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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, which bars patents on certain inventions whose chief value lies in their function as inputs into downstream research. The Article explains that, although it reflects the 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, creating 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 that are used to enforce it. In order to determine whether a patent claim passes this requirement, a new test is proposed that focuses on the generality and unpredictability of a claimed invention's applications. The Article further contends that an amendment to the Patent Act codifying the requirement of completeness is probably the most effective way to implement the proposal. In addition, the Article explores the possibility of awarding a limited patent right to claims that satisfy existing requirements of patentability but fail completeness. The right, herein termed "Research Patent," would provide the intellectual property incentives that are likely needed to develop and commercialize foundational inventions, but help decrease the potential for stifling downstream innovation caused by granting full patent protection to such inventions.

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I. 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. 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.[1]

Or, consider a case where biomedical investigators discover that, by interfering with the function of a certain receptor in the human body, one could 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 upset stomach, irritation, ulcers, and bleeding."[3] The discovery is highly valuable: as one commentator noted, "there is little question that this pioneering . . . work paved the way for a new generation of painkillers that would be easy on the stomach,"[4] including Celebrex. Realizing that a patent merely 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 the dosage 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. The inventors license the technology to a company, which designs a kit for optimizing the drug dosage and makes it commercially available.[5] The invention is hailed as a significant development in the treatment of inflammatory bowel disease,[6] and other researchers and doctors use the kit to make further discoveries.[7] 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.

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

[2] Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 919 (Fed. Cir. 2004).

[3] *Id.*

[4] Seth Shulman, *A Painful IP Ruling*, MIT TECH. REV. (June 1, 2003), http://www.technologyreview.com/article/401948/a-painful-ip-ruling/page/2/ ("[W]e need a patent system that distinguishes between those who would 'preempt' the future and those who actually help create it . . . .").

[5] *See* Product Description, PROMETHEUS THERAPEUTICS AND DIAGNOSTICS, http://www.prometheuslabs.com/Resources/PTM/Thiopurine_Metabolites_Product_Detail.pdf

[6] *See* Symposium Presentation, *Can We Personalize Therapy for IBD*, http://www.cag-acg.org/uploads/syllabus_ibd_symposium.pdf (Feb. 27, 2011).

[7] Troy D. Jaskowski, Christine M. Litwin & Harry R. Hill, *Analysis of Serum Antibodies in Patients Suspected of Having Inflammatory Bowel Disease*, 13 CLINICAL & VACCINE IMMUNOLOGY 655, 656 (2006), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1489548/pdf/0034-06.pdf.

All of these inventions required significant investments, constituted important scientific advances, and promoted further research and development—so it is difficult to fault the inventors for seeking valuable patent claims to protect them.[8] But courts held that none of them could be patented. 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 (e.g., as drugs) rather than to other researchers, and the Supreme Court therefore ruled that the process was not "useful" within the meaning of 35 U.S.C. § 101.[9] As to the second, the inventors did not yet know what specific drugs would reduce the inflammation, and the Court of Appeals for the Federal Circuit (Federal Circuit) held that the patent failed to provide adequate "written description" per 35 U.S.C. § 112.[10] And as to the third, the Supreme Court determined that the patent claims did not "confine their reach to particular applications of" the correlation discovered by the inventors.[11] Thus, the Court concluded, the claims could not be patented because they are directed to a law of nature—one of the judicially recognized exceptions to patent eligibility.[12]

This Article posits that the doctrines that these three cases represent are best understood as products of courts' attempts to test the patent claims at issue against the same unwritten requirement of patentability, here termed "completeness."[13] 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,[14] the invention is too foundational to qualify for a patent. Completeness is critically important because patents on artifacts of

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[8] *See* Elizabeth A. Doherty, FINNEGAN—FULL DISCLOSURE, *Biomarker and Personalized Medicine Patent Claims One Year After* Mayo v. Prometheus, http://www.finnegan.com/files/upload/Newsletters/Full_Disclosure/2013/June/FullDisclosure_Jun13_5.html (June 2013) ("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?*, 23 CITY J. (Autumn 2013), http://www.city-journal.org/2013/23_4_genetic-data.html ("[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.").

[9] Brenner v. Manson, 383 U.S. 519, 535 (1966).

[10] Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927 (Fed. Cir. 2004). 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).

[11] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1302 (2012).

[12] *Id.* at 1298.

[13] This is not to be confused with the notion of a completely conceived invention for the purpose of the on-sale bar in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 65 (1998) ("The word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.'"). In contrast, the label "completeness" as used in this Article is intended to connote inventions that are artifacts of basic research. I thank Janice Mueller for pointing out this area of potential confusion.

[14] 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 it is "written description," I use "specification" to be consistent with common usage.

basic research are thought to disserve utilitarian goals of patent law.[15] Thus, commentators contend that patent-based mechanisms for incentivizing creation and commercialization of basic research and inducing its disclosure are generally outweighed by the harmful effects of such patents on downstream innovation.[16] Accordingly, the unwritten completeness requirement appears to be[17] intended to bar patents that are likely to become "bottlenecks" that would chill further inventive activity.[18] Some courts and scholars speak of the policy of prohibiting "undue preemption"[19] of downstream research through so-called "upstream patenting."[20] But because it is sometimes difficult to measure preemption directly and to say how much preemption is due, courts try to solve the problem of upstream

[15] As we will see throughout the Article, however, the outcomes of some of the completeness cases sometimes belie the courts' utilitarian rhetoric. This disjunction is probably due in part to the difficulty of defining "basic research," an issue that is addressed extensively in the Article. *Cf. infra* notes 17 & 24 and accompanying text.

[16] *See, e.g.*, WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 306-08; STEVEN SHAVELL, FOUNDATION OF THE ECONOMIC ANALYSIS OF LAW 165 (2004); 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" in the context of utility and patentable subject matter requirements and discussing various justification for the bias). *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).

[17] *But see* Tun-Jen Chiang, *Competing Visions of Patentable Subject Matter*, 83 GEO. WASH. L. REV. (forthcoming 2015), *available at* http://ssrn.com/abstract=2469415 (suggesting that there is a strong nonutilitarian streak behind patentable subject matter exclusions, particularly in recent cases). To the extent that courts have begun to depart from patent law's utilitarian moorings in the completeness cases, this Article proposes a path for correcting this trend. *See infra* note 24 and accompanying text.

[18] I generally refer to such inventions as "upstream" inventions.

[19] *See, e.g.*, 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 . . . .").

[20] *See, e.g.* Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 106, 125-29 (1999).

patenting by applying various tests[21] that, in effect, separate patents on basic research, broadly understood,[22] from those on applied research.[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 direct decision-makers to examine whether the outcomes of certain utility, written description, and patentable subject matter cases actually reflect this policy.[24] If the ultimate goal of barring unduly preemptive patents is kept firmly in mind, courts and patent examiners could more readily identify other problematic patents of this sort that courts have nonetheless allowed—or, conversely, determine which patents have been invalidated in error. Indeed, the completeness lens might help decision-makers address the concern that, while 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 decision-makers 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

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[21] Utility asks whether an invention is "useful," Brenner v. Manson, 383 U.S. 519, 535 (1966); written description asks whether the inventor "actually invented" (or "possessed") the claimed subject matter, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351, 1355 (Fed. Cir. 2010) (en banc); and patentable subject matter asks whether the invention is "an inventive application" of a law of nature or abstract idea, Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2358 (2014) (citation omitted), or is "markedly different" from a natural product, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013) (citation omitted).

[22] In other words, a definition of "basic research" that includes inputs into further research and basic discoveries themselves. For a precise and extended definition of "basic research," as used in this Article, see *infra* Subpart V.A.

[23] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012) ("[Precedent] warn[s] us against upholding patents that claim processes that too broadly preempt the use of a natural law.") (patentable subject matter); *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.") (utility); *Ariad*, 598 F.3d at 1353 ("[C]laims to research plans . . . impose costs on downstream research, discouraging later invention.") (written description).

[24] Recent developments in the patent law suggest that courts in patentable subject matter cases, in particular, may have strayed from this policy. *See infra* note 332 and accompanying text.

[25] *See, e.g.*, Dan Burk, *The Problem of Process in Biotechnology*, 43 HOUS. L. REV. 561, 581 (2006) (arguing that the distinctions drawn by the Federal Circuit to justify the unpatentability of certain biochemical research tools as opposed to other types of research tools, such as scientific instruments, are not persuasive); *see also infra* notes 193-211 (addressing related arguments in greater detail).

[26] *See* Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905; Greg R. Vetter, *Patent Law's Unpredictability Doctrine and the Software Arts*, 76 MO. L. REV. 763 (2011). To be sure, there are some upstream

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]

To be sure, technology-specific standards in patent law are sometimes justifiable[29]—and it may well be that patents on research inputs crop up with greater frequency, or are 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 than in others when a patent claim is directed to a "bottleneck" invention, and should therefore be a target for invalidation or rejection.[30] Nevertheless, the bottom-line, utilitarian concern behind granting patents on upstream inventions is undue preemption of downstream research,[31] no matter what the field.[32] In line with this goal, the completeness

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patents in the biomedical field that have been allowed. *See infra* notes 58-59 and accompanying text.

[27] *See generally* Lemley, *supra* note 26.

[28] *See, e.g.*, *Alice*, 134 S. Ct. 2347; Ultramercial, Inc. v. Hulu, LLC, No. 2010-1544, 2014 WL 5904902 (Fed. Cir. Nov. 14, 2014); Digitech Image Techs., LLC v. Elecs. for Imaging, Inc., 758 F.3d 1344 (Fed. Cir. 2014); Walker Digital, LLC v. Google, Inc., C.A. No. 11–318–LPS, 2014 WL 4365245 (D. Del. Sept. 3, 2014). The fact that functionally drafted biotechnology claims have been invalidated under the written description requirement, while some software and business method claims having similar flaws are now being invalidated under a different requirement, further points to the ad-hoc, siloed nature of the completeness case law. *Cf. generally* Kevin Emerson Collins, *An Initial Comment on* Ariad*: Written Description and the Baseline of Patent Protection for After-Arising Technology*, 2010 PATENTLY-O PATENT L.J. 60; *see also infra* note 40 and accompanying text. 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). The means-plus-function doctrine, however, is rarely applied in practice. *See generally* Lemley, *supra* note 26.

[29] *See generally* Dan Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1185-1202 (2002); *see also* DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 95-170 (2009).

[30] The difference in the treatment of biotechnology versus software inventions has sometimes been justified on the basis that the former is an "unpredictable art," but that doctrine seems to provide only a partial answer. *See infra* notes 144-145 and accompanying text; *see also* Sean B. Seymore, *Foresight Bias in Patent Law*, 90 NOTRE DAME L. REV. (forthcoming 2015), *available at* http://ssrn.com/abstract=2397466.

[31] *See supra* note 16; *see also* Dan Burk, *The Curious Incident of the Supreme Court in* Myriad Genetics, 90 NOTRE DAME L. REV. (forthcoming 2015), *available at* http://ssrn.com/abstract=2407094, at *26 (discussing "the policy of fundamental access"). *But cf.* Chiang, *supra* note 17.

[32] *See, e.g.*, *See, e.g.*, Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1327 (Fed. Cir. 2004) (Linn, J., dissenting from the order denying rehearing en banc) ("The burden of [the Federal Circuit's] recent written description cases has fallen on the biotech industry disproportionately . . . ."); *id.* at 1327 ("In my view we have yet to articulate satisfactory standards [for enforcing the written description requirement] that can be applied to all technologies.") (Dyk, J., concurring in the order denying rehearing en banc); 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)

framework might encourage broad scrutiny of attempts to patent upstream inventions[33] and, at the same time, help courts build in limiting principles so that the cases do not sweep in inventions that are no threat to downstream research.

Another potential payoff of recognizing that completeness concerns underlie three seemingly disparate lines of doctrine is 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 that some utility, written description, and patentable subject matter

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(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 (arguing that the utility requirement reflects a bias against chemical inventions).

[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, 692 (2004); *cf.* R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341 (2004) (criticizing the Burk-Lemley thesis); R. Polk Wagner, *Exactly Backwards: Exceptionalism and the Federal Circuit*, 54 CASE W. RES. L. REV. 749 (2004) (similar).

[34] *Cf.* Kevin Emerson Collins, *The Knowledge/Embodiment Dichotomy*, 47 U.C. DAVIS L. REV. 1279, 1348-49 (2014).

[35] Given the high volume of work in these areas, I provide only a small sampling. Utility: Samantha A. Jameson, Note, *The Problems of the Utility Analysis in* Fisher *and Its Associated Policy Implications and Flaws*, 56 DUKE L.J. 311 (2006); Seymore, *supra* note 30; Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1077 (2014); *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, 1338–40 (2008). Written Description: Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 161–63 (2006); Holman, *supra* note 32; 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 (2000); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998); Harris A. Pitlick, *The Mutation on the Description Requirement Gene*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 209 (1998). Patentable subject matter: Bernard Chao, *Moderating* Mayo, 107 NW. U. L. REV. 423 (2012); Joshua Kresh, *Patent Eligibility After* Mayo*: How Did We Get Here and Where Do We Go?*, 22 FED. CIR. B.J. 521 (2013); Mark A. Lemley et al., *Life After* Bilski, 63 STAN. L. REV. 1315 (2011); Katherine J. Strandburg, *Much Ado About Preemption*, 50 HOUS. L. REV. 563 (2012); Allen K. Yu, *Within Subject Matter Eligibility—A Disease and a Cure*, 84 S. CAL. L. REV. 387 (2011). There are also some notable judicial critiques. Utility: *In re* Fisher, 421 F.3d 1365, 1380 (Rader, J., dissenting); *In re* Kirk, 376 F.2d 936, 957 (C.C.P.A. 1967) (Rich, J., dissenting). Written description: Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1361 (Fed. Cir. 2010) (en banc) (Rader, J., dissenting); Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1307, 1315-21 (Fed. Cir. 2004) (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). Patentable subject matter exclusions: CLS Bank Int'l v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1292 (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, 976 (Fed. Cir. 2008) (en banc) (Newman, J., dissenting).

cases reflect judicial subjectivity[36]—or even bias.[37] Although disagreement and criticism are not, in themselves, a sign that there is a problem, it is notable that completeness cases have been described as not merely wrong, but somehow unprincipled.[38] The project of better 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. One possible improvement is to codify the requirement so as to help bring it into line with the core policy aim of limiting undue preemption of downstream research, and to replace and streamline the multiplicity of problematic tests[39] that have been developed under its doctrinally siloed enforcement.[40] Although the functioning of the completeness requirement can, in principle, be improved by courts based on existing conditions of patentability,[41] a statutory fix may be needed because these established provisions come with a great deal of historical and doctrinal baggage.[42] Much like the requirement of nonobviousness, which was judicially created but underwent codification and a course correction in the Patent Act of 1952,[43] the completeness requirement may benefit from codification and course correction today after

[36] Kresh, *supra* note 35, at 540 ("Throughout the decades, courts have struggled with handling patent claims they disliked. Many times they have looked to the exception 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, 46 (2012); Pitlick, *supra* note 35; 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 to strike down "ad hoc, without standard, and as a matter of law claims courts do not like").

