly. In their own words, they made the first sustained, powered, *controlled* flights."). Nevertheless, the Wright brothers' patent was titled "Flying-Machine" and some of the claims were directed to "[a] flying-machine." *See* U.S. Patent No. 821,393 claims 14–15 (filed Mar. 23, 1903).

for achieving controlled flight using this method.[76] A more modern version of what could be described as a hypothesis-type invention is a functionally claimed software or business method patent. The concern is related: some software and business method claims appear only to identify (and appropriate) the problem to be solved rather than propose any specific way of implementing a solution.[77]

The third category of upstream inventions relates to the workings of the natural world and other fundamental principles. Commentators and courts have denominated such inventions "law[s]"[78] or "product[s]"[79] of nature, "natural phenomena,"[80] "scientific truth[s],"[81] "concept[s],"[82] "abstract ideas,"[83] "formula[s],"[84] or by some other similar label.[85] This facet of upstreamness has a rich historical pedigree, harkening back to the distinction

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[76] Assuming the 1903 Wright Flyer was the embodiment of the '393 Patent, there is evidence that the Wright brothers' patent, rather than describe an actual flying machine, only provided a roadmap for how to build one because the Wrights' own implementation of the three-axis principle did not operate well. *See* MALCOLM J. ABZUG & E. EUGENE LARRABEE, AIRPLANE STABILITY AND CONTROL: A HISTORY OF THE TECHNOLOGIES THAT MADE AVIATION POSSIBLE 3 (2d ed. 2002) ("Modern analysis . . . has demonstrated that the 1903 Wright Flyer was so unstable as to be almost unmanageable by anyone but the Wrights . . . ."). But unlike the method of treatment patent at issue in *University of Rochester*, which did not describe a specific drug, the Wright brothers' patent at least provided a proof of principle that some kind of a flying machine *could* be built using three-axis control. *Compare Univ. of Rochester*, 358 F.3d at 929 ("[T]he '850 patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods . . . ."), *with* '393 Patent p. 3 col. 2 ll. 108–09 (providing the means for "restor[ing] the lateral balance of the machine").

[77] *See* Lemley, *supra* note 26, at 923 ("[T]he patentee claims the end it accomplishes, not the means of getting there. The presence of a nominal hardware limitation serves to obscure the fact that the real structure doing the work—the computer program—is absent."); *see also* Letter from Michael Risch, Professor, Villanova Law Sch., to the U.S. Patent & Trademark Office (Mar. 12, 2013) (available at http://www.uspto.gov/patents/law/comments/sw-f_risch_20130312.pdf, *archived at* http://perma.cc/SBZ3-4ABP) (noting that § 112 "allows patentees to own the *solution*" to an algorithm without "disclos[ing] how they actually solved [the] problem" (emphasis added)). *See generally* Kevin Emerson Collins, *Patent Law's Functionality Malfunction and the Problem of Overbroad, Functional Software Patents*, 90 WASH. U. L. REV. 1399 (2013) (identifying root causes behind patent law's failure to curtail software-patent overbreadth and proposing software-specific solutions). For one example of such a claim, see *infra* note 336.

[78] *See Myriad*, 133 S. Ct. at 2117.

[79] *See id.* at 2111.

[80] *See Mayo*, 132 S. Ct. at 1293.

[81] *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (quoting Mackay Co. v. Radio Corp., 306 U.S. 86, 94 (1939)).

[82] *See* Bilski, 561 U.S. at 609.

[83] *See id.* at 608.

[84] *See* Diamond v. Diehr, 450 U.S. 175, 191 (1981).

[85] *See* Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1852) ("[A] principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."); Sarnoff & Holman, *supra* note 35, at 1340–43; Yu, *supra* note 35, at 423–24.

between patentable "industrial property" and unpatentable "scientific property" in the early international patent regimes.[86] In this vein, the Supreme Court described as directed to laws of nature patent claims "tell[ing] doctors to gather data" about the concentration of a probe molecule present in the patient's blood "from which they may draw an inference" of a need to increase the dosage of a drug.[87] Assuming the Court's analysis was correct, it is difficult to think of a stronger example of a claim to a discovery at "the beginning of the development chain" than a claim to a law of nature.[88] Other examples in this general category include inventions as diverse as isolated human genetic material,[89] a method of communicating at a distance using electromagnetism,[90] a method of data processing,[91] and the concept of risk hedging.[92] Upstream inventions of the "fundamental principle" kind, like upstream inventions of the research tool and research plan variety, can come from many areas of technology.

This list is not meant to be exhaustive, and boundaries between the categories are not sharp. Perhaps, some inventions in the second category really belong in the third category—or in both. For example, one scholar argues that a patent adjudged by the Federal Circuit to be directed to a research-plan invention in fact "ties up a natural phenomenon," which fairly places it into the third category as well.[93] And it could also be that at least some inventions in the first category belong in the third category.[94] As Sec-

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[86] *See* Thomas R. Ilosvay, *Scientific Property*, 2 AM. J. COMP. L. 178, 178–80 (1953); Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, 13 SOC. PHIL. & POL'Y 145, 152–57 (1996). *See generally* C.J. HAMSON, PATENT RIGHTS FOR SCIENTIFIC DISCOVERIES (1930) (detailing European proposals for limited patents on "scientific property," which eventually failed).

[87] *See Mayo*, 132 S. Ct. at 1298; *see also supra* notes 5–8, 14–15 and accompanying text (discussing the Court's reasoning in *Mayo*).

[88] *See* Lee, *supra* note 66, at 81.

[89] *See Myriad*, 133 S. Ct. at 2117.

[90] *See* O'Reilly v. Morse, 56 U.S. (15 How.) 62, 112–13 (1853).

[91] *See Benson*, 409 U.S. at 64.

[92] *See Bilski*, 561 U.S. at 611–12.

[93] ROBIN FELDMAN, RETHINKING PATENT LAW 100 (2012); *see id.* at 122 ("[B]y trying to control anything related to a pathway in the human body, the invention [at issue in *Ariad*] preempts a broad area of human genetics and essentially tries to occupy that entire phenomenon.").

[94] Peter Lee describes isolated human embryonic stem cells as "research tools," yet Allen Yu argues that they are also like natural phenomena because they "faithfully preserve the pluripotent properties of stem cells as found in nature." *See* Lee, *supra* note 66, at 82; Yu, *supra* note 35, at 433. And, at least in Yu's own proposals for limiting the patentability of stem cells, the categorization does not end up mattering. *See* Yu, *supra* note 35, at 428–33. If they are to be classified as "research tools," they would probably be unpatentable under his framework as "basic tools of scientific and technological work." *See id.* at 428 (quoting *Benson*, 409 U.S. at 67). And if they

tion B further explains, however, the issues with patents on all basic research-type inventions—whatever category they fall into—are more or less the same.[95]

B. Overarching Problems with Patents on Upstream Inventions

Patenting of inventions described in Section A of this Part can be socially harmful because of the underlying inventions' foundational roles in enabling further research.[96] Indeed, scholars have maintained that certain upstream patents have the potential to impose intolerable costs on downstream inventors.[97] For example, the concern behind allowing a patent on a chemical compound without an identified consumer utility is that subsequent researchers who discover such a use—for example, biological activity against cancer cells—will be beholden to the owner of the patent on the compounds.[98] The patentee might threaten litigation to enjoin downstream research, charge an unreasonable royalty, or tie up the follow-on researcher in extensive, costly negotiations over the patent right.[99] Faced with this prospect, the follow-on researcher might forgo investigating a certain chemical structure during the life of the patent, and society would then lose out on

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are viewed as "natural phenomena," they would probably be unpatentable (again, under one of Yu's proposals) as "discoveries" rather than "inventions." *See id.* at 431–33.

[95] *See infra* notes 96–116 and accompanying text.

[96] In other words, such patents are harmful because they protect artifacts of basic research.

[97] *See, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1046–66 (1989); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 217–26 (1987) [hereinafter Eisenberg, *Proprietary Rights*]; Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698–700 (1998); Rai, *supra* note 21, at 116–20; Richard Li-dar Wang, *Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties*, 10 YALE J.L. & TECH. 251, 258–61 (2008); Yu, *supra* note 35, at 428 (discussing the "cost side of patenting").

[98] *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 253–56 (6th ed. 2013) (explaining that patents on inventions "with largely unknown uses may trigger precisely the sort of inefficient 'gold rush' that we want to avoid"); Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 778–83 (2000) ("[L]arge pharmaceutical and genomics firms are likely to use all of the EST patents they have to extract as high a price as possible from licensees.").

[99] For a general articulation of this argument (beyond upstream patents), see Robert P. Merges & Richard R. Nelson, *On Limiting or Encouraging Rivalry in Technical Progress: The Effect of Patent Scope Decisions*, 25 J. ECON. BEHAV. & ORG. 1, 18–20 (1994); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 908 (1990) [hereinafter Merges & Nelson, *Patent Scope*]; Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 122–29 (Adam B. Jaffe et al. eds., 2001).

promising drug candidates.[100] Scholars have made similar arguments about other research tool patents, like patents claiming human embryonic stem cells.[101] The upshot of the critiques is that "whereas most patents cover the *outputs* of scientific investigation, patents on research tools cover the *inputs* of that investigation."[102] This is problematic because "[a]llowing strict property rights over such research tools permits propertization near the beginning of the development chain and threatens to establish individual control over broad areas of scientific research."[103]

Analogous critiques have been leveled against research-plan patents in biotechnology,[104] functionally claimed software patents,[105] and patents on inventions that are characterized as fundamental principles.[106] In contrast with criticisms of patents on research tools and intermediates, concerns over patents on research plans and fundamental principles have often been articulated in terms of overbroad claim scope rather than in terms of the need for access.[107] But at a higher level of generality, the perceived problem with these types of upstream patents is fundamentally the same as that with patents on research tools—courts and scholars describe them as "bottlenecks" that are thought to stifle further innovation.[108] To prevent such unduly preemptive

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[100] *See* BURK & LEMLEY, *supra* note 29, at 111 ("[D]eveloping a new molecule without any particular use is not a completed innovation, but merely the opening stage of a long and complex research process. Permitting broad upstream patenting of such chemicals might discourage the downstream research necessary to find a market for those chemicals.").

[101] *See* Lee, *supra* note 66, at 82 (arguing that patents on isolated embryonic stem cells "disrupt the balance between freely available basic knowledge and privatized applied knowledge that is crucial to driving innovation").

[102] *See id.* at 81; *see also* Mueller, *supra* note 63, at 4 ("[T]he dispute stems from the broad rights conferred by the patents covering [PCR] tools.").

[103] *See* Lee, *supra* note 66, at 81.

[104] *See, e.g.*, Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1273 (2000).

[105] *See* Lemley, *supra* note 26, at 964 (arguing that allowing functional claims in the software field ignores the principle that "patents spur competition by preventing direct imitation while leaving open avenues for alternative development").

[106] *See* Devlin, *supra* note 19, at 1717 ("These fields of discovery bear unique potential for overcompensation, given their upstream nature and the concomitant proclivity for ubiquitous downstream application.").

[107] *See* Collins, *supra* note 77, at 1455–60 (describing cases in which courts used the written description doctrine to invalidate overbroad software claims); 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, 56–61 (2012) (describing the scope-policing role of the patentable subject matter requirement); Sampson, *supra* note 104, at 1261–65 (explaining that the written description doctrine plays a scope-policing function in the biotechnological arts).

[108] *See Mayo*, 132 S. Ct. at 1301 (addressing "a danger that the grant of patents that tie up [the use of basic tools of scientific and technological work] will inhibit future innovation premised

patents, commentators have either exhorted courts to apply the rules that prohibit them more stringently or praised them for already doing so.[109]

Although it is sometimes unclear what sorts of downstream applications a foundational invention might have, some critics of patents on such inventions find the uncertainty to be highly problematic in itself.[110] Consid-

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upon them"); *see also, e.g.*, Burk, *supra* note 31, at 535 (discussing "the policy of maintaining fundamental access"); Sarnoff, *supra* note 49, at 106 (endorsing categorical exclusions under the patentable subject matter requirement and arguing that the doctrine "direct[s] . . . innovation to activities that most need patent-system incentives while better protecting . . . ideas from encroachment" by the patent system); Jakas, *supra* note 72, at 1328 (arguing that by prohibiting biotechnology patents that do not describe "specific products that will actually have practical use when released to the public," patent law clears the path for "further research . . . without concerns about infringement"); Sampson, *supra* note 104, at 1269 (arguing that if the PTO allowed inventors to claim "genes, cDNAs, or mRNAs without fully disclosing the claimed nucleotide sequences," then inventors would "claim more then [sic] the inventions they possess"). *But cf.* Eisenberg, *supra* note 107, at 61–64 (arguing that "the 'basic tools' concept . . . fails to explain distinctions between patentable and excluded subject matter"); Yu, *supra* note 35, at 428–30 (arguing that prohibitions against patents on nature and abstract ideas fail to distinguish between patents that impede innovation and those that do not).

[109] For arguments regarding the role of the utility requirement in achieving this goal, see Cynthia D. Lopez-Beverage, *Should Congress Do Something About Upstream Clogging Caused by the Deficient Utility of Expressed Sequence Tag Patents?*, 10 J. TECH. L. & POL'Y 35, 87–90 (2005) (proposing a heightened utility requirement for patents on ESTs); Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 200 (2004) (arguing that "[h]eightening the utility requirement may make sense for ESTs with a minimal disclosed utility"); Teresa M. Summers, Note, *The Scope of Utility in the Twenty-First Century: New Guidelines for Gene-Related Patents*, 91 GEO. L.J. 475, 495 (2003) ("One cannot substitute or design around basic biotech research tools. . . . A broad utility requirement exasperates [sic] the tragedy of the anticommons because it grants rights to exclude basic research tools, which are the building blocks of a wide array of downstream innovation."). For arguments regarding the role of the written description requirement in achieving this goal, see Jakas, *supra* note 72, at 1325 ("[T]he [written description] requirement encourages inventors to finalize their inventions and pursue an end product before seeking patent protection . . . . [The] requirement seems to be a positive step towards limiting the problems associated with patents in the biotechnology industry."); Sampson, *supra* note 104, at 1268–71 (urging the PTO and courts to "continue to utilize a heightened written description requirement"). For arguments regarding the role of the patentable subject matter requirement in achieving this goal, see Yu, *supra* note 35, at 417–27; Note, *Diagnostic Method Patents and Harms to Follow-on Innovation*, 126 HARV. L. REV. 1370, 1371 (2013) (suggesting that "granting strong, early patent rights will result in the underdevelopment of technology").

[110] *See, e.g.*, *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intellectual Property of the H. Comm. on the Judiciary*, 106th Cong. 130, 135 (2000) (statement of Dr. Harold Varmus, President and Chief Executive Officer, Memorial Sloan-Kettering Cancer Center) ("[O]ver-valuing inventions, especially research tools, often engenders licensing policies that are unduly restrictive. . . . [O]nerous licensing provisions contain so-called reach-through provisions that would provide royalties from any downstream commercial products to those who own property in very early stages of development that may now be of uncertain value. . . . [P]otential licensees are frequently confronted with so-called 'reach-through' provisions that would provide royalties from any downstream commercial products to those who own property that may now be of *uncertain value and vague utility*." (emphasis added)); *cf.* Oskar Liivak,

er, for example, a patent on a research tool. If such a tool turns out to be highly valuable, the patentees might reap enormous benefits—likely out of proportion to their contribution—if they enter into so-called "reach-through" royalty agreements with downstream users.[111] Commentators fear that such licenses might permit the patent owner "to leverage its proprietary position in upstream research tools into a broad veto right over downstream research and product development."[112] Overbreadth and uncertainty concerns are closely related; indeed, some claims to inventions having uncertain applications are thought to be problematic mainly because of their potential to have overbroad coverage.[113] Thus, patents on upstream inventions might dominate and preempt entire fields of research,[114] cover unpredictable, transformative applications,[115] and massively over-reward their owners.[116]

Establishing an Island of Patent Sanity, 78 BROOK. L. REV. 1335, 1372 (2013) ("Without knowing the ultimate inventions that will flow from the intermediate result, the valuation of those intermediate results remains highly uncertain.").

[111] *See infra* note 405 and accompanying text. Such arrangements base the royalty on products that are made with the aid of the research tool, but are themselves outside the scope of the claims of the research tool patent. *See* Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 441 (2003) ("[S]ome patent holders have charged royalties measured as a percentage of the final product created through a process which included using the research tool. . . . [S]uch payments provide revenues from any downstream commercial products to those who own intellectual property that may now be of uncertain value or utility.").

[112] *See* Heller & Eisenberg, *supra* note 97, at 698–99; *see also* Strandburg, *supra* note 62, at 125 ("Patents on research tools for which no close substitutes are available are 'broad' in the sense that they give the patent holder exclusive control over the development of the research they facilitate and 'early' in the sense that they are granted before the research, which will presumably lead to some kind of commercially useful result, is performed.").

[113] But this is not always the case—the utility and patentable subject matter requirements can bar claims that are relatively narrow in scope. The problem with claims barred by the utility doctrine is not their breadth but the fact that the patent is directed to a research input having unknown end-use utility. *See infra* notes 129–147 and accompanying text. And it is not clear why, from a policy perspective, patentable subject matter cases sometimes bar narrow claims. *See infra* notes 243–258 and accompanying text.

[114] *See, e.g.*, *Mayo*, 132 S. Ct. at 1294 (reasoning that precedent "warn[s] us against upholding patents that claim processes that too broadly preempt the use of a natural law"); *Ariad*, 598 F.3d at 1353 ("[C]laims to research plans . . . impose costs on downstream research, discouraging later invention.").

[115] *See, e.g.*, *Benson*, 409 U.S. at 68 ("Here the 'process' claim is so abstract and sweeping as to cover both known and unknown uses of the [underlying algorithm].").

[116] *See, e.g.*, *Ariad*, 598 F.3d at 1353–54 ("[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" (quoting Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345 (Fed. Cir. 2000))). As argued by one commentator, upstream patents "would reward patentees excessively and would fail to keep their property rights commensurate with their real contribution to the society." Wang, *supra* note 97, at 267. A related argument about the costs of upstream patents entails the application of the anticommons theory to biotechnology. Generally, an anticommons problem arises when "multiple owners are each endowed with the right to exclude others from a scarce resource, and no one

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Although certain critiques are common to patents on all categories of upstream inventions, it does not necessarily follow that all such inventions should be subject to the same patentability requirements. For one thing, patent claims on research tools, research plans, and fundamental principles might look different from one another. A research tool claim might be drawn to a building-block chemical compound of a well-defined structure. A research-plan claim might be drawn to a method that can be implemented in a variety of different ways. And a fundamental principle claim might be drawn to a widely applicable natural law or a very general concept. These distinctions suggest that it is reasonable to apply different tests to the three types of upstream inventions. In fact, courts already appear to follow this approach; the doctrinal routes they use to invalidate the three types of claims loosely track the distinctions between research tool patents, so-called "hypothesis" patents, and patents on fundamental principles.[117] Nonetheless, in spite of the multiplicity of tests that courts use to probe patent validity when they apply the utility, written description, and patentable subject matter requirements, these cases can also be viewed as facets of the overarching requirement against the patenting of artifacts of basic research.[118]

There are substantial benefits to unifying the three lines of doctrine under the principle of completeness and adopting completeness as a standalone requirement of patentability. First, this approach may direct decisionmakers to reexamine the distinctions made within each line and improve upon the extant tests so as to focus on the core policy aim of limiting harmful upstream patents. Indeed, the fact that courts have invalidated patents on some upstream inventions discussed in the previous section (for example, chemical intermediates and methods of treatment based on a newly identified drug target) but not others (for example, stem cells and many software patents) suggests that the current approach may be inconsistent, and the tests inadequate.[119] The holistic completeness framework might

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has an effective privilege of use." Michael A. Heller, *Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 624 (1998). In a seminal article, Michael Heller and Rebecca Eisenberg posit that this problem occurs in the biomedical field "when a user needs access to multiple patented inputs to create a single useful product." *See* Heller & Eisenberg, *supra* note 97, at 699. Heller and Eisenberg explain that granting patents on upstream inventions results in "too many concurrent fragments of intellectual property rights in potential future products." *Id.* They conclude that such patents might impose significant transaction costs on downstream innovation and product development in the biomedical field. *See id.* at 700–01.

[117] *See infra* notes 129–181 and accompanying text.

[118] *See infra* notes 182–196 and accompanying text.

[119] *See* Yu, *supra* note 36, at 911–17; Yu, *supra* note 35, at 401 (explaining that when courts distinguish between different types of upstream inventions, they often rely on "ungrounded legal-

help decisionmakers determine whether or not there is a principled distinction between patents that failed and those that did not, leading to more consistent outcomes.[120]

Second, a standalone completeness requirement might have the beneficial effect of breaking down the doctrinal barriers that courts have erected for dealing with different kinds of upstream patents. In similar contexts, commentators have criticized the Federal Circuit's patent law jurisprudence for maintaining formalistic distinctions between different doctrines and sidestepping larger policy questions,[121] and this criticism may be particularly apt in the context of upstream patents. Although patent claims may be unacceptably upstream in different ways, a different set of doctrinal tools for each form of incompleteness might cause decisionmakers to lose sight of the common policy concerns behind denying such claims. In contrast, placing them all under the completeness umbrella might point the way to more coherent case law and help courts develop sound limiting principles for determining which patents to invalidate.[122]

Third, as suggested in the Introduction, explicit recognition of the completeness requirement might help quell the controversies and diminish legitimacy costs that the utility, written description, and patentable subject matter cases have generated.[123] The rest of this Article proceeds as follows. Parts II and III discuss the three lines of completeness cases, explain the policy concerns that unite them, and critique these cases,[124] and Parts IV and V offer suggestions for changes in patent law that may lead to a better implementation of the policy behind the completeness cases.[125]

II. THE CONTOURS OF PATENT LAW'S COMPLETENESS REQUIREMENT

This Part examines the three lines of doctrine that underlie the unwritten requirement of completeness.[126] Section A explains how courts have

istic and semantics-based arguments" rather than on an "understanding of basic science and technology"); *infra* notes 197–266 and accompanying text.

[120] Of course, this state of affairs could partly be a consequence of litigation strategy; some patent claims that would be incomplete under the proposal outlined in this Article may not have been invalidated under completeness doctrines because they were never challenged in this manner.

[121] *See supra* notes 35–38 and accompanying text. In similar contexts, scholars have criticized certain doctrinal distinctions in patent law as essentialist and overly formalistic. *See, e.g.*, Laakmann, *supra* note 39, at 60–65; *see also* John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 774 (2003) (maintaining that the Federal Circuit has "embraced an increasingly formal jurisprudence").

[122] *See infra* note 371–375 and accompanying text.

[123] *See supra* notes 34–38 and accompanying text.

[124] *See infra* notes 126–266 and accompanying text.

[125] *See infra* notes 267–460 and accompanying text.