[37] *See, e.g.*, Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959, 961 (1986); Seymore, *supra* note 30.

[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.

[39] *See infra* Part IV.

[40] *Cf.* Collins, *supra* note 28, at 70 (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").

[41] *See, e.g.*, Lemley et al., *supra* note 35; Yu, *supra* note 35, at 427-45.

[42] *See infra* Part V.D.

[43] For example, the sentence "Patentability shall not be negated by the manner in which the invention was made" in 35 U.S.C. § 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.*, 314 U.S. 84, 90-91 (1941), and other similar tests. *See* Giles S. Rich, *Why and How Section 103 Came To Be*, FED. CIR. B.J. 521 (2004-2005). *But see* Graham v. John Deere Co., 383 U.S. 1, 15 n.7 (1966) (stating that "flash of creative genius" test was only "a rhetorical embellishment").

years of judicial experimentation.[44] Although imminent Congressional intervention of this sort might seem unlikely in today's political climate, this state of affairs might change if recent judicial developments in this area of patent law lead to widespread dissatisfaction.[45]

One possible statutory solution is a rule mandating that patent claims directed to objects of basic research not be allowed. Although basic research has proven difficult to define, work in the field of science studies provides one possible framework that courts can use.[46] For example, one researcher's characterization calls out 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.[47] 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 developmental stage of the claimed invention is such that the claim has the potential to cover many unforeseeable, transformative applications. Although this test would add administrative costs associated with these factual inquiries, I believe that it would also lead to significant benefits.[48]

Another, more controversial suggestion for change in patent law that might follow the recognition of an overarching requirement of completeness is the rule that patents that fail it should not be invalidated entirely but given some type of a partial patent right—for example, a limited patent that comes only with the remedy of a compulsory license. If the concern is that owners of upstream patents wield an *undue* amount of preemption, then the logical solution appears to be 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.[49] Thus, even if utilitarian considerations would suggest that upstream inventions should not be given full patent protection,[50] partial patent protection might be justifiable on these grounds.

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[44] I thank Rochelle Dreyfuss for drawing this analogy to my attention.

[45] *See infra* note 332 and accompanying text.

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

[47] *Id.* at 204.

[48] As already discussed, among them are increased focus on barring patents on inventions that are actually harmful to downstream innovation and greater transparency and legitimacy of the completeness requirement relative to its current implementation. *See supra* notes 24-38 and accompanying text. *Cf.* Donald S. Chisum, *Weeds and Seeds in the Supreme Court's Business Method Patents Decision: New Directions for Regulating Patent Scope*, 15 LEWIS & CLARK L. REV. 11, 14-15 (2011).

[49] Unless the right amount of preemption is zero, which does not appear to be true in most circumstances. As I suggest *infra* in Subpart VI.A, complete absence of patent protection for upstream invention might be problematic, and likely to result in underinvestment into important technologies and a reduced volume of valuable disclosures.

[50] *See, e.g.*, Joshua D. Sarnoff, *Patent-Eligible Inventions After* Bilski*: History and Theory*, 63 HASTINGS L.J. 53, 106-24 (2011); *see also supra* note 16 and accompanying text.

Of course, the U.S. Patent and Trademark Office (PTO) lacks the power to grant patents that come with a limited remedy. For a given claim, the PTO is faced with only two choices—grant the full patent right, or none at all. Nevertheless, the power to offer a third choice can be given with another statutory fix that creates an intermediate patent right.[51] 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.[52] The Article explores possible 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, but help decrease the potential for stifling downstream innovation caused by granting full patent protection to such inventions.

The rest of this Article proceeds as follows. Part II attempts to define upstream inventions and sets forth judicial and scholarly concerns with allowing patents on such inventions. Part III explains how the law currently deals with some of these inventions. 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 IV canvasses critiques of the completeness cases and explains that they do not consistently implement the policy that motivates the requirement. Part V proposes and justifies a test that would help address these critiques and discusses the mechanics putting the proposed form of the completeness requirement into effect, including its possible codification. 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. Part VI explores whether some form of 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, provides suggestions for the structure of a partial patent right to protect such inventions, and discusses some advantages and disadvantages of the proposal. Part VII concludes.

II. WHAT ARE UPSTREAM INVENTIONS AND WHY ARE UPSTREAM PATENTS PROBLEMATIC?

A. Categories of upstream inventions

"Upstreamness," for lack of a better word, has eluded a clear definition.[53] Several themes emerge from the cases and the literature,

[51] While the courts have the power to tailor remedies by granting or denying injunctions and awarding a higher or lower amount of damages, *see* 35 U.S.C. §§ 283, 284 (2012), when it comes to patent *validity*, they can only uphold or invalidate patent claims. *See id.* § 282. Furthermore, in Subpart VI.B, I explain that it is costly to wait until litigation to determine the value of a patent, and propose a patent right that comes with a limited remedy ex ante.

[52] The lack of intermediate solutions in patent law gives rise to what are 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, 871-75 (2006).

[53] For two approaches, 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

however. The three examples discussed in the Introduction represent three forms of inventions that courts have held to be too upstream to be patentable. 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 are potential targets of the completeness requirement.

Inventions in the first category include materials, objects, and methods whose main functions are to promote further research.[54] Such inventions have been called "research tools"[55] and "research intermediates."[56] One set of inventions falling into this general category, discussed in the Introduction, are chemical compounds not having a known consumer end use and methods of making such compounds.[57] Such chemicals might draw the interest of researchers as, for example, potential drug candidates or as building blocks that could be utilized to make larger molecules. Human embryonic stem cells exemplify another research tool invention known for its broad applicability.[58]

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opposed to patents covering 'downstream' commercial products"); David B. Resnick, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?*, 3 J. PHIL., SCI. & LAW, at n.22 (Jan. 2003), *available at* http://jpsl.org/archives/biotechnology-patent-pool-idea-whose-time-has-come ("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.").

[54] 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 and technological progress.").

[55] For other attempts to define "research tools," 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); Sarnoff & Holman, *supra* note 35, at 1302-03; Strandburg, *supra* note 54, at 123. *But see* F. Scott Kieff, *Coordination, Property, and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 EMORY L.J. 327, 109-10 (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 disagree on the meaning of "research tools" as well. *See, e.g.*, Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., dissenting) ("My colleagues on this panel appear to view the [patents-in-suit] as for a 'research tool.' That is a misdefinition. The [patented molecules] are not a 'tool' used in research, but simply new compositions having certain biological properties.").

[56] *In re* Fisher, 421 F.3d 1365, 1373 (Fed. Cir. 2005); *see also infra* notes 193-202 and accompanying text (exploring the difference between research intermediates and research tools).

[57] *See supra* note 1 and accompanying text.

[58] Mueller, *supra* note 55, at 13; *see also* Peter Yun-Hyong Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine*

Still another group of inventions commonly thought of as belonging to the research tool category relates to methods of manipulating genetic material. One such technique, called the polymerase chain reaction (PCR), enables the preparation of a large quantity of deoxyribonucleic acid (DNA)—a molecule that encodes genetic information—from a small sample. This technique has numerous applications ranging from paternity testing to the diagnosis of cancers and detection of viruses.[59] 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 resolution.[60] The atomic force microscope is viewed a building-block technology that can serve as an input into many areas of downstream research, such as nanotechnology.[61]

A second category of upstream inventions has been variously characterized as a "wish," a "research plan," or "a hypothesis."[62] Like research 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.[63] One upstream invention of this sort that was discussed in the Introduction—which some courts and commentators argue should not even be called "an invention"[64]—is a method of treating a health condition based on a newly identified biological target of drug action.[65] Although the discoverers of the target developed and described search methods for finding the drug that would treat the condition, they did not provide any examples of drugs having the capacity to do so.[66] Hence, it might be said that the

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To Constrain Patents on Biotechnology Research Tools, 19 HARV. J.L. & TECH. 79, 106-08 (2005).

[59] *See* Mueller, *supra* note 55, at 12-13 (describing patents on PCR methods).

[60] *See* Gerd Binnig, Calvin F. Quate & Christoph Gerber, *Atomic Force Microscope*, 56 PHYS. REV. LETT. 930 (1986).

[61] *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 1365, 1380 (Fed. Cir. 2005) (Rader, J., dissenting) (arguing microscopes generally are research tools that "take a researcher one step closer to identifying and understanding a previously unknown and invisible structure").

[62] *See* Michael P. Sandonato & Feng Xu, *Describing Written Description: The Implications of* Ariad, CHINA IP MAGAZINE (Sept. 19, 2010), *available at* http://www.chinaipmagazine.com/en/journal-show.asp?id=622 ("[T]he patent law is directed to the 'useful Arts,' not to research hypothesis, academic theories or scientific principles.").

[63] *See, e.g.*, Joseph Jakas, Note, *Encouraging Further Innovation:* Ariad v. Eli Lilly *and the Written Description Requirement*, 42 SETON HALL L. REV. 1287, 1325 (2012). In some cases where claims have been invalidated for lack of adequate written description, a few examples of chemical structures are provided, but not enough to support the full scope of the claim. *See, e.g.*, Boston Scientific Corp. v. Johnson & Johnson, 647 F. 3d 1353, 1364-67 (Fed. Cir. 2011).

[64] Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 930 n.10 (Fed. Cir. 2004); Oskar Liivak, *Rescuing the Invention from the Cult of the Claim*, 42 SETON HALL L. REV. 1 (2012).

[65] *See supra* notes 2-4 and accompanying text.

[66] 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 that sort of a

inventors only hypothesized a method of treatment and have not completed the invention.[67]

Research-plan inventions, too, 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 famous invention by the Wright brothers, whose key insight was that controlled flight could be achieved by modulating motion along all three axes of rotation about the flying machine's center of mass.[68] If the Wrights had not described how to actually build a plane, but only provided a roadmap for doing so using so called "three-axis control," one could argue that they have at best come up with only a research plan for achieving controlled flight using this method.[69] A more modern version of what could be described a hypothesis-type invention is a functionally claimed software or business method patent. The concern is related: some software and business method claims appear to appropriate the problem to be solved rather than any specific way of implementing a solution.[70]

Yet a third category of upstream inventions relates to the workings of the natural world and other fundamental principles. Commentators and

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patent claim would likely not be worth very much because of the large number of possible design-arounds. Although the knowledge of the drug target is extremely valuable, that invention is difficult to monetize until a drug is actually found. *See* Michael D. Plimier, Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly and Co., 13 BERKELEY TECH. L.J. 149, 161 (1998); *see also supra* notes 1-8 and accompanying text & *infra* note 341 and accompanying text.

[67] *See supra* note 64 and accompanying text.

[68] *See What Did the Wright Brothers Invent*, WRIGHT BROTHERS AIRPLANE COMPANY, http://www.wright-brothers.org/Information_Desk/Help_with_Homework/Help_with_Homework_Intro/What%20did%20the%20Wright%20brothers%20invent.pdf, at *2 ("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." (emphasis in original)). Nevertheless, the Wright Brothers patent was titled "Flying Machine" and some of the claims are directed to "[a] flying machine." U.S. Pat. No. 821,393 claims 14, 15 (filed Mar. 23, 1903) (issued May 22, 1906) ('393 patent).

[69] 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 really work well. *See* MALCOLM J. ABZUG & E. EUGENE LARRABEE, AIRPLANE STABILITY AND CONTROL 3 (2d ed. 2005) ("Modern analysis . . . demonstrated that the 1903 Wright Flyer was so unstable as to be almost unmanageable by anyone but the Wrights . . . ."). The difference from the method of treatment patent where no drug was described was that, at least, the Wright brothers at least demonstrated a "proof of principle"—that some kind of a flying machine *can* be built using three-axis control.

[70] 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 Comments of Michael Risch on Functional Claiming and Software Patents*, Docket No. PTO-P-2012-0052, http://www.uspto.gov/patents/law/comments/sw-f_risch_20130312.pdf. *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). For an example, see *infra* note 306 and accompanying text.

courts have denominated such inventions "law[s]"[71] or "products"[72] of nature, "natural phenomena,"[73] "scientific truths,"[74] "concepts,"[75] "abstract ideas,"[76] "formulas,"[77] or by some other similar label.[78] This facet of upstreamness has a rich historical pedigree, harkening back to the distinction between patentable "industrial property" and unpatentable "scientific property" in the early international patent regimes.[79] As we have seen, the Supreme Court described as directed to laws of nature patent claims "tell[ing] doctors to gather data from which they may draw an inference" that the dosage of a drug should be increased based on the concentration of a probe molecule present in the patient's blood.[80] Assuming that 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"[81] than a claim to a law of nature. Other examples in this general category include inventions as diverse as isolated human genetic material,[82] a method of communicating at a distance using electromagnetism,[83] a method of data processing,[84] and the concept of risk hedging.[85] 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 the categories are not sharp. Perhaps, some inventions in the second category really belong in the third category—or in both. For example, Robin Feldman argued that a patent adjudged by the Federal Circuit to be directed to a research-plan invention in fact "ties up a natural phenomenon,"[86] which fairly places it into the third category as well. Or, it could also be that at least some inventions in the first

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[71] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013).
[72] *Id.* at 2111.
[73] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1296 (2012).
[74] Gottschalk v. Benson, 409 U.S. 63, 67 (1972).
[75] Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010).
[76] *Id.* (citation omitted)
[77] *Id.* at 3233.
[78] *Cf.* 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."); *see* Sarnoff & Holman, *supra* note 35, at 1340-43; Yu, *supra* note 35, at 423-24.
[79] *See* Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, 13 J. SOC. PHIL. & POL'Y 145, 152-57 (1996); *see also* Thomas R. Ilosvay, *Scientific Property*, 2 AM. J. COMP. L. 178 (1953). *See generally* CHARLES J. HAMSON, PATENT RIGHTS FOR SCIENTIFIC DISCOVERIES (1930) (detailing European proposals for limited patents on "scientific property," which eventually failed).
[80] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1298 (2012); *see supra* notes 5-7 and accompanying text.
[81] Lee, *supra* note 58, at 81.
[82] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013).
[83] O'Reilly v. Morse, 56 U.S. (15 How.) 62, 112-13 (1853).
[84] Gottschalk v. Benson, 409 U.S. 63, 67 (1972).
[85] Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010).
[86] ROBIN C. FELDMAN, RETHINKING PATENT LAW 100 (2012); *see also id.* at 122.

category belong in the third category. Peter Lee described isolated human embryonic stem cells as "research tools," yet Allen Yu argued that they are also like natural phenomena because they "faithfully preserve the pluripotent properties of stem cells as found in nature."[87] And, at least in Yu's own proposals for limiting the patentability of stem cells, the categorization does not end up mattering. 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."[88] And if they are viewed as "natural phenomena," they would probably be unpatentable (again, under one of Yu's proposals) as "discoveries" rather than "inventions."[89] As the next Subpart further explains, the issues with patents on all basic research-type inventions are more or less the same no matter what the label.

B. Overarching problems with patents on upstream inventions

Patenting of inventions described in the preceding Subpart can be socially harmful because of their foundational roles in enabling further research.[90] Indeed, scholars have maintained that certain upstream patents have the potential to impose intolerable costs on downstream inventors.[91] 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.[92] The patentee might threaten litigation to enjoin the downstream research, charge an unreasonable royalty, or tie up the follow-on researcher in extensive, costly negotiations over the patent right.[93] Faced with this prospect, the follow-on researcher might decide to forgo investigating a certain type of a chemical structure during the life of the patent, which could mean that

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[87] *See* Yu, *supra* note 35, at 433.
[88] *Id.* at 428-31.
[89] *Id.* at 431, 433.
[90] In other words, because they are artifacts of basic research.
[91] *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); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998); Rai, *supra* note 20, at 116-20; Richard L. Wang, *Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties*, 10 YALE J.L. & TECH. 251, 258-61 (2007-2008); Yu, *supra* note 35, at 428 (discussing the "cost side of patenting").
[92] *See generally* ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 253-56 (4th ed. 2007). *See also* 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, 789-92 (2000).
[93] 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. BEHAVIOR & ORG. 1 (1994); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in* 1 INNOVATION POLICY AND THE ECONOMY 122–29 (Adam B. Jaffe et al. 2001).

society would lose out on promising drug candidates.[94] Similar arguments have been made about other "research tool" patents, like human embryonic stem cells.[95] 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."[96] 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."[97]

Analogous critiques have been lodged against "research-plan" patents in biotechnology,[98] functionally claimed software patents,[99] and patents on inventions that are characterized as fundamental principles.[100] To be sure, in contrast with patents on research tools and intermediates, concerns over patents on "hypotheses" and fundamental principles have often been articulated in terms of overbroad claim scope rather than in terms of the need for access.[101] 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.[102] To prevent such

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[94] BURK & LEMLEY, THE PATENT CRISIS, *supra* note 29, at 111 ("[D]eveloping new molecules 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.").

[95] *See supra* note 58 and accompanying text.

[96] Lee, *supra* note 58, at 81 (emphasis in original); *see also* Mueller, *supra* note 55, at 4 ("[T]he dispute stems from the broad rights conferred by the patents covering [PCR] tools.").

[97] Lee, *supra* note 58, at 81.

[98] *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).

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

[100] Devlin, *supra* note 16, at 1718-20; *see also id.* at 1717 ("These fields of discovery bear unique potential for overcompensation, given their upstream nature and the concomitant proclivity for ubiquitous downstream application.").

[101] Collins, *supra* note 70, at 1455-57 (describing an instance where written description doctrine was used to invalidate an overbroad software claim); 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 98, at 1261-65 (explaining that the written description doctrine plays a scope-policing function in the biotechnological arts).

[102] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1301 (2012) (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 upon them"); *see also, e.g.*, Burk, *supra* note 31, at *26 (discussing "the policy of fundamental access"); Jakas, *supra* note 63, 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 can be performed without concerns about infringement") (footnote omitted); Sampson, *supra* note 98, at 1269; Sarnoff, *supra* note 50. *But cf.* Yu, *supra*

unduly preemptive patents, commentators have either exhorted courts to apply the rules that prohibit them more stringently or praised them for already doing so.[103]

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.[104] Consider, 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.[105] Commentators fear that such licenses might permit the owner "to leverage its proprietary position in upstream research tools into a broad veto right over downstream research and product development."[106] Overbreadth and uncertainty concerns are closely related—indeed, some claims to inventions having

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note 35, at 395 (discussing indeterminacy problems with the concept of basic tools); *see also* Eisenberg, *supra* note 101, at 61-64 (similar).

[103] Utility: 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 (2005); Teresa M. Summers, Note, *The Scope of Utility in the Twenty-First Century: New Guidelines for Gene-Related Patents*, 91 GEO. L.J. 475 (2003). Written description: Jakas, *supra* note 63, at 1325 ("The written description requirement encourages inventors to finalize their inventions and pursue and end product before seeking patent protection. . . . [The] requirement seems to be a positive step towards limiting problems associated with patents in the biotechnology industry."); Sampson, *supra* note 98. Abstract ideas: Yu, *supra* note 35, at 417-27; Note, *Diagnostic Method Patents and Harms to Follow-on Innovation*, 126 HARV. L. REV. 1370 (2013). *See generally* 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, 194-201 (2004).

[104] *See, e.g.*, *Statement of Dr. Harold Varmus on Gene Patents and Other Genomic Inventions*, Hearing Before the Subcomm. on Courts and Intellectual Property of the Comm. on the Judiciary, House of Representatives (July 13, 2000), http://commdocs.house.gov/committees/judiciary/hju66043.000/hju66043_0f.htm ("[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, *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.").

[105] *See infra* note 360 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.

[106] Heller & Eisenberg, *supra* note 91, at 699; *see also* Strandburg, *supra* note 54, 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.").

uncertain applications are thought to be problematic mainly because of their potential to have overbroad coverage.[107] Thus, patents on upstream inventions might dominate and preempt entire fields of research,[108] cover unpredictable, transformative applications,[109] and massively over-reward their owners.[110] 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 society."[111]

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Although critiques common to patents on upstream inventions might suggest that such inventions should be subject to the same patentability requirement, this does not necessarily have to be so. For one thing, patent claims on research tools, research plans, and fundamental principles might look different from one another. A research tool claim could be drawn to a building-block chemical compound of a well-defined structure, a research-plan claim could be drawn to a method that can be implemented in a variety of different ways, and a fundamental principle claim could be drawn to a very broad statement of a concept or a natural law. This suggests that it is reasonable to treat the three types of claims under different tests. And it appears that this is what courts do—the doctrinal routes that they use to invalidate the three types of claims loosely track the

[107] But this is not always the case—the utility requirement can bar claims that are relatively narrow in scope, and so can the patentable subject matter requirement. As explained *infra* in Subpart III.A.1, the problem with claims barred by the utility doctrine is not their breadth as such but the fact that the patent is directed to a research input having unknown end-use utility. And, as explained *infra* in Subparts IV.C and IV.D, it is not clear why exactly why certain patentable subject matter cases bar narrow claims.

[108] *See, e.g.*, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012) (Precedent "warn[s] us against upholding patents that claim processes that too broadly preempt the use of a natural law.") (citations omitted); Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc) ("[C]laims to research plans also impose costs on downstream research, discouraging later invention.").

[109] *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 68 (1972) ("Here the 'process' claim is so abstract and sweeping as to cover both known and unknown uses [of the underlying algorithm].").

[110] *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." (quotation omitted)).

[111] Wang, *supra* note 91, 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 each have a right to exclude others from a scarce resource, and no one 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." Heller & Eisenberg, *supra* note 91, at 699. Heller and Eisenberg explain that granting patents on upstream inventions results in "too many fragments of concurrent 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. *Id.* at 700-01.

distinction between research tool patents, so-called "hypothesis" patents, and patents on fundamental principles.[112] In spite of the multiplicity of tests that courts use to probe patent validity under the utility, written description, and patentable subject matter requirements, however, these cases can also be viewed as facets of the overarching requirement against the patenting of artifacts of basic research.[113]

There are 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 decision-makers to reexamine the distinctions made within each doctrine and improve upon the extant tests so as to focus on the core policy aim of limiting harmful upstream patents. Indeed, the fact that some of the patents on upstream inventions discussed in the previous section (e.g., chemical intermediates, methods of treatment based on a newly identified drug target) have been invalidated, while others (e.g., stem cells, many software patents) have not, suggests that the current approach may be inconsistent, and the tests, inadequate.[114] The holistic completeness framework might help decision-makers determine whether or not there is a principled distinction between the patents that failed and those that did not, leading to more consistent outcomes.[115]

Second, breaking down the doctrinal barriers that courts have caused for dealing with different kinds of upstream patents might itself be beneficial. In similar contexts, commentators have criticized the Federal Circuit's patent law jurisprudence for maintaining formalistic distinctions between different doctrines and sidestepping the larger policy questions,[116] and this criticism may be apt in the context of upstream patents as well. Although patent claims may be unacceptably upstream in different ways, a completely different set of doctrinal tools for each form of incompleteness might cause decision-makers to lose sight of the common policy concerns behind allowing those 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 what patents should be invalidated.[117]

Third, as suggested in the Introduction,[118] the 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 created. Suggestions for changes in patent law that may lead to a better implementation of the policy behind the completeness cases are discussed in the last two Parts of the Article. The two Parts that

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[112] *See infra* Subparts III.A-III.C.
[113] *See infra* Subpart III.D.
[114] *See, e.g.*, Yu, *supra* note 35, at 401; Yu, *supra* note 36, at 911-17. *See generally infra* Part IV.
[115] Of course, this state of affairs could partly be a consequence of litigation strategy—some of these patents may not have been invalidated because they were never challenged in this manner.
[116] In similar contexts, certain doctrinal distinctions in patent law have been characterized as essentialist and overly formalistic. *See, e.g.*, Laakmann, *supra* note 40, at 60 & nn.107-108; *see also* Collins, *supra* note 28. *See generally* John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771 (2003).
[117] *See infra* note 332 and accompanying text.
[118] *See supra* notes 34-38 and accompanying text.

immediately follow discuss the three lines of completeness cases, explain the policy concerns that unite them, and critique these cases.

III. THE CONTOURS OF PATENT LAW'S COMPLETENESS REQUIREMENT

A. Completeness doctrines

1. Utility

One way that patent law polices completeness is via the utility requirement.[119] The modern utility doctrine took shape in the case of *Brenner v. Manson*.[120] At issue was a patent application directed to a process of making chemical compounds falling within a larger class of molecules called steroids.[121] Expecting the Supreme Court's hostility to an older doctrine holding that chemical compounds had "inherent" utility,[122] 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 that were used to treat cancer.[123] The Court, however, held that the asserted utility was not enough: The patent applicant had to demonstrate nothing less than "a *sufficient likelihood* that the [chemical compound] yielded by his process would have . . . tumor-inhibiting characteristics."[124]

The Supreme Court affirmed the rejection of the patent application because the claimed process was not "refined and developed to . . . where specific benefit exists in currently available form."[125] 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. The reason was that such a patent could "block off whole areas of scientific development, without compensating benefit to the public."[126] 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 was not sufficient for patentability.[127] As one commentator aptly noted, *Brenner*

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[119] *See* 35 U.S.C. §101 ("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 . . . ." (emphasis added)); *see supra* notes 1 & 9 and accompanying text.
[120] 383 U.S. 519 (1966).
[121] *Id.* at 520-22.
[122] The inherent utility doctrine derives from the intuition that most chemical compounds are good for something—for example, for making other chemicals. *See, e.g.*, *In re* Nelson, 280 F.2d 172 (C.C.P.A. 1960); Potter v. Tone, 36 App. D.C. 181, 184-85 (1901); *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).
[123] *Brenner*, 383 U.S. at 530-31.
[124] *Id.* at 532 (emphasis added).
[125] *Id.* 534-35.
[126] *Id.* at 534.
[127] *Id.* at 529, 535.

"seem[ed] effectively to exclude research chemists from the class of people for whom an invention may be useful."[128]

Although it has been argued that the utility requirement became "minimal" under the Federal Circuit's interpretation of *Brenner*,[129] recent cases show that the basic rule that the inventor must demonstrate a chemical compound's potential benefit to an end user has not been abandoned. Applying *Brenner*, the Federal Circuit in *In re Fisher* affirmed the rejection of claims to so-called "expressed sequence tags" (ESTs), which 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.[130] The court held that ESTs lacked utility because they are "no more than research intermediates."[131] To pass the requirement, the utility had to 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."[132] As in *Brenner*, research utility did not render the inventions complete enough to be patentable.[133] Thus, courts continue to rely on utility[134] as a "policy lever"[135] to prohibit "premature [patent] filing[s]"[136] on chemical and biotechnological inventions.

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[128] Brent N. Rushforth, *The Patentability of Chemical Intermediates*, 56 CALIF. L. REV. 497, 513 (1968); *see also* Lawrence R. Velvel, *A Critique of* Brenner v. Manson, 49 J. PAT. OFF. SOC'Y 5, 9-10 (1967).

[129] Lopez-Beverage, *supra* note 103, at 64 ("[I]t has been the [Federal Circuit's] position that minimal utility is all that is required to obtain a patent."); *see 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).

[130] 421 F.3d 1365, 1367-69, 1378 (Fed. Cir. 2005); *see also id.* at 1379-80 (Rader, J., dissenting).

[131] *Id.* at 1373.

[132] *Id.* at 1376.

[133] Nonetheless, the PTO has made it clear that the utility doctrine does not work a general prohibition against the patenting of research tools. *See* MANUAL OF PATENT EXAMINING PROCEDURE § 2107(I)(C) (9th ed. Mar. 2014); *cf. id.* § 2107(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 v. Manson, 383 U.S. 519, 534-35 (1966)).