[126] *See infra* notes 127–196 and accompanying text.

applied the tests underlying the utility, written description, and patentable subject matter requirements to patents on upstream inventions.[127] Section B notes that, although these doctrines operate in different ways, courts employ them to address the same policy concern: that patenting of foundational research artifacts is problematic.[128]

A. Completeness Doctrines

1. Utility

One way that patent law polices completeness is through the utility requirement.[129] The modern utility doctrine took shape in 1966, when the Supreme Court in *Brenner v. Manson* held that a novel process for making certain chemical compounds was not patentable.[130] The compounds at issue fell within a larger class of molecules called steroids.[131] Anticipating the Court's hostility to an older doctrine holding that all chemical compounds had "inherent" utility,[132] the patent applicant asserted that the chemicals made by the claimed process were of interest as drug candidates because they were structurally similar to other steroid compounds used to treat cancer.[133] The Court, however, concluded that the asserted utility was not enough, upholding the PTO's finding that the patent applicant failed to demonstrate "a *sufficient likelihood* that the steroid yielded by his process would have similar tumor-inhibiting characteristics" to that of other steroids.[134]

The Supreme Court affirmed the rejection of the patent application because the claimed process was not "refined and developed to . . . where spe-

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[127] *See infra* notes 129–181 and accompanying text.

[128] *See infra* notes 182–196 and accompanying text.

[129] *See* 35 U.S.C. § 101 (2012) ("Whoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter, or any new and *useful* improvement thereof, may obtain a patent therefor . . . ." (emphases added)); *supra* notes 1, 11–12 and accompanying text.

[130] *See* 383 U.S. 519, 534 (1966).

[131] *Id.* at 520–22.

[132] The inherent utility doctrine derives from the intuition that most chemical compounds are good for something, such as making other chemicals. *See, e.g.*, *In re* Nelson, 280 F.2d 172, 179 (C.C.P.A. 1960), *overruled by In re* Kirk, 376 F.2d 936 (C.C.P.A. 1967); Potter v. Tone, 36 App. D.C. 181, 184–85 (D.C. Cir. 1911); *see also* Note, *The Utility Requirement in the Patent Law*, 53 GEO. L.J. 154, 190 (1964) ("To possess 'utility,' it has been shown that an invention must be capable of producing some beneficial result as distinguished from being frivolous."). *But see* Petrocarbon Ltd. v. Watson, 247 F.2d 800, 801 (D.C. Cir. 1957) (adopting the contrary view and holding that the claimed process for the production of new polymers was not patentable because, even though the polymers had "useful properties," the specification failed to "explain [their] use to one skilled in the art").

[133] *See Brenner*, 383 U.S. at 530–31.

[134] *Id.* at 532 (emphasis added).

cific benefit exists in currently available form."[135] Having failed to do this additional work, the applicant could not patent an invention that, in the Court's view, could only serve as a genesis for another research project.[136] The reason was that such a patent could "block off whole areas of scientific development, without compensating benefit to the public."[137] Although a chemical compound that is an "object of scientific inquiry" or "an object of use-testing" can be useful to a research chemist, such an application is not sufficient for patentability.[138]

Despite claims that the utility requirement became "minimal" under the Federal Circuit's interpretation of *Brenner*,[139] recent cases show that courts have not abandoned the basic rule that the inventor must demonstrate a chemical compound's potential benefit to an end user. Applying *Brenner*, the Federal Circuit held in *In re Fisher* that claims to so-called "expressed sequence tags" ("ESTs") were not patentable.[140] ESTs are a class of chemical compounds made from the same building blocks as DNA and are of interest to researchers as tools for identifying and studying genes.[141] The court held that ESTs lack utility because they are "no more than research intermediates."[142] It explained that to satisfy the requirement, the utility must be "specific"—in other words, not widely shared by all chemical compounds—and "substantial"—such that "an asserted use must show that the claimed invention has a significant and presently available benefit to the public."[143] As in *Brenner*, research utility did not render the inventions

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[135] *See id.* 534–35.

[136] *See id.*

[137] *Id.* at 534 (citation omitted).

[138] *See id.* at 529, 535. As one commentator aptly noted, *Brenner* "seem[ed] effectively to exclude research chemists from the class of people for whom an invention may be useful." Brent Nelson Rushforth, Comment, *The Patentability of Chemical Intermediates*, 56 CALIF. L. REV. 497, 513 (1968); *see* Lawrence R. Velvel, *A Critique of* Brenner v. Manson, 49 J. PAT. & TRADEMARK OFF. SOC'Y 5, 10 (1967) (criticizing the Court's decision to "deny patents to products useful in research").

[139] *See* Lopez-Beverage, *supra* note 109, at 64 ("[I]t has been the [Federal Circuit's] position that minimal utility is all that is required to obtain a patent."); *see also In re* Brana, 51 F.3d 1560, 1562 n.3, 1566–67 (Fed. Cir. 1995) (holding that experiments establishing a biological effect of the claimed chemicals on an animal model can be sufficient to establish utility); Cross v. Iizuka, 753 F.2d 1040, 1050–51 (Fed. Cir. 1985) (holding that testing *in vitro*, i.e., in a test tube, can establish utility).

[140] *See* 421 F.3d 1365, 1367, 1377–78 (Fed. Cir. 2005).

[141] *See id.* at 1367–69; *id.* at 1379–80 (Rader, J., dissenting).

[142] *Id.* at 1373 (majority opinion).

[143] *See id.* at 1371. The utility requirement also mandates that an invention have so-called operable and credible utility; that is, the applicant must provide a credible explanation that the invention works for its intended purpose. *See* Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1493–94 & n.10 (2011) (describing the test for operable utility). This aspect of the utility requirement—which rules out patents on perpetual motion, cold fusion, and the like—is not

complete enough to be patentable.[144] Thus, courts continue to rely on utility as a "policy lever"[145] to prohibit "premature [patent] filing[s]"[146] on chemical and biotechnological inventions.[147]

2. Written Description

The written description doctrine provides another line of attack, of more recent vintage than utility, against patents on upstream inventions.[148] Modern developments in the law of written description have fashioned this requirement into a mirror image of utility. While utility bars patents on structurally well-defined chemical compounds having no demonstrated benefit to the public, courts have applied written description in certain cases to deny patents that claim chemical compounds in terms of their beneficial functions, but fail to provide any actual chemical structures.[149]

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at issue in this Article, which focuses on the "specific and substantial" prong of the utility doctrine.

[144] *See In re Fisher*, 421 F.3d at 1377–78. Nonetheless, the PTO has made it clear that the utility doctrine does not work as a general prohibition against the patenting of research tools. *See* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2107.01(I)(C) (9th ed. 2014); *cf. id.* § 2107.01(I)(B) ("Office personnel must be careful not to interpret the phrase 'immediate benefit to the public' or similar formulations in other cases to mean that products or services based on the claimed invention must be 'currently available' to the public in order to satisfy the utility requirement." (quoting *Brenner*, 383 U.S. at 534–35)).

[145] *See* Burk, *supra* note 31, at 535 (defining a "policy lever" as "a type of flexible doctrine that courts can use to modulate an otherwise uniform patent statute to the innovation needs of particular technologies").

[146] *See* Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 18 (1995).

[147] *See* BURK & LEMLEY, *supra* note 29, at 109 ("[T]he utility rule announced in *Brenner v. Manson* is applied only in biotechnology and chemical cases. [This lever] may require courts to differentiate between industries, defining certain inventions as 'biotechnological,' for example, in order to invoke a particular rule."); *see also In re* '318 Patent Infringement Litig., 583 F.3d 1317, 1324 (Fed. Cir. 2009) ("Allowing ideas, research proposals, or objects only of research to be patented has the potential to give priority to the wrong party and to 'confer power to block off whole areas of scientific development, without compensating benefit to the public.'" (quoting *Brenner*, 383 U.S. at 534)); CreAgri, Inc. v. Pinnaclife, Inc., No. 11-CV-6635-LHK, 2013 WL 6673676, at *16–21 (N.D. Cal. Dec. 18, 2013) (invalidating claims to a chemical compound "whose sole 'utility' consists of its potential role as an object of use-testing'" (quoting *Brenner*, 383 U.S. at 535)), *aff'd*, 579 F. App'x 1003 (Fed. Cir. 2014).

[148] The statutory source of the written description requirement is § 112(a)'s statement that "[t]he [patent's] specification shall contain a written description of the invention." *See* 35 U.S.C. § 112(a) (2012).

[149] *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1358 (Fed. Cir. 2010) (en banc); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 929 (Fed. Cir. 2004). In some cases, broad patent claims containing functional language can fail the written description requirement even when applicants disclose some (but not enough) examples of chemical structures. *See* Bos. Sci. Corp. v. Johnson & Johnson, 647 F.3d 1353, 1364–67 (Fed. Cir. 2011).

For example, in *University of Rochester v. G.D. Searle & Co.*, the Federal Circuit held that a method of reducing inflammation using "a non-steroidal compound that selectively inhibits activity" of a certain gene was unpatentable.[150] The inventor discovered the phenomenon of selective inhibition of the gene, which enabled the downstream discovery of pain relievers that lack undesirable side effects like ulceration,[151] and disclosed experiments for finding chemical compounds that would perform the claimed inhibiting function.[152] Nonetheless, the patent did not provide any examples of compounds that would have this effect.[153] Based on the absence of disclosure of chemical structures, the Federal Circuit opined that the patent was only "a research plan for trying to find" the non-steroidal compound having the claimed activity, and invalidated the claims for lack of written description.[154] For the invention to be complete, the court required a chemical structure, not merely a "search method."[155] In doing so, the court rejected the patentee's argument that identifying a biological target and providing a roadmap for finding drugs that would act on that target entitles the inventors to reap a benefit once another researcher discovers such drugs.[156] Citing *Brenner*—a utility case—the court even suggested that the patentees did not invent the claimed methods at all.[157]

In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, the Federal Circuit sitting en banc invalidated claims to a method of inhibiting the binding of a certain important gene-regulating protein to recognition sites in cells for lack of written description.[158] Interference with the activity of this protein, a

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[150] *See* 358 F.3d at 918, 929 (quoting U.S. Patent No. 6,048,850 col. 71 ll. 36–39 (filed June 7, 1995)).

[151] *See supra* notes 2–4, 13 and accompanying text.

[152] *See Univ. of Rochester*, 358 F.3d at 927 (explaining that the patent disclosed "assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that [perform the claimed function]" (quoting '850 Patent col. 8 ll. 2–7)).

[153] *See id.* at 926–27.

[154] *See id.* at 926–27, 929.

[155] *See id.* at 930 n.10.

[156] *See id.*; *cf.* Robert A. Hodges, Note, *Black Box Biotech Inventions: When a "Mere Wish or Plan" Should Be Considered an Adequate Description of the Invention*, 17 GA. ST. U. L. REV. 831, 855 (2001) ("[A] function coupled with basic knowledge of structure and a workable method of production allow those in the art to produce the invention."); *infra* note 453 and accompanying text (describing true hypotheses and conjectures that lack a credible scientific basis, which are different from the claimed methods in *University of Rochester*).

[157] *See Univ. of Rochester*, 358 F.3d at 930 n.10 (citing *Brenner*, 383 U.S. at 536); *cf. In re '318 Pat. Infringement Litig.*, 583 F.3d at 1324 (relying in part on the policy against the patenting of "research proposals" in a utility case); *CreAgri*, 2013 WL 6673676, at *21 (citing *Ariad*, 598 F.3d at 1353) (holding that the claimed invention lacked utility because it was directed to "a research hypothesis").

[158] 598 F.3d at 1340.

so-called "transcription factor," underlies the treatment of a large number of conditions, including cancer, AIDS, and sepsis.[159] In denying a patent on this invention, the court further clarified why claims to "research hypotheses do not qualify for patent protection."[160] The court explained that "[s]uch claims merely recite a description of the problem to be solved while claiming all solutions to it and . . . cover any compound later actually invented and determined to fall within the claim's functional boundaries—leaving it to the pharmaceutical industry to complete an unfinished invention."[161] The court further stated that patent law is directed to inventions "with a practical use" rather than to "basic research."[162] To reinforce the court's point, Judge Pauline Newman wrote separately that "[b]asic scientific principles are not the subject matter of patents," and that "the threshold in all cases requires a transition from theory to practice, from basic science to its application, from research plan to demonstrated utility."[163] The familiar policy concern behind this outcome is that patents on research plans stifle later inventive activity.[164]

Thus, although drawn from a different statutory provision, the written description requirement as applied to research-plan claims has remarkably similar underpinnings as utility. Courts use both to police completeness of the claimed invention, requiring applicants to make their inventions more downstream before they can qualify for a patent. Although the two requirements address different facets of completeness—lack of a specific benefit to an end user under utility and inadequate structural disclosure under written description—courts have used both to prevent inventors from laying claim to basic research and blocking downstream users from enjoying its fruits.

3. Patentable Subject Matter

In addition to mandating the requirement of utility, Section 101 of the Patent Act imposes "an important implicit exception" that places certain claims outside the category of patentable subject matter, barring patents on

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[159] Ariad Pharm., Inc. v. Eli Lilly & Co., 529 F. Supp. 2d 106 (D. Mass. 2007), *rev'd in part, aff'd in part*, 598 F.3d 1336.

[160] *See* 598 F.3d at 1353.

[161] *Id.*

[162] *See id.* (citing *Brenner*, 383 U.S. at 532–36). Interestingly, while the Federal Circuit in *Ariad* cited a utility case in support of the outcome in a written description case, the district court also analyzed the problems with the asserted patent in terms of the patentable subject matter requirement of § 101. *See id.* at 1358 (Newman, J., additional views). Thus, the *Ariad* case implicates, in some way, all three completeness doctrines.

[163] *See Ariad*, 598 F.3d at 1359 (Newman, J., additional views).

[164] *See id.* at 1353 (majority opinion) (reasoning that "claims to research plans . . . impose costs on downstream research, discouraging later invention" by "attempt[ing] to preempt the future before it has arrived" (quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993))).

natural phenomena, laws of nature, and abstract ideas.[165] As the Supreme Court explained in *Gottschalk v. Benson*, "[p]henomena of nature . . . and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."[166] In *Benson*, the Court held that the claimed method of converting so-called "binary-coded numbers" into pure binary numbers was unpatentable because it was drawn to "an idea."[167] The Court found it important that "[t]he mathematical formula involved here *has no substantial practical application* except in connection with a digital computer, which means that . . . the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself."[168] As in the utility and written description cases discussed in the previous two Sections,[169] the argument that the applicant's claims were drawn to an artifact of basic research—here, an algorithm or "an idea"—appeared to persuade the Court to find the claimed method unpatentable.[170] Once again, preemption of downstream research and development associated with the patentee's control of an important upstream input was the policy driver behind this result.[171]

A more recent case further demonstrates how the patentable subject matter doctrine functions to bar patents on inventions that are thought by courts to be too upstream. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court explained that "the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily admin-

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[165] *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).

[166] *See* 409 U.S. 63, 67 (1972).

[167] *See id.* at 64, 71.

[168] *See id.* at 71–72 (emphasis added). For an argument contesting the reasoning in *Benson*, see generally Chisum, *supra* note 37.

[169] *Cf.* Chisum, *supra* note 46, at 20–21 (noting this similarity between the abstract ideas exception and the *University of Rochester* and *Ariad* form of the written description requirement, but highlighting "an important difference": written description, unlike patentable subject matter, "takes into account *facts* concerning the disclosed invention, including, importantly, whether the inventor disclosed one or more examples of the invention and not just the abstract breadth of the claim in question").

[170] In contrast with the utility and written description requirements—where specification disclosures of end uses or of examples of chemical compounds, respectively, might save the claims—the material in the specification probably cannot save the claims at issue in patentable subject matter cases, presumably because of their overbreadth. *See supra* notes 139, 153–155 and accompanying text (explaining how patent claims can satisfy the utility and written description requirements if there is adequate disclosure).

[171] *See Benson*, 63 U.S. at 68 (discussing the varied end uses covered by the claims at issue). *But see* Strandburg, *supra* note 35, at 564 (arguing that, in *Benson* and similar cases, "[p]reemption rhetoric is a distraction from important questions that must be answered to give patentable subject matter doctrine a firm theoretical grounding").

istered proxy for the underlying 'building-block' concern"—the concern over the patenting of basic research inputs.[172] Applying this policy, the Court invalidated claims to methods of "optimizing therapeutic efficacy" that were based on a correlation between the concentration of a certain chemical in a patient's blood and the effectiveness of a drug used to treat gastrointestinal disorders.[173] The Court explained that, "to transform an unpatentable law of nature into a patent-eligible *application* of such a law, [a claim] must do more than simply state the law of nature while adding the words 'apply it,'"[174] and held that the claims at issue were not sufficiently limited. Echoing the rhetoric of other decisions discussed in this Section, the Court heavily relied on the preemption rationale for prohibiting patent claims that are upstream in the development chain.[175] The Court reasoned:

> [T]here is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify.[176]

In another recent pronouncement on patentable subject matter, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Supreme Court explained how the prohibition against basic research functions in a "product of nature" case.[177] In held that claims to isolated genetic material failed the patentable subject matter requirement because they were effectively drawn to the upstream discovery of "the precise location and genetic sequence of [particular] genes" rather than to "new *applications* of knowledge about"

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[172] 132 S. Ct. at 1303.

[173] *See id.* at 1295, 1305 (quoting U.S. Patent No. 6,355,623 (filed Apr. 8, 1999)). At this stage of the Article, I am reserving judgment on whether the Court in *Mayo* was correct in holding the Prometheus patent to be unacceptably upstream. As I explain later, though, *Mayo* relied on the right policy, but used a questionable test to effectuate it and reached the wrong outcome. *See infra* notes 345–350 and accompanying text (explaining how the proposed test for completeness could be applied to the claims at issue in *Mayo*).

[174] *Mayo*, 132 S. Ct. at 1294.

[175] *See id.* at 1301–02.

[176] *Id.* at 1301; *accord* Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014) ("We have described the concern that drives [the] exclusionary principle [rendering unpatentable abstract ideas, natural phenomena, and laws of nature] as one of pre-emption."); *see supra* notes 114–116 and accompanying text (explaining why patents on upstream inventions are problematic). *But see* Chiang, *supra* note 20, at 1865–68 (arguing that the Court's rejection in *Mayo* of Prometheus's argument—that the claim at issue was narrow and unlikely to preempt much of anything—suggests that the Court was not really driven by the utilitarian concern regarding preemption).

[177] *See* 133 S. Ct. 2107, 2111 (2013).

these genes.[178] The Court, furthermore, found it important that the "claim is concerned primarily with the information contained in the genetic *sequence,* not with the specific chemical composition of a particular molecule."[179] Thus, one way to understand (and, perhaps, cabin) the result in *Myriad* is that the Court invalidated the claims because the patentee essentially claimed genetic information, which is akin to a foundational research tool or a basic concept.[180] As in other completeness cases, the Court discussed balancing the need to incentivize new research against the danger of hindering downstream innovation.[181]

B. A De Facto Single Requirement

There are, of course, important differences in the ways the three doctrines operate.[182] Utility is seemingly concerned only with disclosure and would invalidate even narrow claims if a downstream use is not shown in the patent's specification; written description is concerned with both disclosure and claim scope; and patentable subject matter addresses only the nature and scope of what is claimed. But the similarities across utility, written description, and patentable subject matter doctrines are notable.[183] The inventors in all of these cases have discovered something that is valuable and was previously unknown—a chemical compound, a biological target of drug action, and a correlation between the concentration of a probe molecule and a patient's condition.[184] Nevertheless, these inventors were not allowed to capture the value from their respective inventions' downstream applications due to certain deficiencies of the patents. In the utility cases, the patents did not demonstrate a downstream benefit of the claimed com-

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[178] *See id.* at 2116, 2120.

[179] *See id.* at 2118.

[180] *See* Arti K. Rai & Robert Cook-Deegan, *Moving Beyond "Isolated" Gene Patents*, 341 SCI. 137, 138 (2013) (suggesting that *Myriad* would likely "have only a modest effect" outside the realm of human genomic DNA patents); *see also* Transcript of Oral Argument at 161–71, *Myriad*, 133 S. Ct. 2107 (No. 12-398) (Counsel for the petitioner: "Because the isolated gene is the same as the gene in your body, I can tell you that there's a mutation in your body." Justice Sotomayor: "That's a failure of the patent law. *It doesn't patent ideas.*" Counsel for the petitioner: "*And it shouldn't patent ideas*, and—but it also makes the point that isolated gene and the gene in the body are the same." (emphases added)). For a different interpretation, see Chiang, *supra* note 20, at 1873–76 (arguing that moral concerns were at play in *Myriad*).

[181] *See Myriad*, 133 S. Ct. at 2116.

[182] *See supra* notes 169–170 and accompanying text.

[183] *Cf.* Chisum, *supra* note 46, at 22 ("Like the written description requirement, the utility requirement is a response to the concerns underlying decisions such as *Benson* and *Bilski*, that is, restricting patents to real world inventions."); Liivak, *supra* note 110, at 1373 n.206 (noting "a curious, relatively unexplored kinship between many § 101 and § 112 cases").

[184] *See supra* note 9 and accompanying text.

positions in the specification.[185] In the written description cases, the patents failed because the method-of-treatment inventions were claimed in functional terms based on an unknown drug's effect on a biological target.[186] And in the patentable subject matter cases, the claims were ostensibly so broad that they essentially captured a fundamental principle or a natural law rather the principle's or law's particular application.[187] All of these patents failed for a common reason: they were drawn to research artifacts that are too foundational to be patentable.[188] This is the completeness requirement at work.[189]

Indeed, the policy rhetoric of the three strands of cases is nearly indistinguishable. "[A] patent," said the Supreme Court in a utility case, "is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."[190] For the invention to be patentable, said the Federal Circuit in a written description case, it is not enough for the patent's specification to describe a mere "wish" or "plan," for that would be "an attempt to preempt the future before it has arrived."[191] And in a patentable subject matter case, the Supreme Court invalidated claims that "tie[d] up too much future use of laws of nature" by allowing its owner to appropriate "basic tools of scientific and technological work."[192] The three lines of cases therefore serve the same policy goal of preventing undue preemption of downstream research.

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[185] *See supra* notes 129–147 and accompanying text.

[186] *See supra* notes 148–164 and accompanying text. Here, I refer only to the line of cases beginning with *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), and exemplified by the *University of Rochester* and *Ariad* cases that are extensively discussed in this article. There is an uncontroversial aspect to the written description requirement—its use to prevent patentees from introducing during prosecution new or amended claims lacking textual support in the specification. *See, e.g.*, *In re* Ruschig, 379 F.2d 990, 991, 994–95 (C.C.P.A. 1967). This application of the written description requirement ensures that newly added or amended claims properly receive the benefit of the patent application's original filing date. *See* Janis, *supra* note 35, at 59–60 & n.18, 71. The patent applicant is entitled to claim only subject matter that was disclosed in the patent specification at the time of the filing, making anything that was not disclosed impermissible "new matter." *See* 35 U.S.C. § 132(a). "New matter" technically refers to material added to the original specification after filing, which violates § 132, whereas a new claim not supported by the specification violates § 112. *See* Janis, *supra* note 35, at 64 & n.35.