[134] *See also In re* '318 Pat. 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 v. Manson, 383 U.S. 519, 534 (1966)).

[135] *See generally* Burk & Lemley, *supra* note 29.

[136] 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).

2. Written description

Written description doctrine provides another line of attack, of more recent vintage than utility, against patents on upstream inventions.[137] 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, written description has been applied in certain cases to deny patents that claim chemical compounds in terms of their beneficial functions but fail to provide any actual chemical structures.[138]

For example, in *University of Rochester v. G.D. Searle & Co.*, the patentee claimed a method of reducing inflammation using "a non-steroidal compound that selectively inhibits activity" of a certain gene.[139] The patentee discovered the phenomenon of selective inhibition of the gene, which enabled the downstream discovery of pain relievers that lack undesirable side effects like ulceration,[140] and disclosed experiments for finding chemical compounds that would perform the claimed inhibiting function.[141] Nonetheless, the patent did not provide any examples of compounds that would have this effect. 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.[142] For the invention to be complete, the court required a chemical structure, not merely a "search method."[143] 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 such drugs are found.[144] After citing *Brenner*—a utility case—it even suggested that the patentees did not invent the claimed methods at all.[145]

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

[138] In some cases, broad patent claims containing functional language can fail the written description requirement even when some (but not enough) examples of chemical structures are disclosed. *See, e.g.*, Boston Scientific Corp. v. Johnson & Johnson, 647 F. 3d 1353, 1364-67 (Fed. Cir. 2011).

[139] 358 F.3d 916, 918 (Fed. Cir. 2004) (quoting U.S. Pat. No. 6,048,850, claim 1).

[140] *See supra* notes 2-4 and accompanying text.

[141] *See 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]") (internal quotation marks omitted).

[142] *Id.* at 927, 929.

[143] *Id.* at 930 n.10.

[144] *Cf.* Robert A. Hodges, *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, 857 (2001) ("[A] function coupled with basic knowledge of structure and a workable method of production allow those in the art to produce the invention."); *cf. infra* note 406 and accompanying text.

[145] *Rochester*, 358 F.3d at 930 n.10 (quoting Brenner v. Manson, 383 U.S. 519, 536 (1966)); *cf. In re '*318 Pat. Infringement Litig., 583 F.3d 1317, 1324 (Fed. Cir. 2009) (relying in part on the policy against the patenting "research proposals" in a utility case).

In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, the Federal Circuit sitting en banc further clarified why claims to "research hypotheses do not qualify for patent protection."[146] It 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."[147] The court further stated that patent law is directed to inventions "with a practical use" rather than "basic research."[148] This point was reinforced by the additional views of Judge Newman, who wrote 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."[149] The familiar policy concern behind this result is that "claims to research plans . . . impose costs on downstream research, discouraging later invention"[150] by "attempt[ing] to preempt the future before it has arrived."[151]

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, requiring inventors to make their inventions more downstream before qualifying for a patent. Although the two requirements address two different facets of completeness—lack of a specific benefit to an end user under utility and inadequate structural disclosure under written description—both have been used to prevent inventors from laying claims to basic research and blocking downstream users from enjoying its fruits.

3. Patentable subject matter

In addition to mandating the requirement of utility, § 101 of the Patent Act has been read to impose "an important implicit exception"[152] that places certain claims outside the category of patentable subject matter. This exception bar patents to natural phenomena, laws of nature, and abstract ideas.[153] 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."[154] In *Benson*, the Court concluded that a claim to a method of

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[146] 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc).
[147] *Id.*
[148] *Id.* (citing *Brenner*, 383 U.S. at 532-36). While the Federal Circuit cited a utility case in support of the outcome in a written description case, the district court in *Ariad* analyzed the problems with the asserted patent in terms of patentable subject matter requirement of § 101. *See id.* at 1358 (Newman, J., additional views); *infra* Subpart III.A.3. Thus, the *Ariad* case implicates in some way all three completeness doctrines.
[149] *Ariad*, 598 F.3d at 1359 (Newman, J., additional views).
[150] *Id.* at 1353.
[151] *Id.* (alterations and internal quotation marks omitted) (emphasis added).
[152] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).
[153] *Id.*
[154] 409 U.S. 63, 67 (1972). The term "phenomena of nature" may refer to laws of nature and products of nature. *Cf.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013).

converting so-called "binary-coded numbers" into pure binary numbers was unpatentable because it was drawn to "an idea."[155] 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."[156] As with the utility and written description cases discussed in the previous two Subparts,[157] the fact that the claim was drawn to an artifact of basic research—here, an algorithm or "an idea"—appeared to be the reason for holding it unpatentable.[158] Once again, preemption of downstream research and development associated with patentee's control of an important upstream input was the policy driver behind this result.[159]

A more recent case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[160] further demonstrates how the patentable subject matter doctrine functions to bar patents on inventions that are thought by courts to be too upstream.[161] In *Mayo*, 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 administered proxy for the underlying 'building-block' concern"[162]—the concern over the patenting of basic research inputs. It 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.[163] The Court explained that, "to transform an unpatentable law of nature into a patent-eligible application of such a law, a patent must do more

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[155] *Benson*, 63 U.S. at 71.

[156] *Id.* at 71-72. For an argument contesting the reasoning in *Benson*, *see generally* Chisum, *supra* note 37.

[157] *Cf.* Chisum, *supra* note 48, at 20-21 (noting this similarity between the abstract ideas exception and the *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").

[158] In contrast with utility and written description requirements, though, where specification disclosures of end uses or of examples of chemical compounds, respectively, might save the claims, the claims at issue in patentable subject matter cases cannot be saved by the material in the specification—presumably because of their overbreadth. *See supra* notes 129 & 157 and accompanying text.

[159] *Benson*, 63 U.S. at 68 (discussing the varied end uses covered by the claims at issue). *But see* Strandburg, *supra* note 35, at 594 (arguing that, in *Benson* and cases like it, "[p]reemption rhetoric is a distraction from important questions that must be answered to give patentable subject matter doctrine a firm theoretical grounding" and attempting to disentangle "per se exclusions" from preemption).

[160] 132 S. Ct. 1289 (2012).

[161] At this stage of the Article, I am reserving judgment on whether the Court was correct in holding the Prometheus patent to be unacceptably upstream. As I explain later, though, the Court in this case relied on correct policy, but used a questionable test and reached the wrong outcome. *See infra* notes 313-317 and accompanying text.

[162] *Mayo*, 132 S. Ct. at 1303.

[163] *Id.* at 1295; *see also supra* notes 5-8 and accompanying text.

than simply state the law of nature while adding the words 'apply it,'"[164] and invalidated the patent because, in its view, the claims at issue were not sufficiently limited. Echoing the rhetoric of other decisions discussed in this Part, the Court heavily relied on the preemption rationale for prohibiting patent claims that are upstream in the development chain:

> [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.[165]

In another recent pronouncement on patentable subject matter, *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[166] the Supreme Court explained how the prohibition against basic research functions in a "product of nature" case. The patentee's claims to isolated genetic material failed because they were effectively drawn to the upstream discovery of "the precise location and genetic sequence of [particular] genes"[167] rather than "*new applications* of knowledge about"[168] these genes. 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."[169] Thus, one way to understand (and, perhaps, cabin[170]) the result in *Myriad* is that the claims were invalidated because the patentee essentially claimed genetic information—a foundational research tool.[171] As in other completeness cases, the Court discussed balancing "creating incentives that lead to creation invention, and discovery" against "impeding the flow of information that might permit, indeed spur, invention."[172]

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

[165] *Id.* at 1301-02; *see also supra* notes 108-110 and accompanying text. *Accord* Alice Corp. Pty. Ltd. 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."). *But see* Chiang, *supra* note 17, at *9-12 (arguing that the Supreme Court's rejection in *Mayo* of Prometheus' argument that the claim at issue is narrow and unlikely to preempt much of anything suggests that the Court was not really driven by the utilitarian concern regarding preemption).

[166] 133 S. Ct. 2107 (2013).

[167] *Id.* at 2116.

[168] *Id.* at 2120 (emphasis in original).

[169] *Id.* at 2118 (emphasis in original).

[170] *Cf.* Arti K. Rai & Robert Cook-Deegan, *Moving Beyond "Isolated" Gene Patents*, 341 Sci. 137, 138 (2013) (suggesting this limiting principle).

[171] *Cf.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013), Oral Arg. Transcript, p. 16 l. 22 – p. 17 l. 4 (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."). For a different interpretation, see Chiang, *supra* note 17, at *17-21 (arguing that moral concerns were at play in *Myriad*).

[172] *Myriad*, 133 S. Ct. at 2116.

B. A de facto *single requirement*

There are, of course, important differences in the way the three doctrines operate. 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.[173] But the similarities across utility, written description, and patentable subject matter doctrines are notable.[174] 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 the patient's condition. 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 compositions in the specification. In the written description cases,[175] 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. 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. The common reason for the failure of all of these patents is that, according to courts, they were drawn to research artifacts that are too foundational to be patentable.[176] This is the completeness requirement at work.[177]

The policy rhetoric of the three strands of cases is nearly indistinguishable. "A patent," said the Supreme Court in *Brenner* (a utility case), "is not a hunting license. It is not a reward for the search, but

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[173] *See supra* notes 157-158 and accompanying text.

[174] *Cf.* Chisum, *supra* note 48, 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 104, at 1373 n.206 (noting "a curious, relatively unexplored kinship between many § 101 and § 112 cases").

[175] 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 *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 new or amended claims lacking textual support in the specification during the prosecution process. *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. Janis, *supra* note 35, at 64-65, 71; *see* 35 U.S.C. § 120. 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." 35 U.S.C. § 132. "New matter" technically refers to material added to the original specification after filing, which violates § 132, while a new claim not supported by the specification violates § 112. Janis, *supra* note 35, at 64 n.35 (quoting *In re* Rasmussen, 650 F.2d 1212, 1214-15 (C.C.P.A. 1981)).

[176] *See supra* notes 96-103 and accompanying text.

[177] *See supra* note 13 and accompanying text.

compensation for its successful conclusion."[178] For the invention to be patentable, said the Federal Circuit in *Fiers v. Revel* (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."[179] And in *Mayo* (a patentable subject matter case), the Supreme Court invalidated claims that "tie[d] up too much future use of laws of nature"[180] by allowing its owner to appropriate "basic tools of scientific and technological work."[181] The three lines of cases therefore serve the same policy goal of preventing undue preemption of downstream research.

Courts do not like patents on upstream inventions, and, in the absence of a statutory prohibition against the patenting of objects of basic research,[182] they have used three distinct doctrinal sources to invalidate claims that are drawn to them.[183] This approach has put pressure on the statutory provisions used to implement completeness, and, in the views of some, has raised concerns over judicial overreaching.[184] The next Part explains the various criticisms of the completeness cases in greater detail.

IV. PROBLEMS WITH IMPLEMENTING THE COMPLETENESS REQUIREMENT

A. Utility

Completeness cases have drawn a great deal of criticism. As an example, consider utility cases like *Brenner*, which purport to apply the requirement of § 101 that inventions be "useful."[185] The invention at issue in *Brenner* was a method for making chemical compounds.[186] To say that such an invention is not "useful" in the ordinary sense of that word defies common sense, as numerous commentators have observed.[187] Furthermore,

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[178] Brenner v. Manson, 383 U.S. 519, 536 (1966).

[179] 894 F.2d 1164, 1171 (Fed. Cir. 1993). Although *Fiers* did not involve originally filed claims, it is thought to have ushered in the *Lilly-Rochester-Ariad* line of cases that is considered by many to be anomalous. *See* Pitlick, *supra* note 35, at 209-11.

[180] 132 S. Ct. 1289, 1301 (2012).

[181] *Id.* at 1293 (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).

[182] It has been argued that this prohibition has constitutional underpinnings. *See* Liivak, *supra* note 64. Although some cases imply a constitutional link, *see, e.g.*, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351, 1353 (Fed. Cir. 2010) (en banc), they stop short of saying that the prohibition against the patenting of basic research is constitutionally required and focus on public policy.

[183] *Cf.* Kresh, *supra* note 35, at 540.

[184] *See supra* notes 36-38; *see also infra* note 240 and accompanying text.

[185] 35 U.S.C. § 101 (2012).

[186] Brenner v. Manson, 383 U.S. 517, 521 (1966).

[187] 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."); 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 (1997) ("[T]he law [on utility] produces results that defies common experiences of those in the art."); Eric P. Mirabel, *"Practical Utility" Is a Useless Concept*, 36 AM. U. L. REV.

it seems counterintuitive that, while the PTO has been granting patents on silly, ridiculous, and plain useless inventions without issuing § 101 utility rejections,[188] the utility requirement has been enforced in the serious and generally useful fields of chemistry of biotechnology, and only in those fields.[189] In a recent article that puts these concerns into sharp focus, Sean Seymore argues that the utility requirement is highly subjective, reflecting "a bias against granting patentability for certain types of inventions."[190] Of course, results of the utility cases may be defensible as policy judgments that certain inventions in the chemical arts are too upstream to be patentable.[191] But whether or not these judgments are correct, the distinctions made under the utility doctrine have put a great deal of weight on the word "useful." Accordingly, there must be nontrivial legitimacy costs associated with the way in which courts have implemented the utility requirement.[192]

Several scholars have provided policy justifications for the distinctions made by the current utility regime.[193] For example, John Duffy contends that it makes sense to allow patents on research *tools* such as microscopes, which facilitate further research, but to reject patents on research *intermediates* such as ESTs[194] and other materials, like chemical compounds, that might themselves be objects of study.[195] In other words, Duffy argues that research tools are patentable because they have "broad

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811 (1986) ("In common parlance, a thing 'having utility' is, by definition, 'useful." When dealing with chemical compounds, the judiciary has not equated these expressions.").

[188] *Id.* ("The PTO has . . . permitted patents one a wide variety of seemingly frivolous inventions, gutting the requirement that an invention have a purpose other than idle amusement.") (citing U.S. Pat. No. 4,998,724 (filed Aug. 10, 1990) and others); Risch, *supra* note 16, 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. Pat. No. 5,606,748 (filed Jan. 29, 1996)); *see* 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."); *see also id.* 453 n.53.

[189] *See* BURK & LEMLEY, THE PATENT CRISIS, *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.").

[190] Seymore, *supra* note 35, at 1050.

[191] *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 court's reasoning is "so baffling that it is nearly impossible to discern exactly what the court's rationale might be").

[192] *See* Tun-Jen Chiang, *Defining Patent Scope by the Novelty of the Idea*, 89 WASH. U. L. REV. 1211, 1236 (2012) (discussing the problem of legitimacy costs even where "judges achieve good economic results through . . . extra-legal use of discretion").

[193] *See, e.g.*, John F. Duffy, *Embryonic Inventions and Embryonic Patents*, *in* PERSPECTIVES ON COMMERCIALIZING INNOVATION 234, 245-48 (F. Scott Kieff & Troy A. Paredes eds. 2011); Rai, *supra* note 20, at 140-41. One scholar would go further and give the utility requirement an expanded role. Risch, *supra* note 16, at 1234-48; *see also* Michael Risch, *A Surprisingly Useful Requirement*, 19 GEO. MASON L. REV. 57 (2011).

[194] *See supra* notes 131-132 and accompanying text.

[195] Duffy, *supra* note 193, at 246-47.

applicability to researchers generally," while 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."[196]

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[197]—which he views as undesirable. Thus, Duffy finds it problematic that, if ESTs were to be 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.[198] Duffy explains that, in contrast, patents on downstream inventions created with the aid of research tools like microscopes—for example, nano-sized objects[199]—will not be within the scope of the microscope patents.[200] As a result, there are not going to be mutually blocking patents in these circumstances.[201]

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.[202] Mutually blocking patents are routine in patent law.[203] Indeed, the Patent Act expressly contemplates patents for new uses of known things, and this is not prohibited even when the known thing is itself

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[196] *Id.* As Duffy notes, "research facilitated by a microscope is not a step in refining the microscope." *Id.* at 247. Interestingly, though, this might not always hold true for newly discovered specialized microscopes, like the atomic force microscope. *See supra* notes 60-61 and accompanying text. Attempts to observe objects via 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. Pat. No. 7,921,477 (filed Feb. 21, 2006). And conversely, chemical intermediates can facilitate further research by serving as building blocks for larger, more complex molecules rather than as objects for further study. *See* Seymore, *supra* note 30; *see also* Burk, *supra* note 25, at 580-81 (arguing that the utility of ESTs lies in their value as aids for the study of the larger DNA molecules form which they were derived).

[197] *Id.* As explained by Merges and Nelson, "[t]wo 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 the dominant patent cannot practice the particular improved feature claimed in the narrower patent without a license." Merges & Nelson, *On the Complex Economics*, *supra* note 93, at 860-61.

[198] Duffy, *supra* note 193, at 247.

[199] *See supra* note 61 and accompanying text.

[200] Duffy, *supra* note 193, at 247.

[201] *Id.*

[202] Duffy himself admits that this justification for treating research tools and intermediates differently "is not entirely satisfying." *Id.* at 245.

[203] *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).

patented.[204] 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.[205] The critical policy concern behind the completeness requirement is not the presence of mutually blocking patents, but preemption of downstream research and development, whether or not its fruits are themselves eventually patented, due to the "bottleneck" of a research tool patent or another sort of upstream patent.[206] A patent on a broadly applicable new type of a microscope, untethered to a specific downstream use, should worry us because it is directed to an invention having uncertain value and an untold number of applications.[207]

Given these policy considerations, it is difficult to explain why the completeness cases pick out ESTs over microscopes.[208] Patent claims on microscope inventions, just like 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.[209] The utility requirement is on the right track in

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

[205] *See supra* notes 104-106 and accompanying text.

[206] 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 193, 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 blocking patents.

[207] The 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., e.g.*, Rai, *supra* note 20, 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 else the license to make it. Conversely, just like scientific instruments, chemical intermediates and kits for making them are available for sale. *See* Product Catalog, STREM CHEMICALS, INC., http://www.strem.com/catalog. And yet the difference in patent law treatment between these two types of research aids remains. I thank Anna Laakmann, Jake Linford, and Katherine Strandburg for comments that helped me clarify this point.

[208] *But see* Linda Demaine & Aaron 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," that they "are naturally occurring substances" and that "the EST is, at best, a starting point for further research"); Lopez-Beverage, *supra* note 103, at 47-48, 73-75.

[209] Furthermore, the distinction between "intermediates" and "tools" is not robust in the decided cases. Duffy himself notes that "both the case law and the theory suggest that a general technique for identifying ESTs be patentable—even if there is no use for any of the ESTs identified!" Duffy, *supra* note 193, at 246. But the result of *Brenner* is directly contrary to this observation because that case dealt with a *process*

its focus on the "specific and substantial utility" of claimed inventions because this test, at least indirectly, gets at the notion of a research input.[210] But the case law has, at the very least, failed to capture the full range of such inputs and stretched to a breaking point the meaning of the word "useful."[211]

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. While 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.

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.[212] Echoing the complaints about the utility requirement, the written description line of cases exemplified by *Rochester*[213] has been thought to be problematic as a matter of doctrinal development[214] and even statutory interpretation.[215] In addition, numerous scholars and some judges have argued that these cases have unjustifiably imposed heightened disclosure requirements on biotechnology patents.[216]

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patent for making molecules, which the Supreme Court invalidated. Brenner v. Manson, 383 U.S. 519, 520-22 (1966).

[210] *See supra* note 132 and accompanying text.

[211] *See generally* Seymore, *supra* note 30.

[212] *See* JANICE M. MUELLER, PATENT LAW 153 (4th ed. 2013) (calling the written description requirement as applied to biotechnology inventions "anomalous"); Jonathan E. Barbee, Note, *Innovation on the Cutting Edge of* Ariad*: Reinventing the Written Description Requirement*, 86 N.Y.U. L. REV. 1895 (2011); Yu, *supra* note 36, at 895, 898 (calling the written description requirement an "unsatisfactory patchwork of band-aid, ad hoc solutions" for striking down claims that courts deem unacceptable); *see also* references on written description *supra* note 35.

[213] Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004). This is the case about the claim to a method of treatment where the patent did not give an example of a drug. *See supra* notes 139-145 and accompanying text.

[214] *See, e.g.*, Pitlick, *supra* note 35 (explaining how the early written description cases invalidating originally filed claims constituted a radical departure from precedent); *see also supra* note 212 and accompanying text. *But cf. supra* note 175 (discussing uncontroversial aspects of the written description requirement).

[215] *See, e.g.*, *Judicial Howlers:* Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., LAWNLINGUISTICS, http://lawnlinguistics.com/2012/07/26/judicial-howlers-ariad-pharmaceuticals-inc-v-eli-lilly-co (July 26, 2012) (explaining that the separate written description requirement is unsupportable by the grammatical structure of what is now 35 U.S.C. § 112(a)).

[216] *See, e.g.*, Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1325-27 (Fed. Cir. 2004) (Linn, J.) (dissenting from the order denying rehearing en banc); Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 976 (Rader, J., dissenting from the order denying rehearing en banc); BURK & LEMLEY, THE PATENT CRISIS, *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 NAT. BIOTECHNOLOGY 97 (2003); Hodges, *supra* note 144, 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."); Christopher M. Holman, *supra* note 32, at 4 (describing the written description

Unlike the utility requirement, which has been applied only against chemical and biochemical patents, the written description requirement has appeared in other fields.[217] However, outside biotechnology, patent claims are only rarely invalidated under the written description requirement for being directed to a "research plan."[218] Although one reason for this state of affairs could be that patentees do not often draft those sorts of claims in other fields, 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,"[219] a deficiency that is arguably similar to that of research-plan biotechnology claims,[220] appear to be common, but they have not been eliminated by the written description requirement.[221]

To be fair, the written description requirement in its modern form has been accepted by a large majority of Federal Circuit judges, and several scholars have provided justifications for the ways in which it is applied.[222] Supporters of the requirement, starting from 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.[223] Nonetheless, the rhetoric of the cases is also consistent with the conclusion that words like "invent" or "possess" are, in the end, labels for

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requirement as "a 'super-enablement' requirement specifically targeting biotechnology and substantially restricting the patentability of biotechnology-related inventions").

[217] *See, e.g.*, *In re* Katz Interactive Call Processing Patent Litig., 639 F.3d 1303, 1319-20 (Fed. Cir. 2011) (affirming invalidation of claims to 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 cannot be broadened to exclude an element designated as "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).

[218] *See Comments of Michael Risch*, *supra* note 70. Indeed, the specific approach of rejecting claims for lack of written description due to lack of disclosed structures for implementing the invention seems to be generally limited to the biochemical cases.

[219] *See supra* note 70 and accompanying text. For an example, *see infra* note 306 and accompanying text.

[220] *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 for allowing functional claims in the software arts but not in the biotechnological arts).

[221] It appears, though, that courts have started invalidating such claims via § 101. *See supra* note 28 and accompanying text. This phenomenon might lend further support to the notion that these are all facets of the same requirement of patentability.

[222] For some defenses of the written description requirement, see Jakas, *supra* note 63; Liivak, *supra* note 64; Michael Risch, *A Brief Defense of the Written Description Requirement*, 119 YALE L.J. ONLINE 127 (2010); *see also* Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1131 (2008). Lefstin argues that the written description requirement is necessary as a means of defining what the invention is. *Id.* at 1204-07. But he notes that written description doctrine has moved away from this function, *id.* at 1207-10, and a suggests that patent law's requirement of definiteness, *see* 35 U.S.C. § 112(b), may more naturally play this role, *id.* at 1220-22.

[223] Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351, 1355 (Fed. Cir. 2010) (en banc).

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.[224] 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 decision-makers tried to ask directly whether the patents at issue were directed to objects of basic research,[225] rather than rely on tests that seem to obscure this salient question. As things stand now, strong critiques of the written description requirement as somewhat capricious continue unabated in spite of its judicial acceptance.[226]

C. Patentable subject matter

The jurisprudence of § 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[227] or a disproportionate burden on some particular industry or patent type,[228] but about the lack of guidance from courts. As a general matter, 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.[229] The problem is that the Supreme Court has steadfastly refused to provide any clear standards for identifying what should be excluded form patentability on this ground—in other words, it has not explained how to identify patents that belong to these categories.[230] In an article on the abstract idea exclusion, Kevin Collins criticized the Court for

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[224] *See, e.g.*, FELDMAN, RETHINKING PATENT LAW, *supra* note 86, 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"); *see also supra* notes 2-4 and accompanying text.

[225] 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 basic research might be. *See supra* note 148-151 and accompanying text.

[226] *See supra* note 212 and accompanying text.

[227] *See infra* note 240 and accompanying text.

[228] Though disproportionate burdens arguments have been made as well—on the diagnostics industry and, lately, on 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 (2014); *see also* Dennis Crouch, *Twenty Thoughts on the Importance of* Myriad, PATENTLY-O, http://patentlyo.com/patent/2013/06/myriad.html ("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. For a historical perspective on the patentability of software patents, see Adam Mossoff, *A Brief History of Software Patents (and Why They're Valid)*, 57 ARIZ. L. REV. SYLLABUS (forthcoming 2014), *available at* http://ssrn.com/abstract=2477462.

[229] *See supra* note 16 and accompanying text.

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

"an open embrace of an 'I know it when I see it' jurisprudence" that "offers no prospective guidance for the patent community,"[231] and a district court recently joined in that criticism.[232] A similar critique has been lodged against the Supreme Court's laws-of-nature and products-of-nature jurisprudence.[233]

Even if an abstract idea or a law of nature were to be well-defined, it is difficult to know what it takes to render these unpatentable concepts into patentable inventions.[234] In particular, the Court did not clarify the line between an unpatentable "conventional" application of an idea or law and a patentable "inventive" application.[235] A similar difficulty appears in the Court's product-of-nature jurisprudence in the form of the test whether a patent claim is "markedly different" from a natural product.[236] For example, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Court invalidated the 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, but refused to invalidate the claims to the non-naturally occurring molecules encoding the same genetic information.[237] This distinction, while perhaps justifiable as a pragmatic result that gives something to both sides, is unpersuasive.[238]

The Supreme Court's patentable subject matter jurisprudence is so murky that making the doctrine more reasoned and systematic has been a

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[231] Kevin Emerson Collins, Bilski *and the Ambiguity of "An Unpatentable Abstract Idea,"* 15 LEWIS & CLARK L. REV. 37, 39 (2011) (quoting Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010)); *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"). *See generally* Chisum, *supra* note 48 (criticizing the Supreme Court's abstract idea jurisprudence).

[232] Eclipse IP LLC v. McKinley Equip. Corp, No. SACV 14–742–GW(AJWx), 2014 WL 4407592, at *3 (C.D. Cal. Sept. 4, 2014).

[233] Chiang, *supra* note 17, at *11, *21; *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 . . . 'natural' terms any concrete, legal meaning").

[234] 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.'") (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294-95 (2012)).

[235] Rebecca S. Eisenberg, Prometheus *Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J. ONLINE 341 (2013) (criticizing *Mayo* for 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, 322, 349-50 (2012) (calling the *Mayo* doctrine "unadministrable"); 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, Mayo v. Prometheus *and the Method of Invention*, 122 YALE L.J. ONLINE 351 (2013) (criticizing the *Mayo* Court's "well-understood, routine, conventional activity" approach).

[236] *Cf. In re* Roslin Inst., 750 F.3d 1333 (Fed. Cir. 2014).

[237] *Mayo*, 132 S. Ct. at 2118.

[238] Burk, *supra* note 25, at *5-6; 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.

goal of many scholarly projects.[239] Yet in spite of all the work that has been done is this area, patentable subject matter jurisprudence continues to be a struggle. Furthermore, similar to the utility and written description cases, patentable subject matter decisions have been criticized for judicial overreaching and subjectivity, raising the specter of illegitimacy.[240] And even scholars who are generally sympathetic to these cases have been critical of the courts' analytical approaches and advocated for improvements.[241] 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. Thus, the current tests run the risk of invalidating patents that are not directed to basic tools at all.[242]

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.[243] Moreover, it has been argued that many such inventions may have been created anyway, without the patent incentive.[244] Given the absence of conclusive empirical tests for measuring excessive monopoly costs of patents and the lack of clear ways of determining how much value from follow-on innovation the upstream inventor should be allowed to capture in particular cases, the general policy of eliminating socially harmful patents by prohibiting claims that qualify as foundational research inputs is sensible.[245]

However, courts address this concern in a somewhat tentative and unsystematic way. In spite of 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

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[239] *See, e.g.*, Chao, *supra* note 35; Collins, *supra* note 231; Lemley at al., *Life After* Bilski, *supra* note 35; Strandburg, *supra* note 35; *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, 1295-96 (2011) (proposing a "technological arts" approach to patentable subject matter derived from common law).