[187] *See supra* notes 165–181 and accompanying text.

[188] *See supra* notes 96–116 and accompanying text.

[189] *See supra* note 16–23 and accompanying text.

[190] *Brenner*, 383 U.S. at 536.

[191] *See Fiers*, 984 F.2d at 1171. Although *Fiers* did not involve originally filed claims, it is thought to have ushered in the *Lilly-University of Rochester-Ariad* line of cases that many consider anomalous. *See* Pitlick, *supra* note 35, at 209–11.

[192] *See Mayo*, 132 S. Ct. at 1293, 1302 (quoting *Benson*, 409 U.S. at 67).

Courts do not like patents on upstream inventions, and, in the absence of a statutory prohibition against the patenting of objects of basic research,[193] they have used three distinct doctrinal sources to invalidate claims that are drawn to them.[194] Part III shows that the fit between the existing statutory provisions and the rules of utility, written description, and patentable subject matter[195] is an uneasy one. Indeed, the current approach has put great pressure on the statutory provisions used to implement completeness, and, in the views of some, has raised concerns about judicial overreach.[196] Part III explains these criticisms.

III. PROBLEMS WITH COURTS' EXISTING TESTS FOR COMPLETENESS

This Part surveys critiques of the completeness cases. Part A shows that courts have inconsistently applied the utility requirement to exclude patents on only some research inputs.[197] Part B notes problems with courts' modern applications of the written description requirement.[198] Part C surveys arguments that courts have failed to develop coherent tests for patentable subject matter exclusions.[199] Finally, Part D maintains that these three lines of doctrine do not consistently implement the policy that motivates the completeness requirement.[200] Although courts in all three types of cases have expressed a concern about the patenting of upstream, research-input inventions, they have addressed this concern in a tentative, unsystematic way.

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[193] It has been argued that this prohibition has constitutional underpinnings. *See, e.g.*, Liivak, *supra* note 73, at 26–28. Although courts sometimes imply a constitutional source for completeness doctrine, they stop short of saying that the prohibition against the patenting of basic research is constitutionally required, and instead focus on public policy. *See, e.g.*, *Ariad*, 598 F.3d at 1351–53. For an argument that intellectual property laws are not subject to strong constitutional limitations under the proper interpretation of the Intellectual Property Clause, see Paul M. Schwartz & William Michael Treanor, Eldred *and* Lochner*: Copyright Term Extension and Intellectual Property as Constitutional Property*, 112 YALE L.J. 2331, 2363–414 (2003).

[194] *Cf.* Kresh, *supra* note 35, at 540 (explaining that courts "have looked to the exceptions to § 101 . . . to eliminate claims of which they disapproved").

[195] For patentable subject matter in particular, it is the recent, expanded form of the rule mandating judicial exclusions from patentability that raises concerns and potentially leads to tensions with the language of the statute. *See infra* notes 243–258, 345–350 and accompanying text.

[196] *See supra* notes 35–38 and accompanying text; *see also infra* note 256 and accompanying text (canvassing critiques of patentable subject matter cases based on judicial overreach and subjectivity).

[197] *See infra* notes 201–227 and accompanying text.

[198] *See infra* notes 228–242 and accompanying text.

[199] *See infra* notes 243–258 and accompanying text.

[200] *See infra* notes 259–266 and accompanying text.

A. Utility

Completeness cases have drawn a great deal of criticism. In utility cases, courts apply the requirement in Section 101 of the Patent Act that inventions be "useful."[201] The leading case is *Brenner v. Manson*, where the Supreme Court held that the claimed method for making chemical compounds did not satisfy the utility requirement.[202] To say that such an invention is not "useful" in the ordinary sense of that word defies common sense, as numerous commentators have observed.[203] Furthermore, it seems counterintuitive that, although the PTO has been granting patents on silly, ridiculous, and useless inventions without issuing utility rejections,[204] the utility requirement has been enforced relatively vigorously in the serious and generally useful fields of chemistry and biotechnology.[205] In a recent article that puts these concerns into sharp focus, one scholar argues that the utility requirement is highly subjective and reflects a "bias against granting patents for certain types of inventions."[206] Of course, the outcomes in these utility cases may be defensible as policy judgments that certain inventions in the chemical arts are too upstream to be patentable.[207] But whether or not these

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[201] *See* 35 U.S.C. § 101 (2012).

[202] *See* 383 U.S. 517, 520, 534 (1966).

[203] *See* Phanesh Koneru, *To Promote the Progress of Useful Art[icle]s?: An Analysis of the Current Utility Standards of Pharmaceutical Products and Biotechnological Research Tools*, 38 IDEA 625, 658 (1998) ("[T]he law [of utility] produces a result that defies common experiences of those in the art."); Eric P. Mirabel, *"Practical Utility" Is a Useless Concept*, 36 AM. U. L. REV. 811, 811–12 (1987) ("In common parlance, a thing 'having utility' is, by definition, 'useful.' When dealing with chemical compounds, however, the judiciary has not equated these expressions." (citation omitted)); Timothy J. Balts, Note, *Substantial Utility, Technology Transfer, and Research Utility: It's Time for a Change*, 52 SYRACUSE L. REV. 105, 108 (2002) ("[B]y excluding research discoveries from being 'useful,' the substantial utility requirement . . . discourages disclosure and research, and thus, does not promote the progress of the useful arts.").

[204] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1644 (2003) (explaining that "[t]he PTO has permitted patents on a wide variety of seemingly frivolous inventions") (citing U.S. Patent No. 5,076,262 (filed June 7, 1995); U.S. Patent No. 5,031,161 (filed Feb. 15, 1991); U.S. Patent No. 4,998,724 (filed Aug. 10, 1990)); John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 453 (2004) ("[P]atent law has no aversion to awarding commercially worthless property rights."); Risch, *supra* note 19, at 1197–99 ("[T]he Patent Office continues to issue virtually useless patents like the . . . 'Feminine Undergarment with Calendar.' . . . [M]arginally useful inventions like calendar underwear are patentable, while some potentially very useful pioneering medical treatments are not . . . .") (citing U.S. Patent No. 5,606,748 (filed Jan. 29, 1996)).

[205] *See* BURK & LEMLEY, *supra* note 29, at 111 ("The only exceptions to the effective elimination of the utility requirement in patent law are in the fields of biology and chemistry.").

[206] *See* Seymore, *supra* note 35, at 1071.

[207] *Cf.* Burk, *supra* note 25, at 580–81 (attempting to find a rationale for *Fisher* that "is not simply a façade for a policy judgment about the desirability of 'upstream' patents early in the research process" and concluding that the Federal Circuit's reasoning is "so baffling that it is nearly impossible to discern exactly what the court's rationale might be").

judgments are correct, the distinctions made under the utility doctrine have put a great deal of weight on the word "useful." Accordingly, there are non-trivial legitimacy costs associated with the way in which courts have implemented the utility requirement.[208]

Several scholars have provided policy justifications for the distinctions made by the current utility regime.[209] For example, John Duffy contends that it makes sense to allow patents on research *tools* such as microscopes, which facilitate further research, but reject patents on research *intermediates* such as ESTs[210] and chemical compounds, which might themselves be objects of study.[211] In other words, Duffy argues that research tools are patentable because they have "broad applicability to researchers generally," whereas research intermediates are not because they have a "particular applicability only in research directed toward understanding the alleged invention itself or something closely associated with the alleged invention."[212]

Why does this distinction matter? Duffy argues that patents on chemical intermediates are rejected, while patents on microscopes are allowed, because the former, but not the latter, would generate the so-called "mutually blocking" patents scenario—which he views as undesirable.[213] In other

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[208] *See* Tun-Jen Chiang, *Defining Patent Scope by the Novelty of the Idea*, 89 WASH. U. L. REV. 1211, 1235–36 (2012) (discussing the problem of legitimacy costs even where "judges achieve good economic results through . . . extra-legal use of discretion").

[209] *See, e.g.*, John F. Duffy, *Embryonic Inventions and Embryonic Patents: Prospects, Prophecies, and* Pedis Possessio, *in* PERSPECTIVES ON COMMERCIALIZING INNOVATION 234, 245–48 (F. Scott Kieff & Troy A. Paredes eds., 2012); Rai, *supra* note 21, at 140–41. One scholar would go further and give the utility requirement an expanded role. *See* Risch, *supra* note 19, at 1234–48 (proposing a new "commercial utility requirement"); *see also* Michael Risch, *A Surprisingly Useful Requirement*, 19 GEO. MASON L. REV. 57, 111 (2011) (arguing that "[c]onsidering an invention's usefulness can help resolve novelty, obviousness, subject matter, enablement, claim scope, and damages questions").

[210] *See supra* notes 141–143 and accompanying text.

[211] *See* Duffy, *supra* note 209, at 246–47.

[212] *Id.* As Duffy notes, "[r]esearch facilitated by a microscope is not a step in refining the microscope." *Id.* at 247. But Duffy's claim might not always hold true for newly discovered specialized microscopes, like the atomic force microscope. *See supra* notes 69–70 and accompanying text. Indeed, attempts to observe objects using atomic force microscopes have sometimes led to patents on methods of use of atomic force microscopes or to patented *improvements in microscopy*—a classic blocking patent situation. *See, e.g.*, U.S. Patent No. 5,874,668 (filed Oct. 24, 1995). And conversely, chemical intermediates can facilitate further research by serving as building blocks for larger, more complex molecules (rather than, for example, as objects for further study). *See* Seymore, *supra* note 30, at 1118–20.

[213] *See* Duffy, *supra* note 209, at 247. Merges and Nelson explain blocking patents as follows:

> Two patents are said to block each other when one patentee has a broad patent on an invention and another has a narrower patent on some improved feature of that invention. The broad patent is said to "dominate" the narrower one. In such a situation, the holder of the narrower ("subservient") patent cannot practice her invention without a license from the holder of the dominant patent. At the same time, the holder of

words, Duffy finds it problematic that, if ESTs were patentable, downstream researchers who discovered uses for them and patented those uses would need a license from the owners of the ESTs to practice their own patents.[214] In contrast, patents on downstream inventions created with the aid of research tools like microscopes—for example, nano-sized objects[215]—would not fall within the scope of patent claims to microscopes.[216] As a result, there would not be mutually blocking patents in these circumstances.[217]

It is not clear, however, why the prospect of mutually blocking patents should lead to a radically different treatment of research tools and research intermediates.[218] Mutually blocking patents are routine in patent law.[219] Indeed, the Patent Act expressly contemplates patents for new uses of known things, even when the known thing is itself patented.[220] Conversely, even in cases where the downstream invention does not fall within the scope of an upstream research tool patent, the follow-on researcher who uses the tool would need to obtain a license to use it, buy the tool if it happens to be commercially available, or risk exposure to a patent infringement lawsuit.[221] The critical policy concern behind the completeness requirement is not the presence of mutually blocking patents, but preemption of downstream research and development due to the "bottleneck" of a research tool patent or another sort of upstream patent—whether or not the fruits of the follow-on work are themselves eventually patented.[222] A patent on a broadly applicable new type of a microscope, untethered to a specific downstream use,

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> the dominant patent cannot practice the particular improved feature claimed in the narrower patent without a license.

Merges & Nelson, *Patent Scope*, *supra* note 99, at 860–61.

[214] *See* Duffy, *supra* note 209, at 247.

[215] *See supra* note 69–70 and accompanying text.

[216] *See* Duffy, *supra* note 209, at 247.

[217] *See id.*

[218] Duffy concedes that this justification for treating research tools and intermediates differently is "not entirely satisfying." *See id.* at 245.

[219] *See* Kevin Emerson Collins, *The Reach of Literal Claim Scope into After-Arising Technology: On Thing Construction and the Meaning of Meaning*, 41 CONN. L. REV. 493, 497 (2008).

[220] *See* 35 U.S.C. § 100(b) (2012) ("The term 'process' . . . includes a new use of a known process, machine, manufacture, composition of matter, or material.").

[221] *See supra* notes 110–112 and accompanying text.

[222] Furthermore, cross-licensing of mutually blocking patents is generally contemplated for small improvements, not for transformative downstream uses of the dominant patent. *See* Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 78–91 (1994); *see also* Duffy, *supra* note 209, at 245 (predicting a bargaining breakdown where "the discoverer of the initial technology could not even prophesy a use"). Assuming, as seems likely, that uses of patented basic research artifacts are often transformative, one would be concerned about the blockage of downstream research whether or not there are mutually blocking patents.

should worry us because it is directed to an invention having uncertain value and an untold number of applications.[223]

Given these policy considerations, it is difficult to explain why the completeness cases pick out ESTs over microscopes.[224] Patent claims on microscope inventions, just like claims on chemical inventions, can be complete or incomplete depending on the stage of the invention's development and that invention's potential to facilitate (and, if patented, to block) further research and development activity.[225] The utility requirement is on the right track in its focus on the "specific and substantial utility"[226] of claimed inventions because this formulation, at least indirectly, gets at the notion of a research input. But the case law has, at the very least, failed to capture the full range of such inputs and has stretched to a breaking point the meaning of the word "useful."[227]

To sum up, the utility's requirement's exclusive application in the chemical field has questionable statutory support and might not be justifiable as a matter of patent policy. Although the overarching policy rationale of prohibiting patents on research inputs is sound, the utility requirement implements it in ways that are inconsistent and unsatisfying. Thus, a different approach may be in order.

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[223] These concerns may be alleviated somewhat if the tool is available on the market so that anyone who needs to use it can buy one. *Cf.* Rai, *supra* note 21, at 140–41 (arguing that the transaction costs for using inventions embodied in analytical tools are low because such tools "will, in many circumstances, be licensed not for further improvement but for the comparatively straightforward purpose of direct use"). But the issue of over-rewarding the patentee remains, and there may still be chilling effects on downstream research if the tool is expensive, or if the patentee does not make the tool and refuses to give to anyone the license to make it. Conversely, just like scientific instruments, some chemical intermediates and kits for making them are available for sale. *See, e.g.*, *Product Catalog*, STREM CHEMICALS, INC., http://www.strem.com/catalog, *archived at* http://perma.cc/YRC3-WRW6 (last visited Mar. 27, 2015). And yet the difference in patent law treatment of these two types of research aids remains.

[224] *But see* Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 323–24 (2002) (criticizing EST patents because ESTs "have no inherent commercial utility," "are naturally occurring substances[,]" and are, "at best, a starting point for further research"); Lopez-Beverage, *supra* note 109, at 73–75 (arguing that the utility and written description requirements "are not stringent enough to prevent the granting of patents on ESTs").

[225] Furthermore, the distinction between "intermediates" and "tools" is not robust in the decided cases. Indeed, Duffy notes that "both the case law and the theory suggest that a general technique for identifying ESTs should be patentable—even if there is no use for any of the ESTs identified!" Duffy, *supra* note 209, at 247. But the result of *Brenner v. Manson* is directly contrary to this observation because that case dealt with a *process* patent for making molecules, which the Supreme Court invalidated. *See* 383 U.S. at 520–22, 534.

[226] *See supra* note 143 and accompanying text (explaining the valence of the "specific and substantial" prong of the utility requirement).

[227] *See supra* note 203 and accompanying text.

B. Written Description

The application of the written description requirement to bar claims that amount to research plans has also been criticized by numerous commentators as anomalous.[228] Echoing complaints about the utility requirement, critics maintain that written description cases exemplified by *University of Rochester*[229] are problematic as a matter of doctrinal development[230] and even statutory interpretation.[231] In addition, numerous scholars and some judges have argued that these cases have unjustifiably imposed heightened disclosure requirements on biotechnology patents.[232] Unlike the utility requirement, which has been applied only against chemical and biochemical patents, the written description requirement has appeared in other

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[228] *See* JANICE M. MUELLER, PATENT LAW 153 (4th ed. 2013) (calling the written description requirement as applied to biotechnology inventions "anomalous"); Yu, *supra* note 36, at 898 (calling the written description requirement "an unsatisfactory patchwork of band-aid, ad hoc solutions" for striking down claims that courts deem unacceptable); Jonathan E. Barbee, Note, *Innovation on the Cutting Edge of* Ariad*: Reinventing the Written Description Requirement*, 86 N.Y.U. L. REV. 1895, 1907–16 (2011); *see also supra* note 35 (citing scholarly and judicial critiques of the Federal Circuit's written description jurisprudence).

[229] *See* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 929 (Fed. Cir. 2004). The *University of Rochester* court examined a claim to a method of treatment where the patent did not provide an example of a drug. *See supra* notes 150–157 and accompanying text.

[230] *See, e.g.*, Pitlick, *supra* note 35, at 222–26 (explaining how the early written description cases invalidating originally filed claims constituted a radical departure from precedent). *But cf. supra* note 186 (discussing uncontroversial aspects of the written description requirement).

[231] *See, e.g.*, Neal Goldfarb, *Judicial Howlers:* Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., LAWNLINGUISTICS (July 26, 2012), http://lawnlinguistics.com/2012/07/26/judicial-howlers-ariad-pharmaceuticals-inc-v-eli-lilly-co, *archived at* http://perma.cc/PKC9-SCHM (explaining that the grammatical structure of what is now § 112(a) cannot support the a written description requirement that is separate from enablement).

[232] *See, e.g.*, Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1326–27 (Fed. Cir. 2004) (Linn, J., dissenting from the order denying rehearing en banc) (explaining that courts have "construe[d] section 112 to contain a separate written description requirement beyond enablement and best mode," which "disproportionately" affects the biotechnology industry); Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 981–83 (Fed. Cir. 2002) (Rader, J., dissenting from the order denying rehearing en banc) (arguing that the heightened disclosure requirements for biotech patents "prejudice[] university or small inventors who do not have the . . . resources to process every new biotechnological invention to extract its nucleotide sequence"); BURK & LEMLEY, *supra* note 29, at 118 ("[W]ritten description evolved as a highly technology-specific doctrine centered in the chemical arts."); Sasha Blaug et al., Enzo Biochem v. Gen-Probe*: Complying with the Written Description Requirement Under US Patent Law*, 21 NATURE BIOTECHNOLOGY 97, 99 (2003) (explaining that written description "appears to [require] an *actual* reduction to practice of a biotechnology or chemical invention before it can be patented"); Holman, *supra* note 32, at 4 (describing the written description requirement as "a 'super-enablement' requirement specifically targeting biotechnology and substantially restricting the patentability of biotechnology-related inventions"); Hodges, *supra* note 156, at 857 ("There seems no principled reason to find such [functional] descriptions sufficient in the case of electrical and mechanical inventions but not in the case of biotech inventions.").

fields.[233] Nevertheless, outside biotechnology, courts and the PTO rarely invalidate (or reject) patent claims under the written description requirement for being directed to a research plan.[234] Although one reason for this state of affairs could be that patentees in other fields do not often draft research-plan claims, this does not seem to be the case in practice. For example, functionally drafted software claims that are directed to "a problem to be solved"[235]—a deficiency that is arguably similar to that of research-plan biotechnology claims[236]—appear to be common, but they have not been eliminated by the written description requirement.[237]

To be fair, a large majority of judges on the Federal Circuit has accepted the written description requirement in its modern form, and several scholars have provided justifications for the ways in which it is applied.[238]

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[233] *See, e.g.*, *In re* Katz Interactive Call Processing Patent Litig., 639 F.3d 1303, 1319–20 (Fed. Cir. 2011) (affirming the invalidation of claims directed to interactive call processing systems because some of the steps were not described in the specification); Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998) (rejecting claims directed to a non-biotechnology invention for lack of written description because the claims could not be broadened to exclude an element designated as an "essential element" in the specification); *see also* Lizardtech, Inc. v. Earth Res. Mapping, Inc., 433 F.3d 1373, 1376 (Fed. Cir. 2006) (Rader, J., dissenting from the order denying rehearing en banc) (criticizing the Federal Circuit's inconsistent application of the written description requirement to claims that do not involve biotechnology or chemistry).

[234] *See* Risch, *supra* note 77 (explaining that the written description requirement has failed to eliminate many overbroad software patent claims). Indeed, the specific approach of rejecting claims under written description due to lack of disclosed structures for implementing the invention seems to be generally limited to biochemical cases.

[235] *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc); *supra* note 77 and accompanying text. For an example of such a claim in the software/business method field, see *infra* note 336 and accompanying text.

[236] *But see* Ajeet P. Pai, Note, *The Low Written Description Bar for Software Inventions*, 94 VA. L. REV. 457, 486–93 (2008) (arguing that there is a principled distinction that justifies allowing functional claims in the software arts but not in the biotechnological arts).

[237] Nevertheless, courts have started invalidating such claims under § 101 as directed to unpatentable subject matter. *See supra* note 28 and accompanying text. These developments might lend further support to the notion that the three doctrines are all facets of the same unwritten requirement of patentability, which courts have developed and applied in an ad hoc manner.

[238] For defenses of the written description requirement, see Liivak, *supra* note 73, at 16–20 (arguing that the written description requirement "corroborate[s] that the inventor invented the claimed subject matter"); Michael Risch, *A Brief Defense of the Written Description Requirement*, 119 YALE L.J. ONLINE 127, 133–42 (2010), http://www.yalelawjournal.org/pdf/867_hcenirop.pdf, *archived at* http://perma.cc/Y8ZS-DDJE (arguing that the written description requirement "ensure[s] that the applicant has claimed boundaries that she has actually invented"); Jakas, *supra* note 72, at 1290 ("[T]he written description requirement not only fits into the patent system as a whole, but also conforms to Congress's overall policy goals . . . with regard to biotechnology innovation."). Jeffrey Lefstin argues that the written description requirement is necessary as a means of defining what the invention is. *See* Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1204–07 (2008). But he notes that written description doctrine has moved away from this function, and suggests that patent

Supporters of the requirement, including the Federal Circuit itself, explain that a research-plan claim is not an "actual invention" and that the inventor did not demonstrate "possession" of the subject matter of the claim.[239] Nonetheless, the rhetoric of the cases is also consistent with the conclusion that words like "invent" or "possess" are labels for the policy judgment that the inventions at issue are not sufficiently developed to warrant a claim that captures valuable downstream applications made possible by those inventions.[240] As with the utility doctrine, that policy judgment may be correct or incorrect—or, perhaps, on the right track but applied inconsistently. The bottom line, though, is that the results of the written description cases might have been less controversial had decisionmakers asked directly whether the patents at issue were directed to objects of basic research,[241] rather than rely on tests that seem to obscure this salient question. Moreover, vigorous scholarly critiques of the written description requirement continue unabated in spite of its judicial acceptance.[242]

C. Patentable Subject Matter

The jurisprudence of Section 101 patentable subject matter exclusions has also been the subject of numerous critiques. Unlike utility and written description, the complaints here are not only about questionable doctrinal development[243] or a disproportionate burden on some particular industry or patent type,[244] but about the lack of guidance from courts. As a general mat-

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law's requirement of definiteness may more naturally play this role. *See id.* at 1207–10, 1220–22; *see also* 35 U.S.C. § 112(b) (2012) (setting forth the statutory requirement of definiteness).

[239] *See Ariad*, 598 F.3d at 1353, 1355.

[240] *See* FELDMAN, *supra* note 93, at 196 ("A court . . . cannot determine what an inventor possessed at a given time without making assumptions about how far a particular invention can reach."); *cf.* Yu, *supra* note 36, at 910–11 (arguing that the "true purpose [of the written description requirement] is more about the creation of an ad hoc tool for courts to strike down claims that courts do not like than about the creation of a tool that advances sound policy").

[241] The *Ariad* case did mention unpatentability of "basic research" as the overarching reason for the outcome, but it is not clear what the source of law prohibiting the patenting of basic research might be. *See* 598 F.3d at 1353; *supra* notes 162–164 and accompanying text.

[242] *See supra* notes 228–231 and accompanying text.

[243] *See infra* note 256 and accompanying text.

[244] Commentators have also made arguments about disproportionate burdens—on the diagnostics industry and, lately, the software industry. *See, e.g.*, Christopher M. Holman, Mayo, Myriad*, and the Future of Innovation in Molecular Diagnostics and Personalized Medicine*, 15 N.C. J.L. & TECH. 639, 673–77 (2014); *see also* Dennis Crouch, *Twenty Thoughts on the Importance of* Myriad, PATENTLY-O (June 14, 2013), http://patentlyo.com/patent/2013/06/myriad.html, *archived at* http://perma.cc/3LAG-8S6M ("One problem with Supreme Court review of section 101 cases is the risk of alienating entire market areas from patent protection."); Gene Quinn, *The Ramifications of* Alice*: A Conversation with Mark Lemley*, IP WATCHDOG (Sept. 4, 2014), http://www.ipwatchdog.com/2014/09/04/the-ramifications-of-alice-a-conversation-with-mark-lemley/id=51023, *archived at* https://

ter, the proposition that exclusions of natural phenomena, abstract ideas, formulas, and the like from the realm of patentability serve utilitarian goals of patent law is well-established.[245] The problem is that the Supreme Court has steadfastly refused to provide any clear standards for identifying what should be excluded from patentability on this ground—in other words, the Court has not explained how to identify patents that belong to these categories.[246] In an article on the abstract idea exclusion, one scholar criticized the Court for "an open embrace of an 'I know it when I see it' jurisprudence" that "offers no prospective guidance for the patent community."[247] Other commentators have lodged similar critiques against the Court's laws-of-nature and products-of-nature jurisprudence.[248]

Even if an abstract idea or law of nature is well-defined, it is difficult to know what would render these unpatentable concepts into patentable inventions.[249] In particular, the Supreme Court has not clarified the distinction

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perma.cc/VYP3-MRDZ?type=image (describing the heightened patentability requirements the Court imposed on software inventions in *Alice v. CLS Bank*). For a historical perspective on the patentability of software patents, see generally Adam Mossoff, *A Brief History of Software Patents (and Why They're Valid)*, 56 ARIZ. L. REV. SYLLABUS 65, http://www.arizonalawreview.org/pdf/syllabus/56ArizLRevSyl65.pdf, *archived at* http://perma.cc/JS6J-NH3S.

[245] *See* Devlin, *supra* note 19, at 1716–18.

[246] *See* Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2357 (2014) (declining to "delimit the precise contours of the 'abstract ideas' category").

[247] *See* Kevin Emerson Collins, Bilski *and the Ambiguity of "an Unpatentable Abstract Idea*,*"* 15 LEWIS & CLARK L. REV. 37, 39 (2011); *see also* John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1100–11 (2011) (describing the "tangled state of existing judge-made doctrine"); Cal. Inst. of Tech. v. Hughes Commc'ns Inc., No. 2:13-cv-07245-MRP-JEM, 2014 WL 5661290, at *3 (C.D. Cal. Nov. 3, 2014) ("The Supreme Court decisions on § 101 often confuse more than they clarify."). *See generally* Chisum, *supra* note 46 (criticizing the Supreme Court's abstract idea jurisprudence). A district court recently echoed Collins's criticism. *See* Eclipse IP LLC v. McKinley Equip. Corp., No. SACV 14-742-GW(AJWx), 2014 WL 4407592, at *3 (C.D. Cal. Sept. 4, 2014) (explaining that the Supreme Court's patentable subject matter test is "evocative of Justice Stewart's most famous phrase" (citing Jacobellis v. Ohio, 378 U.S. 184, 197 (1964) (Stewart, J., concurring) ("I shall not today attempt further to define the kinds of material I understand to be embraced within that shorthand description; and perhaps I could never succeed in intelligibly doing so. But I know it when I see it . . . .")).

[248] *See* Chiang, *supra* note 20, at 1868, 1872 n.51, 1876–77 (criticizing "the emptiness of [the Court's] reasoning" and observing that the Court "never gives any theory for what constitutes a 'law of nature' or explains why biological correlations fall within the category"); *see also* Jacob S. Sherkow, *The Natural Complexity of Patent Eligibility*, 99 IOWA L. REV. 1137, 1141 (2014) (arguing that "the Supreme Court has struggled to give these 'natural' terms any concrete, legal meaning").

[249] *See* Kresh, *supra* note 35, at 522 ("[T]he [*Mayo*] Court expanded the definition of [laws] of nature, holding that a claim that revolves around a [law] of nature must contain an 'inventive concept.' The Court, however, declined to determine what would qualify as an 'inventive concept.'" (citation omitted) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294–95 (2012))).

between an unpatentable "conventional" application of an idea or law and a patentable "inventive" application.[250] A similar difficulty appears in the Court's product-of-nature jurisprudence in the form of the test that asks whether a patent claim is "markedly different" from a natural product.[251] For example, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Court invalidated claims to isolated segments of human genomic DNA under the natural products exclusion because of the "focus on the genetic information" encoded in the molecules.[252] But the Court upheld claims to other types of molecules encoding the same genetic information.[253] Although the Court may have reached a pragmatic result that offers something to both sides in this case, the distinction it drew between the two types of molecules is unpersuasive.[254]

The Supreme Court's patentable subject matter jurisprudence is so murky that making the doctrine more reasoned and systematic has been the goal of many scholarly projects.[255] However, in spite of the attention that this area of patent law has received, courts continue to struggle with it. Fur-

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[250] *See* Rebecca S. Eisenberg, Prometheus *Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J. ONLINE 341, 342–43 (2013), http://yalelawjournal.org/pdf/1145_umctkba1.pdf, *archived at* http://perma.cc/TAJ5-QX4H (criticizing *Mayo* for its lack of clarity); Samantak Ghosh, Prometheus *and the Natural Phenomenon Doctrine: Let's Not Lose Sight of the Forest for the Trees*, 94 J. PAT. & TRADEMARK OFF. SOC'Y 330, 349–50 (2012) (calling the *Mayo* doctrine "[u]n-administrable"); Kresh, *supra* note 35, at 539 ("[T]he Court chose to return to the inventive step and did so without clarifying how much must be added to a natural law to make a claim eligible."); Jacob S. Sherkow, *And How:* Mayo v. Prometheus *and the Method of Invention*, 122 YALE L.J. ONLINE 351, 351 (2013), http://www.yalelawjournal.org/pdf/1144_obtqyfxe.pdf, *archived at* http://perma.cc/YRL4-EQWH (criticizing the *Mayo* Court's "well-understood, routine, conventional activity" approach (quoting *Mayo*, 132 S. Ct. at 1294)).

[251] *See* Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980); *In re* Roslin Inst. (Edinburgh), 750 F.3d 1333, 1336 (Fed. Cir. 2014).

[252] *See* 133 S. Ct. 2107, 2111, 2118 (2013).

[253] *See id.* at 2119.

[254] *See* Burk, *supra* note 31, at 509–10; Peter Lee, *The Supreme Court's* Myriad *Effects on Scientific Research: Definitional Fluidity and the Legal Construction of Nature*, 5 U.C. IRVINE L. REV. (forthcoming 2015), *available at* http://www.law.berkeley.edu/files/Lee_Peter_IPSC_paper_2014.pdf, *archived at* http://perma.cc/VPP3-6Z95.

[255] *See, e.g.*, Chao, *supra* note 35, at 423, 436–41 (developing "a fuller point-of-novelty framework that explains when a claim has added enough to an unpatentable concept to make it patent eligible"); Collins, *supra* note 247, at 44–61 (identifying four distinct concepts that give meaning to the otherwise ambiguous phrase "unpatentable abstract idea"); Lemley et al., *supra* note 35, at 1337–46 (arguing that courts and the Patent Office should disallow patent claims that "reach too broadly and thereby threaten downstream innovation"); Strandburg, *supra* note 35, at 566 (arguing that per se exclusion of abstract ideas and natural phenomena from patentability—not preemption concerns—grounds the patentable subject matter doctrine); *see also* 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, 1307–13 (2011) (proposing a test for evaluating patentable subject matter questions that would exclude "nontechnological arts").

thermore, similar to utility and written description cases, patentable subject matter decisions have been criticized for judicial overreach and subjectivity, raising the specter of illegitimacy.[256] And even scholars who are generally sympathetic to these cases have been critical of courts' analytical approaches and advocated for improvements.[257] Although the goal to eliminate patents on "basic tools" like laws of nature may be well-intentioned, there is little satisfaction with the decisional law on patentable subject matter due to the lack of clear standards for determining what a patent claim to a basic tool looks like. As a result, the current approach runs the risk of invalidating patents that are not directed to basic tools at all.[258]

D. Summary

Across doctrines, there is an overarching concern about the patenting of upstream, research-input inventions. That concern is justifiable—the patenting of such inventions could have a particularly chilling impact on downstream research.[259] Moreover, some have argued that many such inventions would have been created even without the patent incentive.[260] Given these rationales, the general goal of eliminating socially harmful patents by prohibiting claims that qualify as foundational research inputs is sensible.[261]

Courts, however, address policy concerns with the patenting of upstream inventions in a somewhat tentative and unsystematic way. Despite judicial efforts to develop tests for identifying patent claims on research tools and intermediates, research plans, and fundamental principles, and extensive scholarly work in this area, the current state of affairs remains less than satisfying. Commentators have criticized the utility and written description requirements as anomalous and unsupported by statute, and pointed out that courts have invalidated some patents but not others using controversial jus-

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[256] *See, e.g.*, Chisum, *supra* note 37, at 961; Kresh, *supra* note 35, at 522; Oppenheimer, *supra* note 36, at 2–5; *see also* Ted Sichelman, Funk *Forward*, *in* INTELLECTUAL PROPERTY AT THE EDGE: THE CONTESTED CONTOURS OF IP 361, 370 (Rochelle Cooper Dreyfuss & Jane C. Ginsburg eds., 2014) ("[O]ne need not eliminate conventional applications of laws of nature from patentability to ensure that future innovation involving those laws is not unduly retarded."). *But see* Demaine & Fellmeth, *supra* note 224, at 360 (arguing that the patentable subject matter requirement is coherent and rooted in historical case law); Sarnoff, *supra* note 49, at 106–24 (arguing that the patentable subject matter requirement generates three efficiencies: "reduced costs of administration, reduced overall burdens on the patent system, and clearer signals that direct investment and innovation to activities that most need patent-system incentives").

[257] *See, e.g.*, Sarnoff, *supra* note 49, at 90–106.

[258] *See* Kresh, *supra* note 35, at 540; Oppenheimer, *supra* note 36, at 5. This concern appears to be borne out in recent case law. *See infra* notes 371–372 and accompanying text.

[259] *See supra* notes 96–116 and accompanying text.

[260] *See infra* notes 383–384 and accompanying text.

[261] *See supra* notes 22–23 and accompanying text.

tifications.[262] And patentable subject matter jurisprudence fails to provide any clear tests altogether, making it difficult for the doctrine to vindicate the policy goals behind completeness.

The unwritten completeness requirement pervades patent law and has real force, but its implementation has faltered. The current approach has led to a supervening requirement of patentability that has been difficult to define apart from the facts of the specific cases in which it is applied.[263] A more coherent framework for implementing the completeness requirement should replace the current approach, which relies on ad hoc tests drawn from three different doctrinal sources.[264] Proceeding on the assumption that claims directed to artifacts of basic research should be unpatentable, Part IV considers what a unified completeness requirement of patentability might look like.[265] Then, Part V challenges this assumption and introduces the concept of a limited Research Patent right for inventions that pass the existing requirements of patentability, but fail the proposed form of the completeness requirement.[266]

IV. TOWARD A UNIFIED COMPLETENESS REQUIREMENT

This Part offers a new approach that aims to address to the failure of the unwritten completeness requirement to clearly and consistently implement the policy against the patenting of basic research inputs. Section A proposes a new test to unify the completeness requirement.[267] To determine whether a patent claim satisfies completeness, this test focuses on the generality and unpredictability of the claimed invention's applications. Section B then identifies the substantive and procedural obstacles that could interfere with the test's implementation, and addresses these concerns.[268] Next, using known and hypothetical inventions as examples, Section C illustrates how courts could apply the proposed test.[269] Finally, Section D explains that

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[262] *See supra* notes 36–38 and accompanying text.

[263] *See* Collins, *supra* note 247, at 39 (criticizing the *Bilski* Court for making "a bald and unreasoned assertion" that the claims at issue, directed to a process of hedging, were patent-ineligible abstract ideas because they were like the algorithms at issue in *Benson*); *cf. Alice*, 134 S. Ct. at 2357 (holding claims invalid under § 101 because "there is no meaningful distinction between the concept of risk hedging in *Bilski* and the concept of intermediated settlement at issue here").

[264] *See supra* notes 119–123 and accompanying text (discussing the benefits of a unified completeness requirement).

[265] *See infra* notes 267–378 and accompanying text.

[266] *See infra* notes 379–460 and accompanying text.

[267] *See infra* notes 271–288 and accompanying text.

[268] *See infra* notes 289–319 and accompanying text.

[269] *See infra* notes 320–350 and accompanying text.

codifying the requirement of completeness is likely the most effective way to implement the proposal.[270]

A. The Completeness Test

The proposed test reflects the policy behind the cases that underlie the completeness requirement. But the suggested implementation of this policy differs in significant ways from that of the current doctrine. Most importantly, the test is designed to prompt courts to face the question of whether a claim has the potential to unduly preempt downstream research squarely, rather than through tests like "possession" or labels like "law of nature," "natural product," or "abstract idea."[271] Given that the completeness requirement is concerned with foundational research inputs, which can also be characterized as artifacts of basic research, this Article's approach is to look to how inventors and policymakers understand "basic research," and to attempt to fashion from this definition a test courts can use. Decisionmakers might reasonably look to such sources to operationalize the completeness requirement.[272]

Unsurprisingly, "basic research" has been difficult to define,[273] and the term can mean different things to different audiences.[274] Furthermore, although the concept of basic research is pervasive, few scholars have analyzed in detail what this concept means to various stakeholders.[275] The work

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[270] *See infra* notes 351–378 and accompanying text.

[271] *Cf.* Yu, *supra* note 36, at 913 (discussing "a nebulous notion of 'possession'"); Yu, *supra* note 35, at 418 (criticizing courts' "legalistic and semantics-based posturing" in patentable subject matter cases).

[272] *Cf.* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1715–26 (1996) (discussing the sources Congress consulted in the years leading up to the passage of the Bayh-Dole Act). To be sure, different stakeholders may have divergent interests in terms of what sort of legislation, if any, they want to see passed. *Cf. id.* (describing the "competing interests of universities and innovating firms under the Bayh-Dole Act"). Thus, one would expect a great deal of debate over the definition of basic research.

[273] *See* Calvert, *supra* note 44, at 199 (explaining that "'basic research' is a term that is often heard in science policy without much apparent consensus on what is meant by it").

[274] *See, e.g.*, 32 C.F.R. § 272.3 (2014) (national defense regulations defining "basic research" as "systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind," which "includes all scientific study and experimentation directed toward increasing fundamental knowledge and understanding in those fields of the physical, engineering, environmental, and life sciences related to long-term national security needs"); *cf.* NAT'L SCI. FOUND., *What Is Basic Research?*, *in* THE THIRD ANNUAL REPORT OF THE NATIONAL SCIENCE FOUNDATION 38, 38 (1953) ("Basic research is performed without thought of practical ends. It results in general knowledge and understanding of nature and its laws.").

[275] *See, e.g.*, BENOÎT GODIN, MEASUREMENT AND STATISTICS ON SCIENCE AND TECHNOLOGY: 1920 TO THE PRESENT 262–86 (2005); ORG. FOR ECON. CO-OPERATION AND DEV., FRASCATI

of one scholar, Jane Calvert, represents a significant attempt to develop a comprehensive definition of basic research in recent literature.[276] Calvert surveyed scientists and policymakers and identified two major ways in which they understand the term: epistemologically and intentionally.[277] The intentional definition, which holds "that it is the motivation that drives the research that distinguishes basic research from other types of research," is not suitable for a legal definition of basic research because adopting it "can mean that if the same research is done with different intentions, it is classified differently."[278] The intentional definition is simply too subjective and malleable to serve as a basis for a legal test.

In contrast, the epistemological definition of basic research is more stable and more capable of objective evaluation. According to Calvert, the epistemological features associated with basic research are generality and unpredictability.[279] Both of these factors can be useful as markers of possible effects of an upstream patent claim on future innovation. Specifically, the generality factor captures the notion that "solving a general problem will potentially help solve a wide range of other problems," and unpredictability relates to the kind of research that has the potential to result in "paradigm shifts" and "produce radical innovations."[280] This definition of basic research is unsurprising—it is consistent with courts' intuitions that certain upstream inventions have the potential to preempt broad areas of downstream inventive activity.[281] Furthermore, the generality and unpredictability factors are closely related. Inventions that have unpredictable applications might point the way to many new areas of downstream research, al-

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MANUAL: PROPOSED STANDARD PRACTICE FOR SURVEYS ON RESEARCH AND EXPERIMENTAL DEVELOPMENT 77–78 (6th ed. 2002) [hereinafter FRASCATI MANUAL] ("Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view."); Calvert, *supra* note 44, at 203–05; Charles V. Kidd, *Basic Research—Description Versus Definition*, 129 SCI. 368, 368–71 (1959).

[276] *See generally* Calvert, *supra* note 44 (surveying scientists and policymakers in an attempt to formulate an accurate definition of "basic research").

[277] *See id.* at 204.

[278] *See id.* Interestingly, the unhelpful intentional definition appears to have been dominant in the literature, at least until recently. *See, e.g.*, GODIN, *supra* note 275, at 262, 280; NAT'L SCI. FOUND., *supra* note 274, at 38; FRASCATI MANUAL, *supra* note 275, at 77. *But cf.* Kidd, *supra* note 275, at 369 (discussing "substance-centered definitions" of basic research that focus on the generality of the underlying inventions).

[279] Calvert, *supra* note 44, at 204.

[280] *See id.*

[281] *See supra* notes 182–196 and accompanying text.

lowing owners of patents on such inventions to control those areas or even shut them down.[282]

The proposed test for completeness takes into account these characteristics of basic research and addresses in a comprehensive way the policy concerns behind the completeness cases.[283] The test asks, based on claim scope and the disclosures in the specification: (1) whether the claim at issue is directed primarily to an invention that sets the foundation for future research and development—the generality factor; and (2) whether the claim has the potential to cover many unforeseeable, transformative applications—the unpredictability factor. The test would foster a fact-intensive inquiry of the sort that courts and the PTO undertake to evaluate patent claims for enablement and nonobviousness, which are ultimate questions of law that are resolved based on subsidiary facts.[284] Applying these factors, the PTO (or a court, when a claim's compliance with the completeness requirement is tested in litigation) would decide whether a claim is complete and should therefore be allowed, assuming the claim meets the other requirements of patentability. As with enablement and nonobviousness, and as is generally the case with patent validity doctrines, completeness would be assessed at the time of patent filing.[285]

Although broad claims would be a frequent target of the proposed test, narrowness of the claim would not always provide a way of escaping incompleteness. In this respect, the test borrows from the collective wisdom of the completeness cases; in some of these cases, courts have invalidated seemingly narrow claims due to their upstream nature.[286] To help understand whether patent claims, narrow or broad, comply with the requirement, the test contemplates a larger role for the disclosures in the patent specification. For example, if the specification explains what sorts of research and

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[282] *See supra* notes 110–116 and accompanying text. For illustrations of how the two factors might work in practice, see *infra* notes 320–350 and accompanying text.

[283] *See infra* notes 371–378 and accompanying text (explaining that the proposed test is best implemented through statutory change).

[284] *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415–22 (2007) (explaining that nonobviousness is a question of law based on subsidiary facts); Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1336–40 (Fed. Cir. 2013) (explaining that enablement is a question of law based on subsidiary facts).

[285] *See* Yu, *supra* note 36, at 959–60 ("One of the key tenets of enablement is that contribution to the art be evaluated at the time of filing.").

[286] *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012) (rejecting the argument that "because the particular laws of nature that [the] patent claims embody are narrow and specific, the patents should be upheld"). Claims targeted by the utility requirement can also be quite narrow. *See* Chisum, *supra* note 46, at 22 ("[T]he lack of utility depends on the facts, including the prior art and the content of the inventor's disclosure, not merely the abstract scope of the claim.").

development pathways associated with the invention are outside the scope of the patent,[287] the claims are more likely to satisfy the test because such disclosure would tend to favor the applicant with regard to the generality factor. Furthermore, if the specification shows that the invention works in predictable ways—perhaps by providing examples of well-defined approaches to implementing and applying the subject matter of the claim—the claim would likely satisfy completeness based on the unpredictability factor.[288]

The test's use of the generality and unpredictability factors sharpens the intuitions developed in the completeness cases and bolsters an important information-forcing function of patents. The specification material that might make it easier for claims to pass the completeness requirement would also apprise the public of the invention's benefits, thereby promoting licensing and technology transfer. Moreover, because the proposed approach would encourage patent applicants to reveal in the specification what areas of research the patent has left open, the patent disclosures would encourage productive design-arounds. Inventors who provide such informative disclosures would help mitigate potential harms of claims that might be unacceptably upstream and, in exchange, increase their chances of receiving a patent.

B. Implementation Issues

There are several substantive and procedural obstacles that could interfere with the implementation of the completeness test, but none are likely to be insurmountable.[289] One general objection to the proposed scheme is that patent examiners and courts will make mistakes in the application of the proposed test. Specifically, failures to predict broad downstream applicability of the claimed technology would produce erroneous completeness determinations.[290] And history provides some examples of inability (often of

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[287] *Cf.* 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, 1361 (2011) ("[T]here is much to recommend 'inventing around' as a clue to patentability.").

[288] The theory behind this information-forcing approach and an explanation of how it relates to the current disclosure doctrines will be the subject of a future article.

[289] *See infra* notes 290–319 and accompanying text.