[240] *See, e.g.*, Chisum, *supra* note 37; Kresh, *supra* note 35; Oppenheimer, *supra* note 36; *see also* Ted Sichelman, Funk *Forward*, *in* INTELLECTUAL PROPERTY AT THE EDGE: THE CONTESTED CONTOURS OF IP 361, 370 (Rochelle Dreyfuss, Jane Ginsburg & Carol Rose 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 208, at 360 (arguing that the patentable subject matter requirement is coherent and rooted in historical case law); Sarnoff, *supra* note 50 (similar); Menell, *supra* note 239.

[241] *See, e.g.*, Sarnoff, *supra* note 50.

[242] This concern appears to be borne out in recent case law. *See infra* notes 331-332 and accompanying text.

[243] *See supra* note 16 and accompanying text.

[244] *See infra* note 339 and accompanying text.

[245] *See supra* notes 21-23 and accompanying text; *cf. infra* note 342 and accompanying text (explaining that bright-line rules for eliminating certain classes of patents can, on the whole, be welfare-enhancing).

state of affairs remains less than satisfying. The tests under utility and written description requirements have been criticized as anomalous and unsupported by statute, and they appear to invalidate some patents but not others using justifications that are at best controversial. And patentable subject matter jurisprudence fails to provide any clear tests altogether, which makes it difficult for the doctrine to vindicate the policy goals behind completeness.

The unwritten completeness requirement pervades the patent law and has real force, but its implementation has faltered. The extant approach has led to a supervening requirement for patentability that, in the current form, has been difficult to define apart from the facts of the specific cases in which it is applied.[246] A more coherent framework for implementing this requirement may be needed to replace the current approach, which relies on ad-hoc tests drawn from three different doctrinal sources.[247] Proceeding on the assumption that claims directed to artifacts of basic research should be unpatentable, the Part that follows considers what a unified completeness requirement of patentability might look like. Part VI challenges this assumption and introduces the concept of a limited Research Patent right for inventions that pass the extant requirements of patentability but fail the proposed form of the completeness requirement.

V. TOWARD A UNIFIED COMPLETENESS REQUIREMENT

A. The completeness test

If the courts' unwritten completeness requirement fails to clearly and consistently implement the policy against the patenting of basic research inputs, what should be done? In this section, I suggest a new test to unify the completeness requirement. The proposed test reflects the policy behind the cases that underlie the requirement, but the proposed 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 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."[248] Given that the completeness requirement is concerned with foundational research inputs, which can be further characterized as artifacts of basic research, this Article's approach is to look to how "basic research" is understood by inventors and policymakers and to attempt to fashion from this definition a test usable by courts.

[246] *See, e.g.*, Collins, *supra* note 231, 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 algorithms at issue in *Benson*); *cf.* Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2357 (2014) (invalidating claims because "there is no meaningful distinction between the concept of risk hedging in *Bilski* and the concept of intermediated settlement at issue here").

[247] *Cf. supra* notes 114-118 and accompanying text.

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

Decision-makers might reasonably look to such sources to operationalize the completeness requirement.[249]

Unsurprisingly, the definition of "basic research" has been difficult to pin down,[250] and the term can mean different things to different audiences.[251] Furthermore, although the concept of basic research is pervasive, there have been only a few attempts to analyze systematically what this concept means to various stakeholders.[252] Perhaps one of the most significant attempts to provide a comprehensive definition of basic research in recent literature is the work by Jane Calvert, a scholar in the field of science and technology studies.[253] Calvert surveyed scientists and policymakers and identified two major ways in which they understand the term—epistemologically and intentionally.[254] 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."[255] The intentional definition is simply too subjective and malleable to serve as a basis for a legal test.

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[249] *Cf.* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1715-27 (1996) (discussing the sources consulted by Congress in years leading up to the passage of the Bayh-Dole Act). To be sure, the different stakeholders may have divergent interests in terms of what sort of legislation, if any, they would like to see past. *Cf. id.* Thus, one would expect a great deal of debate over the definition of basic research). For an argument that the completeness requirement is best implemented through codification, see *infra* Subpart V.D.

[250] *See* Calvert, *supra* note 46, at 199 (arguing that "'basic research' is a term that is often heard in science policy without much apparent consensus on what is meant by it").

[251] *See, e.g.*, 32 C.F.R. § 272.3 (2013) (providing a definition of "basic research" as part of national defense regulations 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.* NATIONAL SCIENCE FOUNDATION REPORT, *What Is Basic Research?* (1953), *available at* http://www.nsf.gov/pubs/1953/annualreports/ar_1953_sec6.pdf.

[252] *See, e.g.*, Calvert, *supra* note 46; BENOIT GODIN, MEASUREMENT AND STATISTICS ON SCIENCE AND TECHNOLOGY: 1920 TO THE PRESENT 262-286 (2005); Charles V. Kidd, *Basic Research—Description versus Definition*, 129 SCI. 368 (1959); FRASCATI MANUAL 77 (2002) ("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.").

[253] Calvert, *supra* note 46.

[254] *Id.* at 204.

[255] *Id.* Interestingly, the unhelpful intentional definition appears to have been dominant in the literature, at least until recently. *See, e.g.*, FRASCATI MANUAL, *supra* note 252, at 77; NATIONAL SCIENCE FOUNDATION REPORT, *supra* note 251, at *1; GODIN, MEASUREMENT AND STATISTICS, *supra* note 252, at 262, 280. *But cf.* Kidd, *supra* note 252, at 369 (discussing "substance-based definitions" of basic research that focus on the generality of the underlying inventions).

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,[256] and I believe that 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."[257] This definition is unsurprising—it is consistent with courts' intuitions that certain upstream inventions have the potential to preempt broad areas of downstream inventive activity.[258] Furthermore, the generality and unpredictability factors are closely related. One of the biggest concerns with the unpredictability of how certain inventions might be used is that they might point the way to numerous new areas of downstream research, but at the same time allow the owner of the underlying patent to control those areas or even shut them down.[259]

The proposed test takes account of these characteristics of basic research in attempting to address in a comprehensive way the policy concerns behind the completeness cases.[260] 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 developmental stage of the claimed invention is such that 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.[261] Applying these factors, the PTO (or a court, when the validity of a patent on the ground of completeness is tested in litigation) can decide whether a claim is complete and should therefore be allowed, assuming that other requirements of patentability have been met. 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.[262]

Although one result of applying the test would be invalidation of some claims that are very broad, mere narrowness of the claim will not always provide a way of escaping incompleteness. In this respect, the test borrows from the collected wisdom of the completeness cases—some of which would invalidate even seemingly narrow claims due to their upstream

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[256] Calvert, *supra* note 46, at 204.
[257] *Id.* (internal quotation marks omitted).
[258] *See supra* Subpart III.B.
[259] *See supra* notes 104-111 and accompanying text. For illustrations on how the two factors might work in practice, *see infra* Subparts V.C.
[260] Supbart V.D., *infra*, explains that this test is best implemented through statutory change.
[261] *See* KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 406 (2007) (obviousness); Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1336 (Fed. Cir. 2013) (enablement).
[262] *See* Yu, *supra* note 36, at 959-60.

nature.[263] To help understand whether patent claims, narrow or broad, comply with the requirement, the test contemplates a large role for the disclosures in the patent specification. For example, if the specification explains what sorts of research and development pathways associated with the invention are outside the scope of the patent,[264] the claims would be more likely to pass the test than if it fails to do so because such disclosure would tend to favor the applicant with regard to the generality factor. Furthermore, if the specification tends to show that the invention works in predictable ways, such as by providing examples of well-defined approaches to implementing and applying the subject matter of the claim, that would argue against a conclusion of incompleteness based on the unpredictability factor.[265]

This aspect of the test sharpens the intuitions developed by 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, as well of the space that the patent has left open, thereby encouraging productive design-arounds. By providing such informative disclosures, the inventor would help mitigate potential harms of claims that threaten to be unacceptably upstream and, in exchange, increase his or her chances of receiving a patent.

B. Implementation issues

There are several substantive and procedural obstacles that could interfere with the implementation of this test, but none are likely to be insurmountable. One general objection to the proposed scheme concerns errors due to the failure to predict broad downstream applicability of the claimed technology and the corresponding potential of the underlying patents to impede downstream research and development.[266] To be sure, history provides some examples of inability (often of the inventors themselves) to foresee that an invention would be transformative.[267] But this

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[263] *Cf.* Chisum, *supra* note 48, 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.").

[264] *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.").

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

[266] *See, e.g.*, 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, May-June 1994, *available at* http://news.stanford.edu/pr/94/940601Arc4231.html). The prediction step is required because completeness would be measured at the time that the patent application is filed.

[267] *See, e.g.*, Duffy, *supra* note 193, at 239-40 (discussing the failure to patent Georges Kohler and Cesar Milstein's technique for producing monoclonal antibodies due to a government agency's inability to recognize the commercial potential of this

may not be a pervasive problem.[268] Consider, for example, the inventions discussed in this Article—the identification of selective Cox-1 inhibition that led to a new generation of painkillers,[269] the development of the PCR technique,[270] the derivation of human embryonic stem cells,[271] and the invention of the atomic force microscope.[272] For all of these inventions, the potential for numerous downstream applications was immediately clear to those in the field[273]—and there is no reason to believe that these four inventions are unrepresentative of other inventions that we may wish to prohibit patenting for reasons of incompleteness.[274] The first few ESTs 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 as

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technology). Even so, these researchers themselves apparently recognized the transformative nature of their invention. *See id.*

[268] Yu argues that, for many technologies, it would be impossible for anyone to foresee significant future applications. 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 taken into account. *Id.* at 961-62. Nonetheless, while *specific* applications might not be foreseeable, persons of ordinary skill in the art may nonetheless understand that the invention may be broadly and unpredictably applicable *in general*, which is all that the proposed test requires. Moreover, Yu's proposed "hindsight" approach might present other difficulties. *See infra* Subpart VI.B.1. *Cf. generally* Robin C. Feldman, *The Inventor's Contribution*, 2005 UCLA J.L. & TECH. 6.

[269] *See University Awarded Historic Drug Patent*, 62 ROCHESTER REV. (Spring-Summer 2000), *available at* http://www.rochester.edu/pr/Review/V62N3/inrev06.html. The attribution of the discovery of this process is not without controversy.

[270] *See* DENNIS W. ROSS, INTRODUCTION TO MOLECULAR MEDICINE 39-41 (2008).

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

[272] Ben Ohler, *Perspectives on Over Twenty Years of Life Science Research with Atomic Force Microscopy and a Look Toward the Future*, 16 MICROSCOPY & MICROANALYSIS 1034 (2010) (noting that the atomic force microscope was "immediately recognized as a valuable new technique"). *See* Binnig et al., *supra* note 60.

[273] *See supra* notes 269-272 and accompanying text. Interestingly, patents were obtained on all of these technologies, though the Cox-1 inhibition patent was later invalidated in the *Rochester* case.

[274] To be sure, some patents become might become widely applicable ex post. This may, for example, occur when a patent is denominated as standard-essential. *See, e.g.*, Josh Lerner & Jean Tirole, *Standard Essential Patents*, NBER Working Paper No. 19664, *available at* http://idei.fr/doc/wp/2014/wp_idei_803_v3.pdf. There are, however, specific mechanisms—including those provided by antitrust law—for dealing with these kinds of situations, and they have sometimes been 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); *see also infra* note 382 and accompanying text. In other cases, other ex post measures driven by the need for access may limit the enforceability of such patens or damages for their infringement, but I generally disfavor such measures. *See infra* notes 287-288 and accompanying text; *see also infra* Subpart VI.B.1. I thank Allen Yu for pointing me to the article by Lerner and Tirole.

well.[275] For software patents, the broad functional language of some claims encountered in the field may, on its face, provide a clue that the claim is directed to a foundational input into further development and is therefore incomplete[276]—and this is likely to be confirmed with expert testimony. 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 undertake and apply than the tests under other patentability requirements, like enablement and nonobviousness.[277] 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.[278] The potential for PTO errors due to information asymmetries and other challenges, however, is a systemic issue in the ex parte patent prosecution process, and it affects all of the patentability requirements.[279] For example, to overcome an obviousness rejection, an applicant might submit self-serving "evidence" of unexpected results,[280] and a PTO examiner might err by viewing that evidence as persuasive. Furthermore, PTO errors are not without remedies. For example, if a claim is improvidently granted in spite of incompleteness, it could be invalidated during post-grant review,[281] inter partes review,[282] or in district court litigation.[283] In cases of serious misconduct, a charge of inequitable conduct—which would render the entire patent unenforceable if successful—might be a possibility.[284] These prospects might deter some of the self-serving behavior and induce applicants to draft claims that would comply with the requirement. Another check is the doctrine of prosecution

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[275] *See* Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, ANN. REV. GENOMICS HUM. GENET. 382, 399-400 (2010).
[276] *See supra* note 70 and accompanying text.
[277] *See infra* notes 280-284 and accompanying text.
[278] Potential mistakes in the PTO's evaluations of completeness may be alleviated somewhat by the patent applicants' duty to disclose to the PTO information that is relevant to patentability. *See* 37 C.F.R. § 1.56 (2012). Wide industry praise and predictions of broad applicability by those in the relevant filed would be the kind of information that patent applicants would have to disclose as relevant to the completeness of the pending claims. *See also infra* note 284 and accompanying text (discussing the inequitable conduct doctrine). Interestingly, patent applicants might be additionally 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) (industry praise can be evidence of nonobviousness).
[279] *See generally* Sean B. Seymore, *Asymmetries in Patent Examination* (on file with author).
[280] *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).
[281] 35 U.S.C. § 321 (2012).
[282] *Id.* § 311.
[283] *Id.* § 282.
[284] Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

disclaimer—if the applicant asserts that his or her invention does not cover certain embodiments, he or she might be held to those statements during claim construction in litigation, and claim scope would be narrowed accordingly.[285] Finally, in some cases where the PTO improvidently grants a regular patent on an incomplete invention, the costs of error might be mitigated by the lack of downstream researchers' need to rely on the underlying inventions during the life of the patent.[286]

Measuring completeness at the time of patent filing presents its own set of issues specific to the proposed approach. For example, there may be cases where a patented invention, contrary to expectations, turns out to be surprisingly foundational and transformative at some point after filing. Although there might be a tendency for decision-makers to wish to invalidate such a patent, letting the inventor reap the windfall from a patent on what unexpectedly turned out to be a basic research input is the result contemplated under the proposed scheme.[287] And I believe that this would be the correct result. Upholding such a patent appears more equitable and more conducive to stable transacting and investment than the ex-post invalidation of the patent that would punish the inventor for the patent's unexpectedly broad applicability.[288] Moreover, although it is of course possible that the success of the invention could not have been predicted at all at the time of patent filing, an invention's transformative nature as determined at the time of litigation can serve as a post-filing "book of wisdom" that might cast doubt on the claim that the claim's broad-reaching nature could not have been foreseen.[289]

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 well be more than offset if the approach produces a greater number of outcomes, relative to the current approach, that are correct on utilitarian grounds. In addition, there is independent value in the increased legitimacy and decreased controversy associated with the integrated completeness requirement.[290] Indeed, the proposed test's key advance over the extant approach is that it supplements judicial intuitions—some of which may well evince "foresight bias" and overpessimism about the impact of certain patents on downstream

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[285] Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-36 (Fed. Cir. 2003).