[290] *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1050 (1997) ("Economic history provides some striking examples of inventors who grossly understated the market value of their own inventions." (citing Kathleen O'Toole, *The Future Was "Obviously Not Obvious,"* STAN. OBSERVER, June 1, 1994, at 13, *available at* http://news.stanford.edu/pr/94/940601Arc4231.html, *archived at* http://perma.cc/7UQE-82NG)). The prediction step is required because completeness would be measured at the time the patent application is filed.

the inventors themselves) to foresee that an invention would be transformative.[291]

But difficulties with identifying incomplete patents under the proposed test may not be pervasive—at least when compared to difficulties with implementing extant requirements of patentability.[292] Consider, for example, the inventions discussed in this Article—the identification of selective COX-2 inhibition that led to a new generation of painkillers,[293] the development of the PCR technique,[294] the isolation of human embryonic stem cells,[295] and the construction of the atomic force microscope.[296] For all of these inventions, the potential for numerous downstream applications was immediately clear to those in the field.[297] And there is no reason to believe

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[291] *See, e.g.*, Duffy, *supra* note 209, at 239–40 (discussing the failure to patent Georges Kohler and César Milstein's technique for producing monoclonal antibodies due to a government agency's inability to recognize the commercial potential of this technology). Even so, these researchers themselves apparently recognized the transformative nature of their invention. *See id.*

[292] Yu argues that, for many technologies, it would be impossible for anyone to foresee significant future applications. *See* Yu, *supra* note 36, at 959–60. Accordingly, he suggests that the time-of-filing rule be relaxed and, in the context of the enablement inquiry, post-filing facts be given greater weight than they have now. *See id.* at 961–62. Nonetheless, although *specific* applications might not be foreseeable, ordinary artisans may nonetheless understand that the invention may be broadly and unpredictably applicable *in general*, which is all that the proposed test requires. *See id.* at 960. Moreover, Yu's proposed approach might present other difficulties. *See infra* notes 409–414 and accompanying text (noting problems associated with ex post limitations on patent rights); *cf.* Robin C. Feldman, *The Inventor's Contribution*, 2005 UCLA J.L. & TECH. 6, ¶¶ 99–107, http://www.lawtechjournal.com/articles/2005/06_051223_Feldman.pdf, *archived at* http://perma.cc/2NQ8-MTYK (arguing that the problems associated with hindsight interpretation are "endemic to patent law" and sometimes cannot be overcome).

[293] *See* Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 917–19 (Fed. Cir. 2004); *University Awarded Historic Drug Patent*, ROCHESTER REV. (Spring–Summer 2000), http://www.rochester.edu/pr/Review/V62N3/inrev06.html, *archived at* http://perma.cc/VH5K-HLT9.

[294] *See* DENNIS W. ROSS, INTRODUCTION TO MOLECULAR MEDICINE 39–42 (3d ed. 2002); Mueller, *supra* note 63, at 13.

[295] *See* James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145, 1145–47 (1998).

[296] *See* Binnig et al., *supra* note 69, at 930–33; B. Ohler, *Perspectives on Over Twenty Years of Life Science Research with Atomic Force Microscopy and a Look Toward the Future*, 16 MICROSCOPY & MICROANALYSIS 1034, 1034 (2010) (noting that the atomic force microscope was "immediately recognized as a valuable new technique").

[297] *See* PAUL RABINOW, MAKING PCR: A STORY OF BIOTECHNOLOGY 126–27 (1996) ("There was an overwhelming response [to an early presentation on the PCR technique]. There were a lot of people who wanted to know how to do it. There were all kinds of people who were very excited about it."); Ohler, *supra* note 296, at 1034 (noting that experts predicted the atomic force microscope's "application to a wide variety of questions in the life sciences"); Thomson et al., *supra* note 295, at 1146 (explaining that human embryonic stem cells "should offer insights into developmental events [including] . . . birth defects, infertility, and pregnancy loss"); ROCHESTER REV., *supra* note 293 (predicting that the COX-2 inhibitor class of drugs "will replace aspirin and ibuprofen in the next century"). Incidentally, patents were obtained on all of these technolo-

that these four inventions are unrepresentative of others that decisionmakers may wish to prohibit patenting for reasons of incompleteness.[298] The first ESTs, for example, may not have been immediately recognized as fodder for patent "bottlenecks," but by the time the "gold rush" to patent newly discovered ESTs began, the potential for EST patents to chill downstream research became clear.[299] For software patents, a claim having broad functional language may, on its face, provide a clue that the claim is directed to a foundational input into further development and is therefore incomplete.[300] It is, of course, inevitable that the PTO and courts would make mistakes in the application of the proposed test, leading to erroneous results. Nonetheless, the contemplated completeness inquiries would probably be no more difficult for the PTO and courts to administer than the tests under other patentability requirements, like enablement and nonobviousness.[301] Furthermore, as already discussed at length, the approach that this test is intended to replace has a host of its own problems.

To avoid rejections based on incompleteness, patent applicants may be tempted to downplay the potentially transformative or widely applicable nature of their inventions, and patent examiners may fail to recognize these characteristics.[302] But the potential for PTO errors due to information asym-

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gies, though the *University of Rochester* court later invalidated the patent related to the discovery of COX-2 inhibition. *See* 358 F.3d at 929.

[298] To be sure, some patents might become widely applicable ex post. This may, for example, occur when a patent is denominated as standard-essential. *See* Josh Lerner & Jean Tirole, *Standard-Essential Patents* 5–6 (Institut d'Économie Industrielle, Working Paper No. 803, 2014), *available at* http://idei.fr/doc/wp/2014/wp_idei_803_v3.pdf, *archived at* http://perma.cc/R43C-RQ5K. There are, however, specific mechanisms—including those antitrust law provides—for dealing with these kinds of situations. In addition, contingencies related to standard-essential patents can sometimes be resolved through private ordering. *See* Mark A. Lemley & Carl Shapiro, *A Simple Approach to Setting Reasonable Royalties for Standard-Essential Patents*, 28 BERKELEY TECH. L.J. 1135, 1138–39, 1164–66 (2013). In other cases, ex post measures driven by the need for access may limit the enforceability of such patents, but I generally disfavor such measures. *See infra* notes 312–313 and accompanying text (explaining that, if the completeness requirement is adopted, decisionmakers should uphold patents on inventions that unexpectedly turn out to be foundational or transformative).

[299] *See* Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, 11 ANN. REV. GENOMICS & HUM. GENETICS 383, 400 (2010) (explaining that, although the EST patent controversy did not erupt immediately, companies rushed to the Patent Office once they had "incorporated [ESTs] into their business strategies").

[300] *See supra* note 77 and accompanying text. Expert testimony can also help identify and confirm the preemptive potential of broad functional claims.

[301] *See infra* notes 305–311 and accompanying text (outlining various causes of PTO errors that arise in the patent prosecution process and discussing doctrines that exist to remedy such errors when necessary).

[302] The patent applicant's duty to disclose to the PTO information that is relevant to patentability may somewhat alleviate the potential difficulties in the PTO's assessments of completeness. *See* 37 C.F.R. § 1.56 (2014) ("[An applicant] has a duty of candor and good faith in dealing with

metries and other challenges is a systemic issue in the ex parte patent prosecution process that affects all of the patentability requirements.[303] For example, to overcome an obviousness rejection, an applicant might submit self-serving "evidence" of unexpected results, and a PTO examiner might err by viewing that evidence as persuasive.[304] Furthermore, PTO errors are not without remedies. For example, if the PTO improvidently grants a claim in spite of incompleteness, that claim could be invalidated during post-grant review,[305] *inter partes* review,[306] or in district court litigation.[307] In cases of serious misconduct, a charge of inequitable conduct, if successful, would render the entire patent unenforceable.[308] These prospects might deter self-serving behavior and induce applicants to draft claims that would comply with the requirement. Additionally, the doctrine of prosecution disclaimer applies in litigation to applicants who asserted to the PTO that their inventions did not cover certain embodiments,[309] and courts may hold these applicants to their statements during claim construction and narrow their claims accordingly.[310] Finally, the costs of error may be small in situations where the PTO improvidently grants a patent that is incomplete, but down-

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the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability . . . ."). Industry praise and predictions of broad applicability from those in the relevant field would be the kind of information that patent applicants would have to disclose as relevant to the completeness of the pending claims. Interestingly, patent applicants might be incentivized to reveal this sort of information in some cases in order to satisfy the requirement of nonobviousness. *See, e.g.*, Apple Inc. v. Int'l Trade Comm'n, 725 F.3d 1356, 1365–67 (Fed. Cir. 2013) (explaining that industry praise can be evidence of nonobviousness).

[303] *See generally* Sean B. Seymore, *Patent Asymmetries*, 49 U.C. DAVIS L. REV. (forthcoming 2016), *available at* http://ssrn.com/abstract=2574977, *archived at* http://perma.cc/NUT7-D6C8 (arguing that proof, information, and legal asymmetries in the patent examination process favor patent applicants).

[304] *Cf. In re* Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1075 (Fed. Cir. 2012) (discussing the evidentiary value of unexpected results for proving nonobviousness).

[305] *See* 35 U.S.C. § 321 (2012).

[306] *See id.* § 311.

[307] *See id.* § 282(b)(2) (providing that patent invalidity is a defense to a suit for patent infringement).

[308] *See* Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011) (en banc) ("Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent.").

[309] *See* Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323–28 (Fed. Cir. 2003).

[310] *See id.* at 1327 (narrowing claim scope where "the patentee offered a narrower construction of the verb 'to visibly outline,'" and therefore "has clearly and unmistakably disclaimed the territory between the full ordinary meaning of the claim language and the asserted new meaning").

stream researchers do not rely on the underlying invention during the life of the patent.[311]

Measuring completeness at the time of patent filing presents its own set of challenges. For example, a patented invention could, contrary to expectations, turn out to be surprisingly foundational and transformative at some point after filing. Although some decisionmakers and commentators might argue that patents on such inventions should be invalidated or narrowed, letting the inventor reap the windfall from a patent on what unexpectedly turns out to be a basic research input is a result contemplated under the proposed scheme.[312] Upholding such a patent appears more equitable and more conducive to stable transacting and investment than ex post invalidation of the patent, which would punish the inventor for the patent's unexpectedly broad applicability.[313] Moreover, even if an invention's future success could not have been predicted at the time of patent filing, its transformative nature as determined at the time of litigation can serve as a post-filing "book of wisdom"[314] that might cast doubt on patent owners' arguments that the underlying patent's "bottleneck" quality could not have been foreseen.[315]

Although the proposed test would add administrative costs associated with the factual inquiries into whether claims at issue are directed to artifacts of basic research, these costs may be more than offset if the approach produces a greater number of outcomes consistent with the policy against the patenting of basic research inputs. In addition, there is independent value in the increased legitimacy and decreased controversy that the integrated completeness requirement might foster.[316] Indeed, the proposed test's key advance over the current approach is that it supplements judicial intuitions—some of which may well evince "foresight bias" and over-pessimism

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[311] *Cf.* Lemley, *supra* note 290, at 1050 (explaining that even inventors sometimes underestimate the value of their own inventions); O'Toole, *supra* note 290 (listing examples of researchers' failures to predict markets for their inventions).

[312] Unless, of course, the patent has taken on this role because the patentee violated some other law, breached a contract, or behaved inequitably.

[313] Interestingly, courts sometimes give such claims particularly broad scope through claim construction and the doctrine of equivalents. *See* Brian J. Love, *Interring the Pioneer Invention Doctrine*, 90 N.C. L. REV. 379, 386–94 (2012); John R. Thomas, *The Question Concerning Patent Law and Pioneer Inventions*, 10 HIGH TECH. L.J. 35, 44–45 (1995); *see also* Joshua D. Sarnoff, *The Historic and Modern Doctrines of Equivalents and Claiming the Future: Part II (1870–1952)*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 441, 454–56 (2005) (discussing the Supreme Court's expansion of claim scope for pioneering inventions).

[314] *Cf.* Dmitry Karshtedt, *Damages for Indirect Patent Infringement*, 91 WASH. U. L. REV. 911, 933–37 (2014) (discussing the "book of wisdom" concept in the context of patent damages).

[315] *Cf. id.* at 934–35 (explaining that "post-negotiation" information can help courts assess damages in infringement cases, especially when an invention's market value is unknown).

[316] *See supra* notes 34–38 and accompanying text.

about the impact of certain patents on downstream research[317]—with a structured framework for evaluating claim completeness that can be informed with expert input. Accordingly, the completeness test would provide for comprehensive and transparent evaluations of patentability based on a variety of evidence. To be sure, some cases may present circumstances in which a decisionmaker could determine that a patent claim is incomplete based only on the information in the patent itself.[318] As a general matter, however, evidence extrinsic to the patent—such as whether ordinary artisans[319] would expect the claimed invention to be broadly applicable—would be necessary to determine whether a patent claim is directed to a complete invention.

C. Representative Examples

Many of the claims that now fail utility, written description, and patentable subject matter requirements would be found invalid under the proposed completeness test.[320] After all, the policy concerns behind the results in the cases and the standalone requirement I propose are fundamentally the same. Nonetheless, besides providing a framework that may be more transparent and consistent, the completeness test would supply a more textured and principled analysis than the unsystematic approach manifested by the existing three lines of completeness cases. In this Section, I evaluate how the patents at issue in some utility, written description, and patentable subject matter cases might fare under the requirement.[321] I also examine whether some hypothetical patents might satisfy (or fail) the proposed test.

For example, a chemical compound whose only asserted utility is that of an object of unspecified future research would likely fail under the gen-

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[317] *See* Seymore, *supra* note 30, at 1122. Relevant to this point, Timothy Holbrook has criticized the Federal Circuit's enforcement of the written description requirement based on the perspective of a judge rather than an ordinary artisan. *See* Timothy R. Holbrook, *Patents, Presumptions, and Public Notice*, 96 IND. L.J. 779, 792–96 (2011) ("[T]he court has removed the [ordinary artisan] from the inquiry, notwithstanding its statements that one determines whether the written description requirement is satisfied from the perspective of [that person].").

[318] *See infra* note 336–337 and accompanying text (explaining that some functionally claimed biotechnology, software, and business method patents might fail the completeness test based on the broad language of the claim alone).

[319] An ordinary artisan, also referred to as a "person having ordinary skill in the art," is a theoretical construct, like "the reasonable person" in tort law, from whose perspective factual questions are evaluated. *See* Mark D. Janis & Timothy R. Holbrook, *Patent Law's Audience*, 97 MINN. L. REV. 72, 90, 93–100 (2012).

[320] *See infra* notes 322–350 and accompanying text.

[321] It is important to keep in mind, of course, that patent applicants would have probably drafted their claims and specifications differently had an integrated completeness requirement existed.

erality/unpredictability framework.[322] Let us consider each factor in turn. First, without knowing anything about the compound's utility, one would likely conclude that it would be widely applicable; the compound could become a cancer drug, a lubricant, or a fuel, or it could function as an intermediate for making other chemicals.[323] In other words, the claim to the compound is likely to be directed to an invention that could help solve a number of downstream problems, leading to an inference that such a claim would set the foundation for future research and development. These facts would tend to support the conclusion of incompleteness under the generality factor. Second, under the unpredictability factor, a compound whose utility is completely unknown might in the future play a role in applications that cannot be foreseen, also supporting the conclusion of incompleteness. Thus, the composition claims to chemical compounds in this hypothetical patent are likely to be found incomplete.

In contrast, a method for forming a new chemical bond in a specific structural setting might be entitled to a regular patent. A patent claim on a catalyst for coupling carbon and nitrogen atoms using a very limited set of nitrogen-containing compounds might not be incomplete because the claimed method would probably not lead to transformative and unpredictable downstream applications. Rather, the method would only lead to uses of the compounds as intermediates in connection with a particular, known class of drugs.[324] Although such an invention might set the foundation for some amount of future research, the research area to which it is drawn is so narrowly circumscribed that an ordinary artisan[325] would probably not view the claim as directed to a fundamental research input or as a major impediment to future work.

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[322] *See supra* notes 1, 11–12 and accompanying text (providing an example of a method of making such a compound).

[323] This observation might suggest that many "product" claims, such as claims to chemical compositions, may not be patentable—they would have to be limited to methods of use. Nevertheless, the proposed inquiry is fact-specific, and a fact-finder may conclude that certain chemical structures would *not* have many significant downstream applications. Although this concern in theory applies to all claims because the scope of any patent claim may expand over time, an invention's broad applicability must, under my proposed scheme, be identified with particularity and specificity for the particular claim at issue to support the conclusion of incompleteness. I thank Joshua Sarnoff for a discussion that helped clarify this point.

[324] My own graduate research might be an example of such a method. *See* Dmitry Karshtedt et al., *Platinum-Based Catalysts for the Hydroamination of Olefins with Sulfonamides and Weakly Basic Anilines*, 127 J. AM. CHEMICAL SOC'Y 12640, 12644–45 (2005) (discussing the uses of certain platinum catalysts for forming carbon-nitrogen bonds in a specific structural setting).

[325] For a discussion of the concept of an "ordinary artisan," see *supra* note 319 and accompanying text.

Of course, there will be closer cases between these two examples at the extremes. For example, where a patent reveals a utility for a chemical compound that is "specific and substantial"[326] within the meaning of the current law, but it is also known that the compound would have significant applications in other fields because of its uniquely valuable, functional structure, the underlying claim might fail the completeness requirement. But the invalidity outcome in such a case is not a given; if two different tribunals reached opposite conclusions on such a claim, courts might sustain both decisions on appeal because of the fact-specific nature of the generality and unpredictability inquiries.[327]

The claims at issue in some of the written description cases—for example, those dealing with method-of-treatment claims in patents that provide no (or very few) drug examples—are likely to be invalid under the proposed regime just as under the current one. These claims are drafted in functional terms—based on the effect of a hypothetical drug on a biological target—and thus leave open a large number of avenues for implementation.[328] Indeed, in the representative *University of Rochester* case, the "nonsteroidal" limitation in the claims is not much of a constraint, and one might predict that future researchers would find chemicals falling within the scope of the claim that have completely unexpected structures.[329] Because they threaten research and development pathways involving the synthesis and study of various drug candidates, such claims would likely fail under the completeness test absent a contrary showing of predictability of what types of drugs might work in the patent's specification.[330] The proposed test also disfavors some claims on methods of manipulating genetic material, like PCR, because an ordinary artisan would probably recognize this invention's value as a research input and could attest to its broad and transformative

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[326] *See supra* note 143 and accompanying text (defining the "specific and substantial" prong of the utility requirement).

[327] *See supra* note 284 and accompanying text.

[328] *See supra* notes 72–74 and accompanying text; *see also* AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285, 1299 (Fed. Cir. 2014) ("When a patent claims a genus using functional language to define a desired result, 'the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.'" (quoting Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc))).

[329] 358 F.3d at 918, 929.

[330] *See supra* notes 148–164 and accompanying text (explaining that the rhetoric in many written description cases signals that courts are focused on excluding unacceptably upstream inventions from patentability).

applicability.[331] Isolated human embryonic stem cells would be subject to completeness scrutiny for similar reasons.[332]

Moreover, the proposed form of the completeness requirement would direct decisionmakers to look outside the chemistry and biotechnology fields for potentially problematic claims. One possible area of application involves software (and business method) patents. As discussed above, one commentator argues that many software and business method claims are directed to a problem to be solved rather than to a solution.[333] Because of these characteristics, which resemble those of functionally drafted claims in the area of biotechnology,[334] certain software and business method claims should also be scrutinized for completeness.[335] Claims to general concepts such as the hedging of risk, unconstrained by any methods of implementation, are problematic for reasons similar to functional biotechnology claims: they cover a large number of avenues of further development, including some that might be unforeseeable and quite transformative.[336] Indeed, some claims

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[331] *See supra* note 68 and accompanying text (describing the PCR technique). There is, however, a level-of-generality problem in the background. On the one hand, PCR can be described as a method or a system for amplifying DNA. *See* Mueller, *supra* note 63, at 13. On the other hand, PCR can serve as a method of determining paternity, of finding a crime suspect to a crime scene, or of detecting a virus. *See id.* at 2. Because we are concerned with preemption of downstream applications, the completeness analysis would take into account the latter set of uses.

[332] *See supra* note 66 and accompanying text; *see also* John M. Golden, *WARF's Stem Cell Patents and Tensions Between Public and Private Sector Approaches to Research*, 38 J.L. MED. & ETHICS 314, 315 (2010) (explaining that patents on embryonic stem cells can "restrict use of materials that can serve as platforms for a whole spectrum of subsequent research"); Christopher D. Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157, 157–58 (2002) (explaining that "broad property rights covering" human embryonic stem cells "will limit exploration of the properties and potential uses" of such cells).

[333] *See* Lemley, *supra* note 26, at 907–08, 923; *supra* note 77 and accompanying text.

[334] *See Ariad*, 598 F.3d at 1353 (invalidating claims that "merely recite a description of the problem to be solved while claiming all solutions to it"); *supra* notes 228–232 and accompanying text.

[335] *But cf. supra* note 28 and accompanying text (discussing recent decisions invalidating software and business method patents under the patentable subject matter requirement); Robert Hunt & James Bessen, *The Software Patent Experiment*, BUS. REV., Q3 2004, at 27–30 (arguing that proliferation of patents in the software industry has harmed research and development).

[336] Mark Lemley provides examples of such claims in a recent article. *See* Lemley, *supra* note 26, at 920–22. In *Walker Digital, LLC v. Google, Inc.*, for example, a district court invalidated claims directed to "[a] method for operating a computer system to facilitate an exchange of identities between two anonymous parties," comprising steps such as "receiving from a first party . . . an identity for said first party; receiving from said first party . . . a rule for releasing said identity of said first party . . . [and] releasing said identity of said first party" based on whether the rule is satisfied. *See* No. 11-318-LPS, 2014 WL 4365245, at *4 (D. Del. Sept. 3, 2014) (quoting U.S. Patent No. 5,884,270 col. 23 l. 60—col. 24 l. 7 (filed Sept. 6, 1996)). The accused technologies included LinkedIn and Facebook social networking sites, which make search results available based on users' privacy settings. *See* Complaint at 7, 9, *Walker Digital*, 2014 WL 4365245 (No.

in these fields are so facially broad that they might fail the completeness requirement no matter what the specification (or an expert) might say.[337]

Scientific instruments provide another illustration of how courts and the PTO might apply the completeness requirement outside the realms of chemistry and biotechnology. Claims to some apparatus inventions, like the atomic force microscope—which would be expected to be used primarily in further research, and to have many unforeseeable downstream applications—might fail the completeness requirement.[338] Conversely, claims to apparatus inventions with narrowly defined utility, such as gold metal detectors, would probably satisfy the requirement.

Two final illustrations of how decisionmakers might apply the proposed completeness requirement are based on recent, controversial Supreme Court cases dealing with patents in life sciences fields. In one case, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Supreme Court held that claims to molecules excised from naturally occurring DNA were invalid.[339] The Court invalidated these claims because of their "focus on the genetic information encoded in the [molecules]," but, somewhat inexplicably,[340] upheld the validity of claims to non-naturally occurring DNA encoding the same information.[341] Under the proposed framework, however, both types of molecules would likely fail the completeness requirement due to the large number, variety, and unpredictability of downstream applications of the claimed genetic material.[342] The completeness analysis is agnostic

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11-318-LPS). Although the different social networking sites might have completely different algorithms for carrying out these functions, functionally drafted claims of this sort would cover all of the sites. *See* Lemley, *supra* note 26, at 923 ("[T]the point is that the claims are effectively unlimited *as a matter of structure*. The function they perform may be simple or complex, broad or narrow, but in the modern world the patent claims listed above effectively cover *any device* that performs that function in any way.").

[337] *Cf.* Lemley, *supra* note 26, at 905 ("Software patent lawyers are increasingly writing patent claims in broad functional terms. Put another way, patentees claim to own not a particular machine, or even a particular series of steps for achieving a goal, but the goal itself. The resulting overbroad patents overlap and create patent thickets.").

[338] *See supra* notes 69–70 and accompanying text; *see also supra* note 212 (arguing that atomic force microscopes have broad applicability in downstream research).

[339] *See* 133 S. Ct. 2107, 2111 (2013).

[340] *See supra* notes 253–254 and accompanying text.

[341] *See* 133 S. Ct. at 2111, 2118–19; *supra* notes 252–254 and accompanying text; *see also* Sichelman, *supra* note 256, at 378 (arguing that if "a claim to a gene could very well foreclose many avenues of research not embodied in one type of diagnostic test designed to measure the likelihood of breast cancer," then "the Supreme Court's distinction in *Myriad* between unpatentable, 'naturally occurring' genomic DNA and patentable, 'synthetic' complementary DNA seems one without much of a meaningful difference").

[342] *See, e.g.*, Andrew Chin, *Research in the Shadow of DNA Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 846, 847–48 (2005). *But cf.* Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L.

with regard to whether the previously unknown material is "natural" or not,[343] for a focus on natural-ness would threaten to undermine the utilitarian grounding of the test.[344] Rather, the inquiry focuses on the invention's developmental stage and applicability through the lens of the generality/unpredictability framework.

In contrast, the patent at issue in another recent case would probably pass the completeness test.[345] In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court held that a method enabling doctors to optimize the dosage of a drug used to treat gastrointestinal disorders was unpatentable.[346] The claims at issue were directed to administering a probe molecule along with the drug to a patient and deciding, based on the concentration of the molecule measured after the administration, whether to increase or decrease the dosage of the drug.[347] Although the Court feared that these claims would preempt all uses of the correlation between the measured concentration and the need to increase or decrease the drug's dosage, an ordinary artisan would probably disagree.[348] Indeed, it is not clear

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REV. 295, 300–03 (2007) (attempting to "dispel any perception that a patent claim reciting a human genetic sequence is equivalent to 'ownership' of a human gene"); Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. REV. 563, 596–98 (2012) (maintaining that gene patents will not substantially impede innovation); W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won't Hinder Whole Genome Sequencing and Personalized Medicine*, 33 CARDOZO L. REV. 1601, 1631 (2012) ("[I]nfringement of intellectual property is far less of a systematic and pervasive barrier to [whole genome sequencing] and personalized medicine than is generally assumed.").

[343] There is a caveat: long-standing precedent prohibits the patenting of artifacts that are identical to natural products, such as plant species discovered in the wild. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (citing Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)). The proposed completeness scheme would retain that foundational precedent, but would discard recent extensions of that precedent prohibiting isolated materials that are not "markedly different" from their natural counterparts. *See, e.g.*, *In re* BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 760–61 (Fed. Cir. 2014); *see also infra* notes 378, 447–452 and accompanying text (explaining how the proposed completeness requirement and research patent right would handle these types of patent claims).

[344] *See* Yu, *supra* note 35, at 430 (arguing that "instead of focusing on legally construed notions of what is nature and what is man-made, [the proposed] requirement focuses on articulating the costs of patents"); *see also* Devlin, *supra* note 19, at 1716–18 (arguing that patentable subject matter exclusions can be justified in utilitarian terms); *cf.* Sherkow, *supra* note 248, at 1143 (arguing for the abandonment of terms like "natural" and proposing a different test); Sichelman, *supra* note 256, at 371–72 (calling into question the Court's "ill-formed views of what constitute 'natural laws' and 'products of nature'"). *But cf.* Chiang, *supra* note 20, at 1873–76 (arguing that the justification for the result in *Myriad* might be non-utilitarian).

[345] *See Mayo*, 132 S. Ct. at 1293–94.

[346] *See id.* at 1295, 1305.

[347] *See id.* at 1295–97.

[348] *See* Dreyfuss & Evans, *supra* note 287, at 1360–61 ("[T]here are arguably other ways to achieve the goals of the [*Mayo*] patent."); Sichelman, *supra* note 256, at 376–78.

that the *Mayo* invention has many significant downstream applications, or that the claims at issue preempted all or even most of them. A downstream researcher could, for example, make use of the correlation in a study reviewing outcomes for patients to whom the drug and the probe molecule were administered without infringing the claims.[349] Furthermore, it is difficult to think of applications of the correlation that are unforeseeable and transformative. Thus, the proposed framework would likely produce a different result than the one the Court reached under its patentable subject matter test, which prohibits claims on "conventional" applications of abstract ideas, laws of nature, and natural phenomena.[350] In short, Prometheus's claim would be patentable under the proposed completeness test.

D. The Need for Implementation Through Statutory Change

1. Why a New Statutory Section?

Proposals for reforming the law's treatment of problematic upstream patents tend to suggest an expanded role for the existing requirements of patentability. For example, one group of scholars argues that Congress should reconceive Section 101 of the Patent Act as a backstop against overbroad claims that survive scope restrictions imposed by the enablement requirement, which is set forth in Section 112.[351] Another commentator argues that Section 101 should have the capacious role of prohibiting various types of problematic patents through one of three possible mechanisms: (1) expanding the definition of "basic tools of scientific and technological work"; (2) serving as a basis for distinguishing inventions and discoveries; and (3) serving as a basis for distinguishing technological from nontechnological innovations.[352] And yet another scholar proposes that the concern about research preemption that courts currently address under the utility requirement should be dealt with through the enablement and nonobviousness requirements.[353] Similarly, it may be possible to implement the completeness requirement under one of the extant patentability require-

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[349] *Cf.* Dreyfuss & Evans, *supra* note 287, at 1361 (explaining that future researchers could "invent around" the patented method in *Mayo* with relative ease). *But see* Note, *supra* note 109, at 1386–87 (arguing that the patent at issue in *Mayo* was harmful to downstream innovation).

[350] *See supra* notes 249–250 and accompanying text (criticizing the Court for failing to clarify where the line falls between "conventional" and "inventive" applications).

[351] *See* Lemley et al., *supra* note 35, 1337–46.

[352] *See* Yu, *supra* note 35, at 427–37.

[353] *See* Seymore, *supra* note 30, at 1122.

ments—for example, enablement or patentable subject matter. Nonetheless, such an approach might have significant drawbacks.[354]

Despite the enablement requirement's focus on overclaiming,[355] several factors make it a less than ideal fit for enforcing completeness. The enablement requirement attempts to answer, based on a number of factors, whether an ordinary artisan could practice the full scope of the claim based on the disclosures in the specification without undue experimentation at the time of patent filing.[356] The timing aspect of the requirement generally means that claims can cover after-arising technology without an enablement violation.[357] Thus, although the enablement requirement helps ensure that there is a reasonable correlation between what is disclosed and claimed,[358] it is not explicitly concerned with the research-input nature of patent claims and their impact on downstream research—a concern shared by utility, writ-

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[354] *See infra* notes 355–366 and accompanying text. In addition to the drawbacks discussed in the paragraphs that follow, attempts at course correction by courts themselves might challenge the institutional competence of the judiciary, and therefore might be better left for Congress. *See* John R. Thomas, *Statutory Subject Matter in Context: Lessons in Patent Governance from* Bilski v. Kappos, 15 LEWIS & CLARK L. REV. 133, 151 (2011) (arguing that Congress is better positioned to change the contours of patentable subject matter than courts because, among other reasons, "[t]he legislative decision-making process may better reflect the views of a wide range of stakeholders and offers the advantage of enhanced democratic accountability," and because "Congress is . . . better able to address patent law reform holistically, rather than in a piecemeal fashion by raising questions in rehearing orders"). John Thomas concludes:

> In *Bilski v. Kappos*, the Supreme Court . . . [said] as little as possible about the patent law doctrine of statutory subject matter. The Court's opinions offer more significant lessons concerning patent law institutions and the process of law reform. *Bilski v. Kappos* refutes claims that the preferred course is for Congress to defer to the judiciary to address longstanding concerns about the operation of the U.S. patent system. Although proposed reforms to the U.S. law of statutory subject matter have not yet taken center stage in congressional deliberations to date, they may in days soon to come—and ultimately may prove the driver of a long-deferred overhaul of the U.S. Patent Act of 1952.

Id. But see Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 102–03 (2010) (arguing that the judiciary is better positioned than Congress to address patentable subject matter issues in part because of the threat of industry capture).

[355] *See In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (holding that the enablement requirement mandates a "reasonable correlation" between what is claimed and what is disclosed in the patent). *See generally* Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1083 (2009) (contending that three rules guide the Federal Circuit's application of the enablement doctrine, and that all three rules help restrict claim scope with respect to some types of after-arising technologies).

[356] *See In re* Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988). In contrast, the completeness requirement in the form that I propose focuses in part on predicting at the time of filing whether a large number of after-arising technologies will fall within the scope of the claim.

[357] *See* Collins, *supra* note 355, at 1086; Collins, *supra* note 219, at 510 n.65; Lemley et al., *supra* note 35, at 1330–32.

[358] *See* Collins, *supra* note 355, at 1089.

ten description, and patentable subject matter cases. Moreover, these three doctrines exist in part because, even if the claims at issue were enabled under the undue experimentation test, there is still a problem because of the upstream, basic-research nature of the claimed inventions.[359] In contrast, a claim might be invalidated or rejected for lack of enablement even when the claimed invention is not so upstream and transformative as to be considered an artifact of basic research.[360] The enablement requirement is best left alone to play its current role.

Giving an expanded role to Section 101 may not effectively implement the goals of completeness either. Patentable subject matter jurisprudence is already highly controversial and carries with it a great deal of baggage that would be challenging for courts to leave behind. In addition, it would be difficult to square the language of the statute, which allows a patent on any "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,"[361] with a prohibition of patents on tangible entities such as an atomic force microscope or a chemical compound, which are probable outcomes under the proposed scheme.[362] Two other potential textual hooks for completeness in Section 101 are the words "new" and "useful."[363] Neither term, however, would be an adequate source of the prohibition against the patenting of basic research. Although some scholars have relied on the word "new" to support a distinction between patentable "inventions" and unpatentable "discoveries,"[364] I have already rejected this distinction in this Article in favor of a general utilitarian test for basic research.[365] And, as already discussed in the context of the utility requirement, reliance on the word

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[359] *Cf.* Lemley et al., *supra* note 35, at 1330–32 (explaining that because the enablement requirement does not bar patent claims that "will foreclose later-developed technology," courts must rely on § 101 to exclude patents on broadly claimed inventions).

[360] *See, e.g.*, Sitrick v. Dreamworks, LLC, 516 F.3d 993, 1002–03 (Fed. Cir. 2008) (invalidating claims directed to integrating a user's audio signal or visual image into a pre-existing video game or movie for lack of enablement).

[361] *See* 35 U.S.C. § 101 (2012).

[362] *Cf.* CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1314 (Fed. Cir. 2013) (en banc) (Moore, J., dissenting in part) ("How can [a] system, with its first party device, data storage unit, second party device, computer, and communications controller, be an 'abstract idea'?"), *aff'd*, 134 S. Ct. 2347 (2014).

[363] *See id.*

[364] *See, e.g.*, Demaine & Fellmeth, *supra* note 224, at 346–49 (arguing that "courts have interpreted the requirement of newness as excluding from patentable subject matter certain discoveries that lack invention"); Yu, *supra* note 35, at 431–33 (suggesting that "Ariad's method" is an unpatentable discovery because it "provides no *new* biochemical pathways . . . and produces no *new* effects in the human body" (emphasis added)).

[365] To be sure, certain discoveries that are pure natural phenomena and products of nature will remain unpatentable even under the proposed approach. *See infra* notes 447–452 and accompanying text.

"useful" comes with its own problems. In particular, a prohibition on patents on inventions that have research utility reflects a highly controversial interpretation of "useful."[366] Thus, an approach that attempts to leverage this word would not resolve legitimacy problems associated with the current implementation of the completeness requirement.

More fundamentally, it would not be appropriate to anchor the proposed completeness requirement in an existing requirement of patentability because completeness draws its doctrinal and intellectual parentage from three distinct statutory sources. None of them is more important than the other two, and, although all three lines of cases answer to the same policy justifications, none by itself fully captures the overarching notion of completeness. Instead, the proposed requirement is a blend that incorporates the concerns animating these cases—claim overbreadth, the sense that basic research should be unpatentable, and the policy of unfettered access to certain fundamental ideas and tools.

The completeness insight, to be sure, helps explain why requirements as seemingly different as patentable subject matter and utility are drawn from the same section of the Patent Act,[367] and why certain written description cases call to mind Section 101's concern about natural phenomena and cite a case on utility.[368] But Section 101 as it currently stands has already been stretched to (and perhaps past) its limit and, in any event, the Supreme Court has recently declined to implement a scholarly suggestion to reorient its patentable subject matter jurisprudence so that it more clearly serves utilitarian goals.[369] A codified completeness requirement may stand a better chance of providing a sensible, vigorous, and legitimate mechanism for dealing with patents on basic research inputs.

2. The Plausibility and Form of Codification

The proposal for a statutory completeness requirement brings with it its own difficulties. An obvious one is the challenge of getting the proposal through Congress. Given the current focus on procedural rather than sub-

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[366] *See supra* notes 201–227 and accompanying text.

[367] *Cf.* John M. Golden, Flook *Says One Thing,* Diehr *Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1765, 1768 (2014) (arguing that the Federal Circuit's patentable subject matter jurisprudence between 1998 and 2008 centered on "an inquiry that could be hard to distinguish from the requirement that a patentable invention be useful").

[368] *See supra* notes 93, 157–164 and accompanying text.

[369] Sichelman, *supra* note 256, at 374–77 (arguing that the *Mayo* Court attempted, but ultimately failed, to ground its opinion in the scope theory of patentable subject matter developed by Lemley, Risch, Sichelman, and Wagner) (citing *Mayo*, 132 S. Ct. at 1301–02 (citing Lemley et al., *supra* note 35)).

stantive patent reform, this sort of a change seems unlikely in the near future.[370] Nevertheless, recent developments in the completeness doctrine—particularly patentable subject matter cases—have become a cause for concern.[371] Depending upon how they are applied by the lower courts and the PTO, these cases might effectively eliminate certain types of diagnostic patents, patents on chemicals isolated from natural sources, and software and business method patents on inventions that might not necessarily be directed to foundational research inputs.[372] If a consensus develops that these developments are unsatisfactory—but a rule barring patents that are harmful from the research preemption perspective is still required—codification of the completeness requirement may become a possibility.[373] Indeed, although completeness reflects crucially important policies, courts' current implementation of this requirement may be nearing its "flash of genius" moment,[374] and codification and course correction might be in order. In addition, as already suggested, codification would help reduce legitimacy costs associated with the current implementation of the completeness requirement.[375]

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[370] *See* ANDREW S. BALUCH, PATENT REFORM 2015: A COMPREHENSIVE GUIDE TO CURRENT PATENT REFORM DEVELOPMENTS IN CONGRESS, THE EXECUTIVE BRANCH, THE COURTS AND THE STATES 3–33 (2015), *available at* http://ssrn.com/abstract=2414306, *archived at* http://perma.cc/4XZS-N497.

[371] *See, e.g.*, Holman, *supra* note 244, at 677–78 (warning that "a stringent application of *Mayo* . . . could substantially impact the availability of effective patent protection for molecular diagnostics and personalized medicine"); Christopher M. Holman, *Patent Eligibility Post-*Myriad*: A Reinvigorated Judicial Wildcard of Uncertain Effect*, 82 GEO. WASH. L. REV. 1796, 1812–23 (2014); Laura W. Smalley, *Will Nanotechnology Products Be Impacted by the Federal Courts' "Product of Nature" Exception to Subject-Matter Eligibility Under 35 U.S.C. 101?*, 13 J. MARSHALL REV. INTELL. PROP. L. 397, 437–43 (2014) (explaining that the *Mayo* and *Myriad* cases may weaken "patent protections for biotechnology inventions" and threaten companies' ability to secure venture capital financing).

[372] *Cf.* Planet Bingo, LLC v. VKGS LLC, 576 F. App'x 1005, 1009 (Fed. Cir. 2014) (invalidating patents for managing the game of bingo); *In re* Roslin Inst. (Edinburgh), 750 F.3d 1333, 1339 (Fed. Cir. 2014) (rejecting patent claims to a cloned animal); PerkinElmer, Inc. v. Intema Ltd., 496 F. App'x 65, 73 (Fed. Cir. 2012) (invalidating a patent on screening methods for estimating the risk of fetal Down syndrome); McRO, Inc. v. Activision Pub., Inc., No. CV 14-336-GW(FFMx), 2014 WL 4759953, at *12 (C.D. Cal. Sept. 22, 2014) (invalidating claims to methods of automatically animating lip synchronization of cartoon characters), *appeal docketed*, No. 2015-1080 (Fed. Cir. Oct. 27, 2014); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 19 F. Supp. 3d 938, 954 (N.D. Cal. 2013) (invalidating claims to methods of performing prenatal diagnoses), *appeal docketed*, No. 2014-1139 (Fed. Cir. Dec. 4, 2013); Sichelman, *supra* note 256, at 372 (arguing that "gatekeeping rules often take on a life of their own, continually removing themselves with each additional judicial opinion or agency interpretation from their fundamental purposes").

[373] *See, e.g.*, Paul R. Michel, *The Supreme Court Saps Patent Certainty*, 82 GEO. WASH. L. REV. 1751, 1756 (2014) ("Maybe there will be Congressional intervention on § 101.").

[374] *See supra* note 41 and accompanying text.

[375] *See supra* notes 208, 256 and accompanying text. For other suggestions for statutory changes in response to the developing law of § 101, see generally Robert R. Sachs, *Twenty-Two*

The completeness requirement, as codified, could provide in a new section (or subsection, say, 35 U.S.C. § 112(g)(1)) that "basic research shall be unpatentable." The generality/unpredictability framework introduced in Section A of this Part provides one way to implement the requirement and might itself be codified. Alternatively, policymakers might develop a different test that evaluates whether a claim is directed to a foundational research input. In addition, just as the codified nonobviousness requirement abrogated the "flash of genius" test with the statement that "[p]atentability shall not be negated by the manner in which the invention was made,"[376] the proposed statutory change could include abrogation of the holdings of cases that gave rise to the current completeness doctrine. Thus, subsection (g)(2) could provide:

> A patent claim shall not be denied solely on the basis that the claimed invention has only general research utility. A patent claim shall not be denied solely on the basis that the specification does not provide a sufficient number of structures for carrying out the claimed result, unless drafted in means-plus-function format.[377] A patent claim should not be denied solely on the basis that it is not directed to an inventive application of, or is not markedly different from, a law or a product of nature, a natural phenomenon, or an abstract idea.[378]

Ways Congress Can Save Section 101, *BILSKI* BLOG (Feb. 12, 2015), http://www.bilskiblog.com/blog/2015/02/twenty-two-ways-congress-can-save-section-101.html, *archived at* http://perma.cc/MG7J-ECAG.

[376] *See* 35 U.S.C. § 103 (2012).

[377] This proviso excludes claims that are governed by § 112(f). For these so-called "means-plus-function" claims, unlike regular claims, the statute explicitly requires structural disclosures, such as algorithms, in the specification. *See id.* § 112(f); Lemley, *supra* note 26, at 907–08. I do not propose to change this aspect of patent law.

[378] It is important to note that this language would not completely eliminate the utility, written description, and patentable subject matter requirements. The utility requirement would still bar patents on inventions lacking in operable or credible utility. *See infra note* 143. The written description requirement would continue to play the so-called "priority-policing" function. *See infra* note 186. And the patentable subject matter requirement would still bar patents on pure laws of nature, natural phenomena, and abstract ideas—though this issue can present difficult line-drawing problems. *See infra* notes 447–452 and accompanying text (discussing some difficulties with this approach); *see also supra* notes 246–248 (discussing courts' struggles with defining standards for determining what claims are directed to laws of nature, natural phenomena, and abstract ideas). The proposed approach deals with some of these challenges by eliminating the "inventive application" and "markedly different" tests and, more importantly, by reducing the pressure on the patentable subject matter doctrine to do the work of trying to eliminate large numbers of unduly preemptive patents. *See supra* note 196 and accompanying text.

The purpose of this statutory structure is to help replace current approaches to completeness with a unified solution to the problem of undue preemption of downstream research. It is of course possible that, in the course of implementing the new completeness requirement, courts might revert to some of the discarded tests as they attempt to determine what qualifies as a foundational research input. Furthermore, the proposed requirement leaves room for technology-specific standards developed by the cases, which may be appropriate in some scenarios. Nonetheless, the new statutory sections, along with the generality/unpredictability framework suggested for their implementation, would lead to fresh approaches. In addition, with the completeness requirement having been unified under a single statutory provision, precedent would apply to all types of upstream patents. As a result, a more coherent body of law governing these sorts of patent claims would likely develop.

V. THE RESEARCH PATENT PROPOSAL

This Part explores the possibility of awarding a limited patent right to certain upstream inventions. Section A challenges the assumption underlying Part IV: that artifacts of basic research should be unpatentable.[379] It also weighs the competing policies of preventing undue preemption of downstream innovation and incentivizing basic research. Next, Section B examines prior proposals for limiting patent rights in upstream inventions.[380] Finally, Section C proposes a limited bundle of rights for patents that pass the extant requirements of patentability, but fail completeness.[381] This suggestion stems from the intuition that if owners of certain upstream patents wield an undue degree of preemption, then the logical solution appears to be to weaken the available remedy until the patentee receives some smaller amount of preemption.

A. Do Limited Rights for Incomplete Patents Make Sense?

The undue preemption concern arises for many reasons. First, as discussed extensively in the Article, upstream patents might chill downstream innovation.[382] Second, non-patent mechanisms may incentivize creation and commercialization of upstream inventions.[383] These mechanisms include

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[379] *See infra* notes 382–400 and accompanying text.

[380] *See infra* notes 402–417 and accompanying text.

[381] *See infra* notes 418–460 and accompanying text.

[382] *See supra* notes 96–116 and accompanying text.

[383] *See* Lisa Larrimore Ouellette, *Patentable Subject Matter and Non-Patent Innovation Incentives*, 5 U.C. IRVINE L. REV. (forthcoming 2015), *available at* http://ssrn.com/abstract=2499204,

professional advancement and reputational gains, governmental and non-governmental support for basic research in the form of grants, tax incentives, regulatory exclusivities, and others.[384] Yet it is difficult to make the case that the right amount of intellectual property protection for such inventions is zero.[385] And even though narrower patent claims can provide adequate patent protection for some inventions,[386] there are circumstances where such claims would not be of much value.[387]

Given the concern with granting full patent rights to upstream inventions, another logical alternative is a limited right in such inventions. Nonetheless, for a given patent claim, the PTO (or a court) can either allow a full patent right or entirely reject (or invalidate) the claim; there is no middle ground under the current regime.[388] The absence of ex ante mechanisms for modulating remedies for successful enforcement of patents generates uni-

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archived at http://perma.cc/MCP3-848U. *See generally* Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303 (2013) (evaluating the use of non-patent-based mechanisms, such as prizes, government grants, and tax incentives, to facilitate the production of new knowledge).