[286] *Cf.* O'Toole, *supra* note 266 (listing examples).

[287] Unless, of course, the patent has taken on this role because the patentee has violated some other law, or behaved inequitably. *See supra* note 273 and accompanying text.

[288] Interestingly, courts have sometimes gone in the opposite direction and gave 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 (2012); 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 (2005); John R. Thomas, *The Question Concerning Patent Law and Pioneer Inventions*, 10 HIGH TECH. L.J. 35 (1995). For ex post approaches generally, *see infra* Subpart VI.B.1.

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

[290] *See supra* notes 34-38 and accompanying text.

research[291]—with a structured framework for evaluating claim completeness that can be informed with expert input. Accordingly, the 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 decision-maker could determine that a patent claim is incomplete based only on the information in the patent itself.[292] As a general matter, however, evidence extrinsic to the patent, such as whether those skilled in the relevant art[293] would expect the claimed invention to be broadly applicable, would be necessary in order 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 § 101 patentable subject matter requirements would be found invalid under the proposed completeness test. After all, the concerns behind the results in the cases and the overarching requirement I propose are fundamentally the same. Nonetheless, besides providing a framework that may be more transparent and consistent, the completeness test would lead to a more textured analysis than that developed by the messy case law. Keeping in mind that, if there were a completeness requirement in the form that I propose, patent applicants would have probably drafted their claims and specifications differently, I evaluate how the patents at issue in some utility, written description, and patentable subject matter cases might fare under the requirement—and how some hypothetical patents might do.

For example, a chemical compound whose only asserted utility is that of an object of unspecified future research would likely fail under the generality/unpredictability framework. 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, a fuel, and perhaps as an intermediate for making other chemicals.[294] In other words, the claim to the compound is likely to be directed to an invention that could help solve a number of

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[291] Seymore, *supra* note 30, at *1. 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, 794-96 (2011) ("[T]he court has removed the [person of ordinary skill in the art] from the inquiry, notwithstanding its statements that one determines whether the written description requirement is satisfied from the perspective of" that person.).

[292] *See infra* note 307 and accompanying text.

[293] For a discussion of the concept of an "ordinary artisan," *see infra* note 296 and accompanying text.

[294] 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 inquiry is fact-specific—and a fact-finder may well conclude that certain chemical structures are in fact 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, *see* Collins, *supra* note 203, 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.

downstream problems, leading to the finding that such a claim would set the foundation for future research and development as provided by the generality factor. Second, one would expect that a compound whose utility is completely unknown to end up playing a role in applications that cannot even be foreseen, tending toward the finding of incompleteness under the unpredictability factor. This, 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 method would be unlikely to lead to transformative and unpredictable downstream applications, but only uses of the compounds as intermediates in connection with a particular, known class of drugs.[295] 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[296] would probably not view the claim as directed to a fundamental research input or as a major impediment to a future work. Of course, there will be closer cases between these two extremes. For example, where a patent reveals a utility for a chemical compound that is substantial and specific 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,[297] the underlying claim might fail the completeness requirement. But the invalidity outcome in such a case is not a given, and one would imagine that if two different tribunals reached the opposite conclusions on such a claim, both decisions might be sustained on appeal because of the fact-specific nature of the generality and unpredictability inquiries.

The claims at issue in some of the written description cases—for example, those addressing method-of-treatment claims without a showing of any specific drugs[298]—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.[299] In addition, in

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[295] 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. CHEM. SOC'Y 12640 (2005).

[296] An ordinary artisan, also referred to as a "person of 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, 99 (2012).

[297] *Cf.* Seymore, *supra* note 30, at *46; *see also In re* Kirk, 376 F.2d 936, 960-61 (C.C.P.A. 1967) (Rich, J., dissenting).

[298] Or, a showing of very few drug examples. *See supra* notes 63 & 138 and accompanying text.

[299] *See supra* notes 63-66 and accompanying text; *see also* Abbvie Deutschland GMBH 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

the representative *Rochester* case, the "non-steroidal" limitation in the claims is not much of a constraint, and one might predict that future researchers will find chemicals falling within the scope of the claim that have completely unexpected structures. Because they threaten research and development pathways involving the synthesis and study of various drug candidates, such claims are likely to fail under the completeness test absent a contrary showing in the patent's specification.[300] Other patents in the biotechnology arena that could be in danger are methods of manipulating genetic material, like PCR, because it is likely that an ordinary artisan would recognize this invention's value as a research input and could attest to its broad and transformative applicability.[301] Isolated human embryonic stem cells would be subject to completeness scrutiny for similar reasons.[302]

Moreover, the proposed form of the completeness requirement would direct decision-makers to look outside chemistry and biotechnology fields for potentially problematic claims. One possible area of application involves software (and business method) patents. As discussed above, it has been argued in a recent article that many software and business method patents seem, generally speaking, to be directed to a problem to be solved rather than to a solution.[303] This critique is quite similar to the concerns about functionally drafted claims in the area of biotechnology,[304] which suggests that certain software and business method claims should be scrutinized for completeness as well.[305] 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.[306] Indeed, some of the

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Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc)).

[300] *See supra* Subpart IV.B.

[301] *See supra* note 59 and accompanying text. 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, but on the other, PCR can serve as a method of determining paternity, of finding a crime suspect to a crime scene, or of detecting a virus. Since we are concerned with preemption of downstream applications, the latter set of uses would be taken into account in the incompleteness analysis.

[302] *See supra* notes 58 and accompanying text.

[303] *See* Lemley, *supra* note 26; *see also supra* note 70 and accompanying text.

[304] *See supra* notes 212-218 and accompanying text. *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").

[305] *But cf. supra* note 28 and accompanying text (discussing recent invalidations of software and business method patents under the patentable subject matter requirement).

[306] Mark Lemley provides a number of examples of such claims in a recent article. *See* Lemley, *supra* note 26, at 920-22. One example is a patent that was recently invalidated in *Walker Digital, LLC v. Google, Inc.*, C.A. No. 11–318–LPS, 2014 WL 4365245 (D. Del. Sept. 3, 2014), which includes 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 first data including an identity for said first party," "receiving from said first party at least two first-party rules for releasing said first data including a rule for releasing said identity of said first party," and "releasing said identity of said first party" based on whether

claims one encounters in these fields are so facially broad that they might fail the completeness requirement no matter what the specification (or an expert) says.[307] Scientific instruments provide another illustration of how the completeness requirement might be applied. Thus, 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.[308] Claims to others, perhaps gold metal detectors, would probably pass the requirement because of their narrowly defined utility.

Two final illustrations of how the proposed completeness requirement may be applied are based on recent, controversial Supreme Court cases in the life sciences area. One example relates to the patentability of DNA molecules at issue in *Association for Molecular Pathology v. Myriad Genetics, Inc.*[309] As discussed above, the Supreme Court in *Myriad* invalidated the claims to the molecules excised from naturally occurring DNA because of the "focus on the genetic information" encoded in the molecules, but refused to invalidate the claims to the non-naturally occurring molecules encoding the same information.[310] 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.[311] The incompleteness analysis is agnostic to whether the previously unknown material is "natural" or not, for a focus on natural-ness would threaten to undermine the utilitarian grounding of the test.[312] Rather,

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the rule is satisfied. *Id.* at *4 (citing U.S. Patent No. 5,884,270, claim 1); *see* Lemley, *supra* note 26, at 920 & n.67. The accused technology included LinkedIn and Facebook social networking sites, which make results of searches available based on users' privacy settings. *See Complaint*, Walker Digital, LLC v. Google, Inc., C.A. No. 11–318–LPS, ¶¶ 25, 30 (Apr. 11, 2011). The different social networking sites might have completely different algorithms for carrying out these functions, but they would all be covered by the functionally drafted claims of this sort. 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.").

[307] *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.").

[308] *See supra* notes 60-61 and accompanying text; *see also supra* note 196 and accompanying text.

[309] 133 S. Ct. 2107 (2013).

[310] *Id.* at 2118; *see supra* notes 238-238 and accompanying text.

[311] *But cf.* W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won't Hinder Whole-Genome Sequencing and Personalized Medicine*, 33 CARDOZO L. REV. 1602 (2011).

[312] Yu, *supra* note 35, at 430 (arguing that, "instead of focusing on legally construed notions of what is nature and what is man-made, [his proposed requirement] focuses on articulating the costs of patents"); *see also* Devlin, *supra* note 16, at 1716-18 (explaining patentable subject matter exclusions in utilitarian terms); *cf.* Sherkow, *supra* note 233, at 1143 (arguing for the abandonment of terms like "natural" and proposing a different test); Sichelman, *supra* note 240, at 371-72 (describing

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 *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[313] would probably pass the completeness test. The claims in that case were directed to administering a probe molecule along with a 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.[314] Although the Supreme Court was concerned that this claim 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 tell the Court that this was not the case.[315] Indeed, it is not clear that the *Mayo* invention has many significant downstream applications, and that all or even most possible applications were necessarily preempted by the claims. 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.[316] Furthermore, it is difficult to think of applications of the correlation that are unforeseeable and transformative. Thus, the proposed framework would likely lead to a different result in this case than the Supreme Court's test that prohibits "conventional" applications of abstract ideas, laws of nature, and natural phenomena.[317] In other words, Prometheus's claim would be patentable.

D. The need for implementation through statutory change

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, Mark Lemley, Michael Risch, Ted Sichelman, and Polk Wagner argue that § 101 should be reconceived as a backstop against overbroad claims that survive scope restrictions imposed by the enablement requirement, which is set forth in § 112.[318] Allen Yu argues that § 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 non-technological innovations.[319] And Sean Seymore proposes the concern about research preemption that courts currently address under the utility requirement should be dealt with through the enablement and

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difficulties in identifying "natural laws" telling apart "natural" and "synthetic"). *But cf.* Chiang, *supra* note 17, at *18-25 (arguing that the justification for the result in *Myriad* might be nonutilitarian).

[313] 132 S. Ct. 1289 (2012).

[314] *Id.* at 1295-97.

[315] *See* Dreyfuss & Evans, *supra* note 264, at 1360-61 ("[T]here are arguably other ways to achieve the goals of the [*Mayo*] patent.").

[316] *Cf. id*. *But see* Note, *Diagnostic Method Patents and Harms to Follow-on Innovation*, 126 HARV. L. REV. 1370, 1386-87 (2013) (arguing that the patent at issue in *Mayo* was harmful to downstream innovation).

[317] *See supra* notes 231-235 and accompanying text.

[318] Lemley et al., *supra* note 35.

[319] Yu, *supra* note 35, at 427-38.

nonobviousness requirements.[320] Similarly, it may be possible to implement the completeness requirement via one of the extant patentability requirements. Nonetheless, such an approach would be problematic.

Although the enablement requirement might seem to be a good candidate for enforcing completeness because of its focus on overclaiming,[321] several factors make it a less than ideal fit. The enablement requirement attempts to answer, based on a number of factors, whether a person of ordinary skill in the art could practice the full scope of the claim based on the disclosures in the specification without undue experimentation at the time of patent filing.[322] The timing aspect of the requirement generally means that claims can cover after-arising technology without an enablement violation.[323] Indeed, while the enablement requirement helps ensure that there is a reasonable correlation between what is disclosed and claimed,[324] it is not as explicitly concerned with the research-input nature of patent claims and their impact on downstream research as the applications of the requirements of utility, written description, and patentable subject matter considered in this Article. Indeed, current completeness doctrines appear to exist in part because, even assuming 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.[325] Conversely, a claim might be invalidated for lack of enablement even when the claimed invention is not so upstream and transformative as to be considered an artifact of basic research.[326] The enablement requirement is best left alone to play its current role.

Nor do I think giving § 101 an expanded role would be effective at carrying out the goals of completeness. 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 statue, which allows a patent on any "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,"[327] with a prohibition of patents on a tangible entity such as an atomic force microscope or a chemical compound, which could eventuate under my proposed scheme. Two other potential hooks in § 101 are the words "new" and "useful," but I believe that neither can adequately do the job of supporting the prohibition against the

[320] Seymore, *supra* note 30, at *26-41.
[321] *In re* Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970) (requiring 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).
[322] *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). In contrast, the completeness requirement in the form that I propose focuses in part on whether it can be predicted at the time of filing whether a large-number of after-arising technologies will fall within the scope of the claim.
[323] *See* Collins, *supra* note 321; Collins, *supra* note 203; Lemley et al., *supra* note 35, at 1329-32.
[324] *See supra* note 321 and accompanying text.
[325] *Cf.* Lemley et al., *supra* note 35, at 1329-32.
[326] *See, e.g.*, Sitrick v. Dreamworks, LLC, 516 F.3d 993 (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).
[327] 35 U.S.C. § 101 (2012).

patenting of basic research. The word "new" has been relied upon by some scholars to support a distinction between patentable "inventions" and unpatentable "discoveries,"[328] a distinction I reject here in favor of a general utilitarian test for basic research. And, as already discussed in the context of the utility requirement, the word "useful" comes with its own baggage—in particular, a prohibition on patents on inventions that have research utility reflects a highly controversial interpretation of "useful."[329] Thus, an approach relying on this word would not resolve the legitimacy problems associated with the current implementation of the completeness requirement.