[384] *See* Ouellette, *supra* note 383.

[385] *Cf.* Howard F. Chang, *Patent Scope, Antitrust Policy, and Cumulative Innovation*, 26 RAND J. ECON. 34, 48 (1995) (arguing for patent protection of an invention that may be "a technological breakthrough in that it generates great spillovers in the form of improvements likely to be far more valuable than the basic invention itself"); Devlin, *supra* note 19, at 1718 ("Given that vast rates of intellectual and pecuniary capital may be required to successfully discover rules of nature that bear great potential value for society, the utilitarian case for patent protection would appear to be strong.").

[386] In particular, the so-called means-plus-function claim format can provide a route for narrowing some of the broader functionally drafted claims. *See supra* notes 28, 377 and accompanying text. In other cases, method-of-use or apparatus claims might provide appropriately narrow claim formats.

[387] Indeed, narrow claims often have little commercial value, and do not allow the inventor to capture any significant monetary reward from a path-breaking contribution. *See, e.g.*, Mueller, *supra* note 35, at 651 (arguing that the rule prohibiting research-plan patents "reduces incentives to invest in innovation by depriving potential patentees of the opportunity to fully benefit from their research"); Plimier, *supra* note 74, at 161 ("The written description requirement only allows very narrow patents, so narrow and easily dodged as to be almost worthless."); *cf.* Rai, *supra* note 21, at 141 ("[F]or some research tools—laboratory machines, analytical and purification methods, certain types of genetically engineered mice—the costs of invention may be fairly high. Equally important, because these research tools will, in many circumstances, be licensed not for further improvement but for the comparatively straightforward purpose of direct use, the transaction and creativity costs associated with licensing will be relatively low. Where transaction and creativity costs are low relative to invention costs, patent protection is probably desirable." (citation omitted)); Benjamin N. Roin, *Solving the Problem of New Uses* (Sept. 2014) (unpublished manuscript), *available at* http://petrieflom.law.harvard.edu/assets/publications/Roin_Solving_the_Problem_of_New_Uses.pdf, *archived at* http://perma.cc/XE47-B5UT (describing a particular type of patentable but often effectively valueless claim).

[388] To be sure, patent law does permit tailoring of rights during patent prosecution by allowing the inventor to vary the *scope* of patent claims. For a discussion of the option of narrowing claim scope, see *supra* note 386.

formity costs and is thus one of the patent system's imperfections.[389] A limited right would help reduce these costs. Thus, although full patents on upstream inventions can be socially harmful, *some form* of patent incentive—one that is less threatening to downstream research—might be appropriate for inducing their creation and commercialization.[390]

The proposition that some sort of a patent right is necessary to incentivize basic research is reasonable. For example, the absence of patent protection for upstream inventions in certain fields, such as biotechnology, is inconsistent with the goals of the Bayh-Dole Act, which Congress enacted to incentivize the technology transfer and commercialization of university inventions through patenting.[391] One of the arguments advanced in favor of Bayh-Dole was that, even if university researchers' need to publish and drive for prestige would induce the creation of upstream inventions in the absence of patent protection, firms would be uninterested in commercializing these inventions without patent coverage.[392] The Bayh-Dole regime has not, of course, escaped criticism.[393] But the theory underlying this law makes some sense for commercialization of upstream inventions in the bio-

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[389] *See* Carroll, *supra* note 51, at 871–74; *cf.* LEO KATZ, WHY THE LAW IS SO PERVERSE 145–51 (2011) (contrasting all-or-nothing results in law with intermediate or "continuized" results).

[390] *See supra* note 385 and accompanying text; *cf.* Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 395–411 (2010) (discussing the role of patents in promoting commercialization and proposing a new "commercialization" patent to incentivize the manufacture and commercial distribution of embodiments of inventions).

[391] *See* 35 U.S.C. §§ 200–211 (2012); *see also id.* § 200 ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . [and] to promote collaboration between commercial concerns and . . . universities . . . ."). The Federal Circuit in *University of Rochester v. G.D. Searle & Co.* rejected the argument that patent protection for basic research incentivizes research at universities on the basis that the policy of bringing pioneering innovations to the public does not trump the statutory requirements. *See* 358 F.3d 916, 929 (Fed. Cir. 2004). But the court's reasoning is questionable because the Federal Circuit's modern written description requirement itself appears to be an expression of public policy. *See* Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc) (stating that basic research cannot be patented without identifying a clear source of law for this proposition); *infra* notes 160–164, 238–242 and accompanying text (explaining the Federal Circuit's policy against the patenting of research inputs and other upstream inventions).

[392] *See* Lisa Larrimore Ouellette, Comment, *Addressing the Green Patent Global Deadlock Through Bayh-Dole Reform*, 119 YALE L.J. 1727, 1731 (2010) ("Patents are not needed to motivate university researchers to innovate; instead, the justification for Bayh-Dole patents is that they provide the incentive to commercialize.").

[393] *See, e.g.*, DAVID C. MOWERY ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES 183–84 (Martin Kenney & Bruce Kogut eds., 2004) (calling into question claims that the Bayh-Dole Act substantially increased the contributions of university research to the economy in the 1990s).

technology industry[394]—the very sorts of inventions that often fall victim to the completeness requirement. Finally, concerns that drive early patent filings are not limited to technologies invented in universities. The certainty a patent right provides is also a draw for commercial researchers who would like to enter into licensing agreements and otherwise disclose their inventions to potential partners.[395]

Relatedly, a limited patent right would serve as a mechanism for inducing disclosure of widely applicable inventions, which would be particularly valuable in settings where other such mechanisms, like the publication of scientific articles, are not present. Indeed, one justification for allowing upstream patents is that they "speed[] up disclosure with consequent facilitation of research."[396] Adherents of this view argue that patents on inventions early in the development chain would encourage scientists to "invent and disseminate new processes and products [that] may be vital to progress" and aid in "achieving and publicizing basic research."[397] Although patents may not always be widely read,[398] the patenting might still facilitate so-called

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[394] *See* Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611, 622–23 (2008) ("[V]alidity of commercialization theory depends a great deal on the industry in question and the particular nature of the technology. In the pharmaceutical and biotechnology industries, where coming up with an invention is only the first step down a very long road of regulatory process that can take hundreds of millions of dollars and several years, the commercialization argument makes some sense. . . . *We give the right to the university, but we do so expecting that they will transfer or exclusively license that right to a private company that will recoup the hundreds of millions of dollars they spend in clinical trials, product development, and marketing*. . . . In these industries, Bayh-Dole is probably a good thing." (emphasis added) (citations omitted)).

[395] *See* Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1, 27 (2012) ("Government or academy-funded researchers may traditionally have been willing to publish their inventions even in the absence of patents, but industry-funded researchers may be less willing or unable to do so without that security."). *But cf.* Michael J. Burstein, *Exchanging Information Without Intellectual Property*, 91 TEX. L. REV. 227, 274–82 (2012) (arguing that intellectual property rights are not always necessary for facilitating the exchange of information).

[396] *See In re* Kirk, 376 F.2d 936, 957 (C.C.P.A. 1967) (Rich, J., dissenting).

[397] *See* Brenner v. Manson, 383 U.S. 519, 539 (1966) (Harlan, J., concurring in part and dissenting in part). Several scholars have argued that patents fail at their teaching function. *See, e.g.*, Holbrook, *supra* note 35, at 136–46 ("The patent system has a number of structural flaws that inhibit the ability of a patent to perform its teaching function."); Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 641–46 (2010) (proposing reforms to improve the teaching function of patents). But patents *can* more readily aid in disseminating information by facilitating other disclosures, such as academic publications and sales of products embodying patented inventions. *See* Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 561–65 (2012) (concluding that many researchers use patents as a source of technical information); Rantanen, *supra* note 395, at 21–37 (providing examples of disclosures that would not occur in the absence of a patent system).

[398] *See* Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 21–22 (explaining that patent lawyers often advise their clients not to read patents when they begin their research process).

"peripheral" disclosures, such as communications of the underlying inventions to potential investors.[399] In addition, if the completeness test incorporates information-forcing mechanisms that would induce patentees to inform the public about the applicability of the underlying invention and suggest approaches to designing around the claims, the disclosures supporting upstream patent claims might become quite socially valuable.[400]

B. Prior Proposals for Limited Rights in Upstream Inventions

1. Ex Post Approaches

The intuition that upstream patents should be allowed—but cabined in some form—might explain proposals for ex post limitations on rights that are triggered at the point of enforcement of these patents.[401] One solution preserves the validity of upstream patents but provides for a revival of a personal "experimental use" exemption to patent infringement.[402] This approach would shield the accused infringer from liability when the claimed invention is used for certain kinds of research purposes.[403] Conceptually

[399] *See* Rantanen, *supra* note 395, at 16–21 (setting forth the peripheral disclosure theory); *cf.* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 615 (1962) ("In the absence of special legal protection, the owner cannot . . . sell information on the open market. Any one purchaser can destroy the monopoly, since he can reproduce the information at little or no cost. Thus the only effective monopoly would be the use of the information by the original possessor. This, however, will not only be socially inefficient, but also may not be of much use to the owner of the information either, since he may not be able to exploit it as effectively as others."); *supra* note 395 and accompanying text (explaining that patents facilitate the licensing of inventions).

[400] *See supra* notes 286–288 and accompanying text.

[401] For a general discussion of this issue, see generally Maureen E. Boyle, *Leaving Room for Research: The Historical Treatment of the Common Law Research Exemption in Congress and the Courts, and Its Relationship to Biotech Law and Policy*, 12 YALE J. L. & TECH. 269 (2010).

[402] The experimental use exemption is practically defunct. *See* Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) ("[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense."). *But see* 35 U.S.C. § 271(e)(1) (2012) (providing a form of experimental use defense under narrow circumstances).

[403] *See, e.g.*, Mueller, *supra* note 63, at 36–37; Strandburg, *supra* note 62, at 96–100. In addition, Katherine Strandburg suggests that there is a distinction between an accused infringer's "experimenting on" a research tool invention (i.e., figuring out how the invention works) and "experimenting with" it (i.e., using a research tool invention for further inventive development). *See* Strandburg, *supra* note 62, at 100–46. Strandburg argues that "experimenting on" should be exempt from infringement, and proposes a specialized scheme for "experimenting with" research tool patents. *See id.* at 119–21, 142–46. Strandburg's proposal entails several years of complete exclusivity for the research tool patent, followed by a period of compulsory licensing for the remainder of the patent term. *See id.* at 142–46.

related to the experimental use exemption are proposals that entail expanding the reverse doctrine of equivalents, which shields "radical improvements" of the patented technology from infringement liability,[404] and the doctrine of patent misuse, which could be deployed to render patents unenforceable when the patent owner attempts to extract "reach-through" royalties.[405] Generalizing from these proposals, one scholar argues that contextual infringement determinations based on a flexible, multifactor test inspired by the statutory fair use factors in copyright law can account for implications of technological unpredictability—such as uncertain value and applicability of upstream inventions.[406] And there is yet another existing "ex post policy lever" for curtailing patent rights that is available in patent law: courts' flexibility to award damages rather than injunctions based on whether the patent owner itself uses the technology and on the nature of the downstream use of the patent.[407]

The difficulty with ex post approaches, however, is that the rights of the parties might not be clearly established until after litigation concludes.[408]

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[404] *See* Koneru, *supra* note 203, at 663–65 (explaining that the reverse doctrine of equivalents can "confine the scope of ESTs claimed so that other ESTs to be discovered . . . can remain patentable"); Lemley, *supra* note 290, at 1010–13 ("Where the value of the improvement greatly exceeds the value of the original invention, application of the reverse doctrine of equivalents seems most likely."); Merges & Nelson, *Patent Scope*, *supra* note 99, at 865–68 ("The reverse doctrine of equivalents solves the [holdup] problem by, in effect, excusing the improver from infringement liability . . . ."); *see also* Chisum, *supra* note 46, at 24–28 (discussing deploying the doctrine of equivalents, the reverse doctrine of equivalents, and claim construction to limit the reach of some upstream patents). *See generally* Merges, *supra* note 222 (arguing that courts should expand the role of the reverse doctrine of equivalents). Although academic literature often discusses the reverse doctrine of equivalents in the context of "mutually blocking" patents, the application of the doctrine is theoretically not limited to those circumstances. *See supra* notes 213–223 and accompanying text.

[405] *See* Bayer AG v. Housey Pharm., Inc., 228 F. Supp. 2d 467, 469 (D. Del. 2002) ("Patent misuse is an equitable defense to a charge of patent infringement. The basic allegation is that the patentee has 'extend[ed] the economic benefit beyond the scope of the patent grant.'" (quoting C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998))); Feldman, *supra* note 111, at 439–49 (criticizing courts for applying antitrust rules to test for patent misuse and proposing changes to the doctrine).

[406] *See* Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 U.C. IRVINE L. REV. 265, 292–304 (2011). *See generally* Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000) (proposing a fair use defense to patent infringement).

[407] *See* Strandburg, *supra* note 406, at 277–78 ("[L]ower courts have relied on the [*eBay*] case to provide leeway to take account of the effects that patent injunctions can have on complex, interrelated technologies, particularly in dealing with nonpracticing entities."); *see also* eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 393–94 (2006) (reasoning that "the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts"). For a recent proposal for tailoring damages based on patent disclosures, see Bernard Chao, *The Infringement Continuum*, 35 CARDOZO L. REV. 1359, 1404–12 (2014).

[408] *Cf.* LAWRENCE LESSIG, FREE CULTURE: HOW BIG MEDIA USES TECHNOLOGY AND THE LAW TO LOCK DOWN CULTURE AND CONTROL CREATIVITY 99 (2004) ("The fuzzy lines of the

And the costs of figuring out ex post whether the accused infringer should be shielded by a personal defense, whether the patentee is entitled to an injunction, and what the amount of damages should be can be very high.[409] Indeed, expenses associated with patent litigation can distort patent value.[410] Although the parties can settle or choose arbitration,[411] the very threat of a patent lawsuit creates opportunities for holdup, and this affects the value of settlements and the decision whether or not to go to arbitration. Added to the mix is the unpredictability of juries, which makes the ex post approach even more unattractive.[412] And in general, as argued by one com-

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law, tied to the extraordinary liability if lines are crossed, means that the effective fair use for many types of creators is slight. The law has the right aim; practice has defeated the aim."); *id.* (discussing the ineffectiveness of the copyright fair use doctrine in protecting downstream users). For an illustration of the difficulties encountered in applying the narrow statutory experimental use provision in patent law under § 271(e)(1), compare Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1072 (Fed. Cir. 2011) (finding no statutory experimental use), with Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1359 (Fed. Cir. 2012) (finding statutory experimental use under factually similar circumstances).

[409] *Cf.*, James Bessen & Michael J. Meurer, *The Direct Costs from NPE Disputes*, 99 CORNELL L. REV. 387, 388, 404–05 (2014) (reporting the significant costs associated with patent litigation initiated by nonpracticing entities); Colleen V. Chien & Michael J. Guo, *Does the US Patent System Need a Patent Small Claims Proceeding?* (Santa Clara Univ. Sch. of Law, Working Paper No. 10-13, 2013), *available at* http://ssrn.com/abstract=2249896, *archived at* http://perma.cc/ZX3Q-UL6N (explaining that rising patent litigation costs have made it increasingly difficult for small companies to bring meritorious defenses). *But see* Greg Reilly, *Linking Patent Reform and Civil Litigation Reform*, 47 LOY. U. CHI. L.J. (forthcoming 2015), *available at* http://ssrn.com/abstract=2568443, *archived at* http://perma.cc/MVP5-XF78?type=live (proposing reforms that could make patent litigation less expensive).

[410] *See* Judge T.S. Ellis, III, Distortion of Patent Economics by Litigation Costs, Presentation at the 1999 CASRIP Summit Conference, *in* 5 CASRIP SYMP. PUB. SER.: STREAMLINING INTL'L INTELL. PROP. 22, 23 (2000) ("[B]urgeoning litigation costs have distorted patent markets by significantly discouraging potential patent challenges, hence distorting competition to a degree beyond that justified by the intrinsic strength or merit of the patent."); *see also* J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917, 952 (2011) (explaining that patent litigation "costs upwards of $15 billion per year to patentees and accused infringers"). Although patent validity can, with some restrictions, also be adjudicated under various forms of post-grant review in the PTO, this forum is not available for determining infringement liability and remedies. *Cf.* Gaia Bernstein, *The Rise of the End User in Patent Litigation*, 55 B.C. L. REV. 1443, 1448 (2014) (describing the limited scope of *inter partes* review).

[411] *See* 35 U.S.C. § 294 (2012).

[412] *See, e.g.*, FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION 161–62 (2011), *available at* www.ftc.gov/os/2011/03/110307patentreport.pdf, *archived at* http://perma.cc/4LUE-ALCB; *cf.* LESSIG, supra note 408, at 98–99 (citing unpredictability of the doctrine and potential exposure to a large amount of damages as reasons why filmmakers rarely rely on fair use defenses). *But see* Michael J. Mazzeo et al., *Explaining the "Unpredictable": An Empirical Analysis of U.S. Patent Infringement Awards*, INT'L REV. L. & ECON., Aug. 2013, at 58, 69 (concluding that "observable factors explain[] a large portion of the variation in actual patent infringement awards" and rejecting arguments that damages are unpredictable); *cf.* Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive*

mentator, "[i]ndeterminate ex post interference in proprietary rights by courts tends to inject further uncertainty into an already flawed system, to undermine efficient contractual exchange, and to endanger ex ante technological research."[413] In contrast, the proposed framework largely avoids the ex post determination of patent value of certain types of patents during litigation.[414]

2. *Sui Generis* Approaches

A few other approaches to limiting upstream inventions are worth noting. In particular, some commentators have proposed to deal with uniformity costs generated by the all-or-nothing nature of the patent right by proposing *sui generis* intellectual property protection regimes for particular subject matter. Some have suggested a shortened term for patents on upstream inventions in fields ranging from biotechnology to software,[415] while others have advocated compulsory licensing for patents on certain types of technology[416] and proposed other limits on remedies for successful enforcement

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Remedies, 97 MICH. L. REV. 985, 994–1013 (1999) (arguing that uncertainty in the type of remedy for patent infringement may be socially beneficial).

[413] Alan Devlin, *Restricting Experimental Use*, 32 HARV. J.L. & PUB POL'Y 599, 635 (2009); *see* Richard A. Epstein, *Steady the Course: Property Rights in Genetic Material*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 153, 168–79 (F. Scott Kieff ed., 2003) (highlighting problems with forced transfers of patent rights, such as compulsory licenses); *see also* Eisenberg, *Proprietary Rights*, *supra* note 97, at 225 ("[T]he case for allowing the [experimental use] defense appears weakest where the research user is essentially consuming a patented invention in an unrelated research effort—for example, by using a patented laboratory machine. To allow such a user to avoid infringement liability on the ground that the machine was used in research would eviscerate patent protection for technologies used primarily in research laboratories."); Rai, *supra* note 21, at 140–41.

[414] *Cf.* J.H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743, 1746 (2000) (proposing a "regime built on compensatory liability principles [that] could stimulate investment without chilling follow-on innovation"); J.H. Reichman, *Saving the Patent Law from Itself: Informal Remarks Concerning the Systemic Problems Afflicting Developed Intellectual Property Regimes*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, *supra* note 413, at 289, 289–303 (advocating liability rules for protecting certain classes of "subpatentable" innovations).

[415] *See* Julian David Forman, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 681–82 (2002) (proposing a shortened patent term for ESTs); Holman & Munzer, *supra* note 98, at 810–21 (proposing a shortened patent term and registration system for ESTs); *cf.* Clarisa Long, *Information Costs in Patent and Copyright*, 90 VA. L. REV. 465, 546 n.194 (2004) (listing proposals for *sui generis* forms of intellectual property protection for software). For an approach to software patent scope that can, in principle, be implemented under existing law, see Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L. REV. 1, 37–56 (2001).

[416] *See* Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 2678–90 (2001) (proposing a system of compulsory licens-

of certain types of patents.[417] Implicitly or explicitly, these proposals appear to respond to the concern that the completeness requirement in its current form may not be entirely effective at balancing the considerations in the debate over the patenting of upstream inventions. These proposals are important, but they tend by their nature to be technology-specific and limited in scope. My goal here is to sketch out a more comprehensive alternative.

C. Toward a Research Patent Right

1. Features of the Research Patent

This Section provides suggestions for the structure of a partial patent right to protect inventions that satisfy the current requirements of patentability, but fail to comply with the proposed form of the completeness requirement.[418] As one scholar explained:

> If one considers patent protection to be excessively generous in over-incentivizing ex ante innovation and imposing costly impediments to follow-on innovation, then the superior solution [to ex post limitations on patent rights] is to reduce the scope and duration of that protection ex ante through legislative fiat.[419]

The Research Patent ("RP") proposal adopts a form of this approach.[420] Assuming that limited patent protection for upstream, basic-research inventions is justified, the proposed completeness requirement could provide a vehicle for a comprehensive ex ante approach toward setting forth patent rights for such inventions. Rather than invalidate claims to these inventions, the PTO would grant a limited patent right in the form of

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ing for patents on DNA sequences); Lopez-Beverage, *supra* note 109, at 90–91 (proposing a system of compulsory licensing for patents on ESTs).

[417] *See* Cara Koss, Note, *Oysters & Oligonucleotides: Concerns and Proposals for Patenting Research Tools*, 25 CARDOZO ARTS & ENT. L.J. 747, 767–72 (2007) (proposing various *sui generis* solutions for patenting research tools); *see also* J.H. Reichman, *A Compensatory Liability Regime to Promote the Exchange of Microbial Genetic Resources for Research and Benefit Sharing*, *in* DESIGNING THE MICROBIAL RESEARCH COMMONS: PROCEEDINGS OF AN INTERNATIONAL SYMPOSIUM 43, 45–48 (Paul F. Uhlir ed., 2011) (proposing various *sui generis* solutions for patenting microbial materials and other research inputs); Michael J. Stimson, *Damages for Infringement of Research Tool Patents: The Reasonableness of Reach Through Royalties*, 2003 STAN. TECH. L. REV. 3, at ¶¶ 23–53, *available at* https://journals.law.stanford.edu/sites/default/files/stanford-technology-law-review/online/stimson-damages-for-infringement.pdf, *archived at* https://perma.cc/75E7-2UNR (proposing an approach to damages for infringement of research tool patents within the statutory reasonable royalty framework).

[418] *See infra* notes 419–460 and accompanying text.

[419] Devlin, *supra* note 413, at 634–35.

[420] The shortened patent term suggestion would be unsuitable here because the holdup problem would remain. *See supra* notes 409–414 and accompanying text.

an RP to any patent claim that meets the extant requirements of patentability, but fails the completeness requirement.

The key features of the RP right would be liability-rule protection and enforcement in a specialized tribunal, such as a patent small claims court.[421] Liability-rule protection of upstream patents makes sense because full rights in such patents appear to be associated with a high rate of market failure.[422] Because of their uncertain valuation, negotiations over upstream, basic-research patents are thought to impose high transaction costs—a classic justification for a liability-rule regime.[423]

One potential feature of the proposed system is a cap on past and future damages associated with an RP patent portfolio asserted against a given accused infringer.[424] Damages caps are a familiar feature of tort reform efforts; for example, a number of states instituted caps on compensation for pain and suffering damages (and sometimes even economic losses) due to medical malpractice.[425] Because legislatures already cap damages for phys-

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[421] Thus, the RP is distinguishable from so-called "petty" or utility-model patents in foreign jurisdictions, which are easier to obtain but generally have shorter terms than regular patents. These patents are enforceable in the same tribunals (i.e., regular courts) where parties enforce normal utility patents. *Cf.* Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. INT'L L.J. 151, 218 (1999) ("[C]urrent property rights regimes are not the answer for protecting subpatentable innovation.").

[422] *See* FELDMAN, *supra* note 93, at 126 (explaining that upstream patents may cause bargaining problems that "can affect the development of other inventions"); *see also* Rochelle Cooper Dreyfuss, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, *supra* note 413, at 195, 200 ("[A]s long as patenting continues to move upstream, it behooves us to consider interventions, such as the compulsory licensing patents of social significance, to reduce the costs associated with blocked innovation markets."); Liivak, *supra* note 110, at 1372 (explaining that research plans and abstract ideas "are too hard to price because it is too difficult to later separate out the relative contributions that produced the actual invention"). *See generally* Ben Depoorter, *Property Rules, Liability Rules and Patent Market Failure*, 1 ERASMUS L. REV. 59, 59 (2008) (arguing that liability rules can help correct patent market failures).

[423] *See* Daniel A. Crane, *Intellectual Liability*, 88 TEX. L. REV. 253, 270 (2009); *see also* Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information?*, 85 TEX. L. REV. 783, 793–97 (2007) (identifying the holdup and scope concerns that justify the use of a liability rule).

[424] This approach, of course, does not eliminate attorney's fees and costs of filing the suit in the small claims court. But because the stakes are lower and the procedure is more streamlined, these costs would probably be much lower that the costs of litigating a regular patent in district courts.

[425] *See, e.g.*, CAL. CIV. CODE § 3333.2 (West 2014) (limiting noneconomic damages from medical malpractice to $250,000); COLO. REV. STAT. § 13-64-302 (2014) (limiting noneconomic damages from medical malpractice to $300,000). Colorado also has an "umbrella" cap of $1,000,000 on the total amount of compensation that a medical malpractice plaintiff can receive in a tort suit. *Id.* § 13-64-302(b). For a summary, analysis, and criticism of malpractice cap statutes, see generally Catherine M. Sharkey, *Unintended Consequences of Medical Malpractice Damages Caps*, 80 N.Y.U. L. REV. 391 (2005).

ical injury, damages caps or scheduled damages for patent infringement also appear to be reasonable,[426] and would likely mitigate holdup problems stemming from unpredictable jury verdicts.[427] The fact that most private arrangements such as patent pools have not succeeded for many of the upstream patent types discussed in this Article underscores the potential value of a government-mandated liability-rule solution.[428]

In addition to damages caps, a specialized tribunal would be needed to reduce the threat of holdup associated with the costs of patent litigation in federal district courts.[429] One possibility is a specialized patent small claims court.[430] Supporters of recent proposals to reform the Patent Act by adding small claims proceedings maintain that this kind of a tribunal could help reduce the incidence of lawsuits intended to extract nuisance-value settlements.[431] Critics of this aspect of patent litigation reform argue that small claims court proceedings could dilute patent rights, and that requiring litigants to make use of these tribunals would violate their Seventh Amendment right to a jury trial.[432] In contrast, if a statute specifically provides for a liability rule regime that applies only to a specific set of patents at the time of their issuance, the first concern is diminished and the second is not present.

In keeping with the goal of facilitating low-cost resolutions of disputes over RPs, the tribunal would evaluate only ordinary infringement and limit

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[426] *Cf.* Samuel L. Bray, *Announcing Remedies*, 97 CORNELL L. REV. 753, 774–81 (2012) (arguing that scheduled damages reduce administrative costs and foster greater faith in the legal system by preventing major variations in damages that the public may perceive to be due to jury biases regarding the entity involved in litigation, variations among venues, and other factors that open the legal system to manipulation). On scheduled damages for physical injury, see generally Randall R. Bovbjerg et al., *Valuing Life and Limb in Tort: Scheduling "Pain and Suffering,"* 83 NW. U. L. REV. 908 (1989).

[427] *Cf.* Lemley & Shapiro, *supra* note 298, at 1156, 1165–66 (proposing a royalty arbitration system to avoid the holdup problem associated with unpredictable damages awards).

[428] *See* Scott Iyama, Comment, *The USPTO's Proposal of a Biological Research Tool Patent Doesn't Hold Water*, 57 STAN. L. REV. 1223, 1230–35 (2005) (arguing that patent pools cannot solve the problem of research tool patent thickets); Bradley J. Levang, Comment, *Evaluating the Use of Patent Pools for Biotechnology: A Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 229, 249–50 (2002) (explaining that difficulties associated with the valuation of biotechnology patents can hinder a patent pool's formation). In contrast, parties have formed patent pools and made related private arrangements, such as standard-setting organizations, in order to reduce holdup problems with standard-essential patents in fields such as telecommunications. *See* Lemley & Shapiro, *supra* note 298, at 1136.

[429] *See supra* notes 409–414 and accompanying text (describing the holdup problem).

[430] The PTO has issued a request for comments on a patent small claims court. *See* Request for Comments on a Patent Small Claims Proceeding in the United States, 77 Fed. Reg. 74,830, 74,830–31 (Dec. 18, 2012).

[431] *See* Chien & Guo, *supra* note 409.

[432] *See, e.g.*, Robert P. Greenspoon, *Is the United States Finally Ready for a Patent Small Claims Court?*, 10 MINN. J.L. SCI. & TECH. 549, 554–57 (2009).

invalidity theories to those based on patents and printed publications.[433] This approach avoids costly, discovery-intensive subjects like inequitable conduct and willfulness,[434] as well as non-prior-art invalidity.[435] Reflecting the limited nature of the RP right, the specialized tribunal would not allow claims for infringement under the doctrine of equivalents,[436] which might also add significant costs to resolution of RP disputes.[437]

2. Challenges of the Approach

The tentative RP proposal described herein is open to numerous objections.[438] One potential challenge is that the RP game is not worth the candle—that the "coarse-grained filter" solution of invalidating all incomplete patents is more effective from the utilitarian perspective.[439] Two possible difficulties associated with the RP right include determining the damages cap (or the amount of scheduled damages to be awarded) and drawing the line between inventions that would remain completely unpatentable and those that should be the subject of an RP. I briefly address these objections in the remainder of this Section.[440]

Because each patent—and each patent infringement case—is unique, scheduled damages will seldom reflect the actual value of a patent in a particular case. Differences in value among patents on various technologies, and the degree to which infringers use the technologies, are just two examples of why scheduled damages are likely to be inaccurate. Nonetheless, the scheduling approach has the advantage of sidestepping the notoriously dif-

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[433] Moreover, to encourage the limited validity challenges, tribunals would not allow claim amendments.

[434] *See* Letter from Michael Risch, Professor, Villanova Law Sch., to the U.S. Patent and Trademark Office (Mar. 9, 2013), (available at http://www.uspto.gov/ip/global/patents/comments/comments_to_us_pto_re_patent_small_claims.pdf, *archived at* https://perma.cc/87BB-XLU8?type=pdf).

[435] Notably, patent validity challenges not based on patents or printed publications are already disallowed in *inter partes* review of issued patents. *See* 35 U.S.C. § 311(b) (2012).

[436] *Cf. generally* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997) (confirming the existence of the doctrine of equivalents, but placing limits on this doctrine).

[437] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 732 (2002) ("It may be difficult to determine what is, or is not, an equivalent to a particular element of an invention.").

[438] The RP proposal will be worked out further, and objections examined in greater detail, in a separate article. Besides the objections discussed here, litigants may challenge such a system on constitutional grounds. *Cf.* Liivak, *supra* note 73, at 26–28 (arguing that there is a constitutional basis for prohibiting patents on objects of basic research). *But see generally* Schwartz & Treanor, *supra* note 193 (arguing that constitutional arguments are unlikely to prevail in the intellectual property arena).

[439] *Cf.* Golden, *supra* note 247, at 1058–74.

[440] *See infra* notes 441–460 and accompanying text.

ficult problem of litigation-forced valuation of patents by courts, which have often questioned their own competence to gauge patent damages.[441]

In addition, at least the extent of infringement might be taken into account in some way under the scheduling approach.[442] For example, damages owed for a successful claim of infringement of an RP might be limited to some amount X for a "micro entity" infringer, amount 2X for a "small entity," and 4X for a "large entity." Within these categories, the small claims adjudicator might be allowed to further adjust the amount of the award based on whether the infringer's use of the claimed invention is "maximum," "medium," or "small" according to some preset schedule.[443]

Moreover, capping or scheduling approaches shift the focus from measuring the damages for infringement by some specific defendant to rewarding the RP owner for how broadly others use the technology. And it is

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[441] *See, e.g.*, Fromson v. W. Litho Plate & Supply Co., 853 F.2d 1568, 1574 (Fed. Cir. 1988) (measuring patent damages requires "more the talents of a conjurer than those of a judge"). The valuation problem is one of the common objections to ex post compulsory licensing of issued patents. *See* Epstein, *supra* note 413, at 169–71; Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742, 1775 (2007) ("Compulsory licenses . . . require courts or other officials to engage in costly and context-dependent evaluation.").

[442] Relatedly, RP suits would follow the rules of res judicata—that is, all the available claims should be brought at once. Moreover, the plaintiff would be able to recover only once from a given user for a particular portfolio (i.e., a group of patents that are part of the same patent family or are directed to closely similar technologies).

[443] The overall approach resembles the determination of copyright royalties for song covers, but with more rigid "scheduling" awards. *Cf.* Sandra Schmieder, *Scope of Biotechnology Inventions in the United States and in Europe—Compulsory Licensing, Experimental Use and Arbitration: A Study of Patentability of DNA-Related Inventions with Special Emphasis on the Establishment of an Arbitration Based Compulsory Licensing System*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 163, 226–27 (2004) (discussing the Copyright Royalty Board). Indeed, if the scheduling approach proves unsatisfactory, the small claims court could be empowered to set the royalty for each particular invention, as is done for covers of copyrighted songs. As the experience with copyright royalty panels has shown, this system has generally functioned well and has even promoted private negotiation. *See* Daniel R. Cahoy, *Breaking Patents*, 32 MICH. J. INT'L L. 461, 498–99 (2011) ("The system has been widely criticized as unwieldy and argued to be an inappropriate conversion of a property regime to a liability-focused one. But there are some positive lessons to be learned. First, the system ensures that the rights are available for use without the problem of holdouts. Further, the existence of a defined licensing fee has enabled private negotiation to exist concurrently. The U.S. copyright office, in consultation with interested parties, determines the fee. It is actually a functional system in many respects." (citations omitted)). For a recent criticism of this regime, see Aloe Blacc, Irina D. Manta & David S. Olson, *Music Streaming Demands New Wave of Licensing Rules*, CHI. TRIB. (Apr. 3, 2015), *available at* http://www.chicagotribune.com/news/opinion/commentary/ct-jay-z-pandora-songwriters-compensation-copyright-justice-perspec-0402-20150403-story.html, *archived at* http://perma.cc/GH9Y-M4V6. Whatever one thinks of the Copyright Royalty Board and the underlying licensing scheme, the market failure problem with upstream patents is probably more acute than that with cover songs. *See supra* notes 422–428 and accompanying text. Also, patents will likely present greater valuation difficulties, which may support the sensibility of the capped (or scheduled) damages approach.

easier to quantify the *number* of infringers than the *value* of any particular infringement.[444] Indeed, the relatively small amount of recoverable damages from any individual infringer would encourage the RP owner to search out as many downstream users as possible to obtain adequate compensation.[445] This approach results in the spreading of liability as opposed to a focus on a few infringers with "deep pockets" in an effort to obtain a large amount of damages or an injunction, which is a strategy that is sometimes pursued with regular utility patents.[446] Thus, if the subject matter of the RP is broadly applicable, RP owners may recoup their research and development costs in spite of relatively low capped or scheduled damages. Finally, although investigating potential infringers before bringing an RP claim can be costly, the RP owner can likely obtain economies of scale for its pre-claim investigations after identifying the first few suspected downstream infringers and proving that they infringed.

Line-drawing between completely unpatentable inventions and those that qualify for an RP also presents difficult questions. As an initial matter, Section 101 limits patentable subject matter categories to "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[447] Thus, claims directed to subject matter outside of these prohibited categories would not be entitled even to an RP. In addition, even if a claim nominally fits into an allowable statutory category, long-standing precedent prohibits patents that are manifestly directed to[448] abstract ideas, natural laws, formulae, or natural phenomena.[449] But it

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[444] To ensure that users of RPs do not game the system, this approach would prohibit sublicensing of the right to use the RP subject matter by the infringer to another party.

[445] Indeed, "[i]f you create enough certainty in the commercial and regulatory landscape, a private market will fill in the spaces unless impeded by some other barrier." Cahoy, *supra* note 443, at 506; *see* Dreyfuss, *supra* note 422, at 202 ("Knowing that arrangements will be imposed if they do not act voluntarily, patentees are pushed to the bargaining table."). *See generally* Mark A. Lemley, *Contracting Around Liability Rules*, 100 CALIF. L. REV. 463 (2012) (explaining that, like property rules, liability rules also induce private bargaining in some circumstances).

[446] For one example, see Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd, No. 09–290, 2014 WL 1320154, at *1 (W.D. Pa. Mar. 31, 2014) (verdict of $1,169,140,271.00), *appeal docketed*, No. 2014-1492 (Fed. Cir. May 20, 2014). To be sure, this is not always the patent owner's strategy; some choose to go after numerous smaller targets and collect settlements. Nevertheless, a sophisticated patent owner with substantial resources for litigation will likely choose a target with deep pockets.

[447] 35 U.S.C. § 101 (2012).

[448] Claims that are *directed to* these artifacts are distinct from claims that are "inventive application[s]" of, or "markedly different" from, such artifacts—the tests elaborated in recent cases expanding the scope of the patentable subjectable matter exclusions. *See supra* notes 250–251 and accompanying text.

[449] An example of a claim that would fall into one of these categories is a method of calculating energy from mass—the hypothetical claim to "a method of multiplying mass by the square of the speed of light." *Cf.* Parker v. Flook, 437 U.S. 584, 595 (1978) ("[I]f a claim is directed essen-

would be difficult to decide whether a claim falls within this prohibition and should thus be excluded from patentability completely, or whether the claim is sufficiently limited so that it should qualify for an RP. To answer this question, a decisionmaker would have to identify claims to "relatively 'pure' abstract ideas, natural laws, and natural phenomena"[450]—claims that simply state a fundamental discovery and do not purport to apply it outside the realm of basic science—and differentiate them from claims that come close to appropriating such subject matter but are not actually directed to any excluded category. Although this distinction can be very challenging to make,[451] scholars have suggested approaches to identifying "embryonic" inventions that might be distinguishable from pure ideas and laws of nature.[452]

Perhaps, one way that embryonic inventions can be distinguished from pure ideas is that the former, as claimed, provide a clear roadmap for useful and specific applications in the hands of downstream researchers. Thus, some of the upstream inventions discussed in this article can: (1) be used to make new chemical compounds; (2) guide experiments for discovering valuable drugs; and (3) stimulate the development of algorithms or structures for carrying out the claimed functions. Applications of this sort should per-

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tially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory." (quoting *In re* Richman, 563 F.2d 1026, 1030 (C.C.P.A. 1977)) (internal quotations omitted)); *see also* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) ("[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity."); Brief for the United States as Amicus Curiae Supporting Neither Party at 12, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (No. 10-1150), 2011 WL 4040414, at *12 ("[A] patent that expressly claims a law of nature, physical phenomenon, or abstract idea is invalid, no matter how important the discovery."); *supra* note 86 and accompanying text (discussing unpatentable "scientific property" in early international patent regimes).

[450] *See* Sichelman, *supra* note 256, at 370.

[451] *See id.* at 363 ("[D]iscerning the line between a law of nature and an 'application' of such can be tricky in practice.").

[452] *See id.* at 370 ("Although there would be gray areas in determining what is 'pure,' since relatively few claims under such a test would possibly constitute unpatentable subject matter, there would be few 'hard cases' to resolve."); *cf.* Oren Bar-Gill & Gideon Parchomovsky, *A Marketplace for Ideas?*, 84 TEX. L. REV. 395, 402 (2005) (distinguishing between "ideas" and "embryonic inventions"). These authors do suggest treating ideas and embryonic inventions the same way—via ex post liability rule protection or an auction. *See* Bar-Gill & Parchomovsky, *supra*, at 403–12. Others have argued that different limiting principles—perhaps a prohibition on patents on "organizing human activity"—should distinguish patentable from unpatentable subject matter. *See* Collins, *supra* note 247, at 68 (quoting Bilski v. Kappos, 561 U.S. 593, 617 (2010) (Stevens, J., concurring)) (describing this approach); *cf.* Bar-Gill & Parchomovsky, *supra*, at 426 (arguing that the "make love not war" idea should not be entitled to any intellectual property protection). But this latter approach might have its own problems. *See* Robert Stoll, *Methods of Organizing Human Activities*, IP WATCHDOG (Mar. 10, 2015), http://www.ipwatchdog.com/2015/03/10/methods-of-organizing-human-activities/id=55607, *archived at* https://perma.cc/ERB5-6SJQ?type=source.

haps be sufficient to allow the invention to pass the initial hurdle of patent eligibility. Although all of these invention types may be validly viewed as upstream in the research process, they involve more than mere ideas or statements of a scientific principle.

In contrast, true hypotheses (those without any roadmap for implementation) and conjectures without a credible scientific basis should continue to be ineligible for intellectual property protection even under the proposed scheme.[453] For example, the PTO and courts can disallow such claims for lack of credible or operable utility under Section 101.[454] I do not purport to propose any changes to this area of patent law; inventions that are completely inoperative should not qualify even for limited patent protection.[455] And other requirements of patentability,[456] such as enablement,[457] novelty,[458] and nonobviousness[459] will continue to serve as backstops against

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[453] This is in contrast to claims invalidated in *University of Rochester*, for example, where the claimed invention surely had a credible scientific basis. *See* 358 F.3d at 919. Indeed, the disclosure in the Rochester patent by hypothesis provided a roadmap for finding compounds that would perform the claimed methods of treatment; without that roadmap, the claims would not have been enabled and the court would not have needed to resort to the written description doctrine. *See supra* notes 150–157 and accompanying text.

[454] *See, e.g.*, *In re* Swartz, 232 F.3d 862, 864 (Fed. Cir. 2000) (affirming the PTO's finding that the claimed process of "cold fusion" lacked operable utility); Seymore, *supra* note 143, at 1493–94.

[455] To be sure, courts may at times deploy the enablement requirement as a completeness requirement. I focus on the other three doctrines, however, because they tend to concentrate more squarely on the developmental stage of the invention rather than on an ordinary artisan's ability to practice the invention's full scope.

[456] I refer here to requirements in addition to those prohibiting the patenting of pure abstract ideas, natural laws, formulae, or natural phenomena. *See supra* notes 448–449 and accompanying text.

[457] *See supra* notes 355–360 and accompanying text.

[458] *See* Dan L. Burk, *Anticipating Patentable Subject Matter*, 65 STAN. L. REV. ONLINE 109, 111 (2013), *available at* http://www.stanfordlawreview.org/sites/default/files/online/articles/Burk_65_SLRO_109.pdf, *archived at* http://perma.cc/J52H-7UW7; *see also* Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1377–81 (Fed. Cir. 2003) (applying the doctrine of anticipation by inherency); *In re* Cruciferous Sprout Litig., 301 F.3d 1343, 1349–52 (Fed. Cir. 2002) (same).

[459] *See In re* Fisher, 421 F.3d 1365, 1382 (Fed. Cir. 2005) (Rader, J., dissenting) (suggesting that obviousness would have been the correct ground on which to reject claims to ESTs). Arguably, ESTs would have been adjudged to be obvious under the reasoning of *In re Kubin*—which, however, was decided four years after *Fisher*. *See In re* Kubin, 561 F.3d 1351, 1353–54 (Fed. Cir. 2009); Mark D. Janis, *Tuning the Obviousness Inquiry After* KSR, 7 WASH. J.L. TECH. & ARTS 335, 339–40 (2012) ("[T]he PTO [in *Fisher*] had elaborated a more robust form of the utility doctrine as a counterbalance to a toothless obviousness requirement—but, as Judge Rader recognized, this was an inferior solution. The problem, as Judge Rader saw it, was potential obviousness, and the obviousness doctrine should supply the solution. . . . In . . . *In re Kubin*, Judge Rader dealt with the obviousness standard directly, as he had been unable to do in *Fisher*." (citation omitted)); Anna Bartow Laakmann, *Restoring the Genetic Commons: A "Common Sense" Approach to Biotechnology Patents in the Wake of* KSR v. Teleflex, 14 MICH. TELECOMM. & TECH. L. REV. 43, 69–76 (2007) (explaining how the nonobviousness requirement could be used to limit up-

many socially harmful patents.[460] These requirements would ensure that RPs are awarded only to inventions that have some demonstrable technical merit and improve sufficiently upon the prior art.

CONCLUSION

Patents on upstream, basic-research inventions have created problems for the law. Courts have had difficulty developing a coherent body of doctrine for curbing such unduly preemptive patents. Concerns over upstream patenting have produced many controversial cases under the rubrics of the utility, written description, and patentable subject matter requirements—a controversy that has become particularly acute of late in patentable subject matter jurisprudence. I argue that these cases are best explained by a supervening, unwritten requirement of patentability that I call "completeness," and maintain that an explicit recognition and codification of this requirement might improve the state of patent law. In addition, I suggest the possibility of a limited patent right for inventions that pass the current requirements of patentability, but fail completeness. I justify these proposals on utilitarian grounds.

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stream patents in the biotechnology field); *cf.* Janis, *supra*, at 340–42 (explaining that the Federal Circuit's holding in *Kubin* "demonstrates that by refining the obviousness inquiry, courts can reduce the need to rely on the written description requirement").

[460] *Cf.* Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 609–35 (2008) (arguing that the patentable subject matter requirement is unnecessary because other conditions of patentability, if properly applied, can help eliminate many of the socially harmful patents targeted by that requirement).