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 substantive patent reform,[330] this sort of a change seems unlikely in the near future. Nevertheless, recent developments in the completeness doctrine—particularly patentable subject matter cases—have become a cause for concern.[331] For example, some recent decisions, depending on how they are applied by the lower courts and interpreted by the PTO, might threaten to 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 inputs into future research and development.[332] If consensus develops that a new test for separating useful from harmful patents is required, perhaps a codification of the completeness requirement—adopting suggested modifications that would bring it closer into line with patent law's utilitarian goals—might become a possibility. Indeed, although completeness reflects crucially important policies, the court's current implementation of this requirement may be nearing its "flash of genius" moment,[333] and codification and course correction might be in order. In addition, as already suggested, codification would likely help reduce the legitimacy costs of the current implementation of the completeness requirement.[334]

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[328] *See, e.g.*, Demaine & Fellmeth, *supra* note 208, at 345-49.

[329] *See supra* Subpart IV.A.

[330] *See* Andrew Baluch, *PATENT REFORM 2014: A Comprehensive Guide to Current Patent Reform Developments in Congress, the Executive Branch, the Courts and the States*, *available at* http://ssrn.com/abstract=2414306, at *3-27.

[331] *See, e.g.*, Holman, *supra* note 228; Laura W. Smalley, *Will Nanotechnology Products Be Impacted by the Federal Courts' "Products of Nature" Exception to Subject-Matter Eligibility Under 35 U.S.C. 101?*, 13 J. MARSHALL REV. INTELL. PROP. L. 397 (2014).

[332] *Cf. In re* Roslin Inst., 750 F.3d 1333 (Fed. Cir. 2014) (rejecting a patent on a cloned animal under § 101); Planet Bingo, LLC v. VKGS LLC, 576 Fed. Appx. 1005 (Fed. Cir. 2014) (nonprecedential) (invalidating patents for managing the game of bingo); PerkinElmer, Inc. v. Intema Ltd., 496 Fed. Appx. 65 (Fed. Cir. 2012) (nonprecedential) (invalidating a patent on screening methods for estimating the risk of fetal Down's syndrome); *see also* Ariosa Diagnostics, Inc. v. Sequenom, Inc., No. C 11-06391, 2013 WL 5863022 (N.D. Cal. Oct. 30, 2013), *appeal docketed*, 2014-1139 (Fed. Cir.). *Cf.* Sichelman, *supra* note 240, 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").

[333] *See supra* note 43 and accompanying test.

[334] *See supra* notes 192 & 240 and accompanying text.

The requirement, as codified, might simply say, in a new section 35 U.S.C. § 112(g)(1), that "basic research shall be unpatentable." The generality/unpredictability framework introduced above provides one way of implementing the requirement and might itself be codified, but perhaps other tests for evaluating whether a claim is directed to a foundational research input could be developed. In addition, just as the codified nonobviousness requirement abrogated the "flash of genius" test by the statement that "[p]atentability shall not be negated by the manner in which the invention was made,"[335] the codified completeness requirement might be accompanied by abrogation of the holdings of cases that gave rise to the current completeness doctrine. Thus, section (g)(2) might be added stating that

> A patent claim should not be denied solely on the basis that the claimed invention has only general research utility. A patent claim should 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.[336] A patent claim should not be denied solely on the basis that it does not constitute an inventive application of, or is not markedly different from, a law or a product of nature, a natural phenomenon, or an abstract idea.[337]

The purpose of this statutory structure is to help replace the extant approaches to completeness with a unified approach. It is of course possible that, in the course of implementing the new completeness requirement, courts might revert to some of the discarded tests in their attempts to figure out 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. But I believe that the new statutory provisions, 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 develop.

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[335] *Id.*

[336] This proviso excludes claims that are governed by 35 U.S.C. § 112(f). For these co-called "means-plus-function" claims, unlike regular claims, the statute explicitly requires structural disclosures, such as algorithms, in the specification. I do not propose to change this aspect of patent law. *See supra* note 28 and accompanying text.

[337] To be sure, the utility, written description and patentable subject matter requirements would not be completely eliminated as a result of this change. The utility requirement would still bar patents on inventions lacking in operable or credible utility, *see infra note* 407, the written description requirement would continue to play the so-called "priority-policing" function, *see infra* note 175, 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 supra* notes 400-405 and accompanying text.

VI. THE RESEARCH PATENT PROPOSAL

A. Do limited rights for incomplete patents make sense?

The foregoing Part assumes that artifacts of basic research should be unpatentable. This Part questions this assumption and proposes a limited bundle of rights for patents that pass the extant requirements of patentability but fail completeness. This suggestion stems from the intuition that if 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.[338]

The undue preemption concern arises for many reasons. First, as discussed extensively in the Article, it is thought that upstream patents might chill downstream innovation. Second, creation and even commercialization of upstream inventions might be particularly likely to be incentivized by non-patent mechanisms, including professional advancement and reputational gains, governmental and non-governmental support for basic research in the form of grants, tax incentives, or other mechanisms, and regulatory exclusivity.[339] Yet it would be difficult to make the case that the right amount of intellectual property protection for the products of such research is zero.[340] And while narrower patent claims can provide adequate patent protection for some inventions, there will be circumstances where such claims would be inadequate.[341]

One powerful explanation for certain bright-line exclusions from patentability, as now implemented under the aegis of § 101, is that they can

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[338] *See supra* notes 49-50 and accompanying text.

[339] *See* Lisa Larrimore Ouellette, *Patentable Subject Matter and Non-Patent Innovation Incentives*, 5 U.C. IRVINE L. REV. (forthcoming 2015), at *11-12 *available at* http://ssrn.com/abstract=2499204.

[340] *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 16, at 1735 ("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 quite strong.").

[341] Indeed, narrow claims often have little commercial value, and do not allow the inventor to capture any significant reward from a path-breaking contribution. *See, e.g.*, Mueller, *supra* note 35, at 651 (arguing that the rule prohibiting "research plan"-type patents "reduces incentives to invest in innovation by depriving potential patentees of the opportunity to fully benefit from their research"); Plimier, *supra* note 66, at 161 ("The written description requirement only allows very narrow patents, so narrow and easily dodged as to be almost worthless."); *see also supra* notes 8 & 66 and accompanying text. *Cf.* Benjamin N. Roin, *Solving the Problem of New Uses*, *available at* http://ssrn.com/abstract=2337821 (describing a particular type of patentable but effectively valueless claims); *see also* Rai, *supra* note 20, 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.").

be welfare-enhancing for subject matter with respect to which the PTO is particularly likely to make mistakes when it evaluates the underlying claims under other patentability requirements.[342] But this explanation is premised on the current state of affairs in which the consequence of the error is the formidable right of the regular utility patent. In other words, for a given patent claim, the PTO (or a court) can either allow a full patent right or entirely reject (or invalidate) the claim, without the option of an in-between solution.[343] The all-or-nothing approach with respect to any given claim is one of the patent system's imperfections, resulting in what Michael Carroll terms "uniformity costs."[344]

Bright-line exclusions of artifacts of basic research from patentability represent one way to address the concern regarding the consequences of improvidently granting patents under the other requirements of patentability. Another approach, however, might be to mitigate the uniformity (and error) costs through granting a patent right that is limited in some way. This approach might be warranted if one accepts the proposition that, while full patents on upstream inventions might be socially harmful, *some form* of a patent incentive—which might not be quite as threatening to downstream research—might be appropriate for inducing their creation and commercialization.[345]

The proposition that some sort of a patent right is required to incentivize basic research is not implausible. For example, absence of patenting for upstream inventions in certain fields is inconsistent with the goals of the Bayh-Dole Act, which was enacted to incentivize the technology transfer and commercialization of university inventions through patenting.[346] One of the arguments advanced in favor of Bayh-Dole was that, even if university researchers' need to publish and drive for prestige would cause the creation of upstream inventions in the absence of patent protection, firms would be uninterested in commercializing these inventions without patent coverage.[347] The Bayh-Dole regime has not, of course, escaped

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[342] Golden, *supra* note 231, at 1066-70.

[343] To be sure, patent law does permit tailoring of rights during patent prosecution by allowing the inventor to vary the *scope* of the patent claims. For a discussion of the option of narrow claims, *see supra* note 341.

[344] *See supra* note 52 and accompanying text. *Cf. See* LEO KATZ, WHY IS THE LAW SO PERVERSE? 145-51 (2012) (contrasting all-or-nothing results in law with intermediate or "continuized" results).

[345] *See supra* notes 340 and accompanying text; *cf.* Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341 (2010).

[346] See 35 U.S.C. § 200 *et seq.* Although this argument was rejected in *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929 (Fed. Cir. 2004), on the basis that the policy of bringing pioneering innovations to the public does not trump the statute, this reasoning is questionable because *Rochester* and related cases themselves appear to be expressions of public policy. *See infra* notes 146-151 & 222-226 and accompanying text.

[347] *See* 35 U.S.C. § 200 (2012) ("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 . . ."); *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.").

criticism,[348] but it is thought to make some sense for commercialization of upstream inventions in the biotechnology industry[349]—the very sorts of inventions that often fall victim to the completeness requirement. Finally, concerns that drive early patent filing are not limited to university inventions. The certainty provided by a patent right is also a draw for commercial researchers who would like to engage in licensing transactions and otherwise disclose their inventions.[350]

Relatedly, a patent right would serve as a mechanism for inducing disclosure of widely applicable inventions in research 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."[351] 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"[352] and aid in "achieving and publicizing basic research."[353] Even if such patents might not always be widely read,[354] the patenting might facilitate so-called "peripheral" disclosures, such as communications of the underlying inventions to potential investors.[355] In addition, if the completeness test incorporates information-forcing

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[348] *See, e.g.*, DAVID C. MOWERY ET AL., IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT (2004).

[349] *See* Mark A. Lemley, *Are Universities Patent Trolls?*, 17 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 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.") (citations omitted) (emphasis added).

[350] *See* Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1, 29 (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 (2012) (arguing that intellectual property rights are not always necessary for facilitating the exchange of information).

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

[352] Brenner v. Manson, 383 U.S. 519, 539 (1966) (Harlan, J., dissenting)

[353] *Id.* Several scholars have argued that patents fail at their teaching function. *See, e.g.*, Holbrook, *supra* note 35, at 136-46; Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 641-46 (2010) (similar). But patents *can* more readily aid in disseminating information by facilitating other disclosures, such as publications of academic papers and the placing of products embodying the patented invention into the stream of commerce. *See generally* Rantanen, *supra* note 350; *see also* Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 531 (2012).

[354] *See, e.g.*, Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19.

[355] *See generally* Rantanen, *supra* note 350; *see also* Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609 (1962). *See also supra* note 350 and accompanying text.

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 made might become quite socially valuable.[356]

B. Prior proposals for limited rights in upstream inventions

1. Ex post approaches

The intuition that upstream patents should be allowed—but limited in some form—might explain proposals for ex post limitations on patent rights that are triggered during enforcement of some of these patents. One solution preserves the validity of upstream patents but provides for a revival of a personal "experimental use"[357] exemption to patent infringement. Proponents of this approach argue that, depending on the nature and purpose of use of the claimed invention, the accused infringer should be shielded from liability.[358] Conceptually related to the experimental use exemption are proposals that entail expanding the so-called reverse doctrine of equivalents,[359] which shields "radical improvements" of the patented technology from infringement liability, and the doctrine of patent misuse, which could be deployed to render patents unenforceable when the patent owner attempts to extract "reach-through" royalties.[360] Generalizing from

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[356] *See supra* notes 263-264 and accompanying test.

[357] 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).

[358] These scholars argue that, depending on the nature and purpose of use of the claimed invention, the accused infringer should be shielded from liability. *See, e.g.*, Mueller, *supra* note 55, at 36-37; Strandburg, *supra* note 54, at 96-100. In addition, Strandburg has suggested 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. Strandburg argues that "experimenting on" should be completely exempt from infringement, but proposed a specialized scheme for "experimenting with" research tool patents. 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. Strandburg, *supra* note 54, at 119-38.

[359] *See* Koneru, *supra* note 187, at 663-65; Lemley, *supra* note 266, at 1011-13 ("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, *On the Complex Economics*, *supra* note 93, at 860-68; *see also* Chisum, note 48, 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 206. Although academic literature often discusses the reverse doctrine of equivalents in the context of "mutually blocking" patents, *see supra* notes 193-202, the application of the doctrine is theoretically not limited to those circumstances.

[360] *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

these proposals, Katherine Strandburg argues that contextual infringement determinations based on a flexible, multifactor test inspired by the statutory fair use factors in copyright law[361] can account for implications of technological unpredictability—such as uncertain value and applicability of upstream inventions.[362] And there is yet another, existing "ex post policy lever" for curtailing patent rights currently deployed 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.[363]

The difficulty with the ex post approaches, however, is that the rights of the parties might not be clearly established until after the conclusion of the litigation.[364] Indeed, a major worry is that the costs associated with figuring out ex post whether the accused infringer is liable and how much it should pay are very high.[365] Expenses associated with patent litigation, which is needed to ultimately sort out whether a user is liable for infringing a valid patent and what the infringement remedies should be are thought to distort patent value.[366] Although the parties can of

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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."); *see* Bayer AG v. Housey Pharm. , Inc., 228 F. Supp. 2d 467 (D. Del. 2002).

[361] *See* Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 UC IRVINE L. REV. 265, 277 (2011). *See generally* Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

[362] Strandburg, *supra* note 361, at 274-79.

[363] *Id.* at 277-79 ("[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* eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 393-94 (2006). For an interesting recent proposal for tailoring damages based on patent disclosures, see Bernard Chao, *The Infringement Continuum*, 35 CARDOZO L. REV. 1359 (2014).

[364] *Cf.* LAWRENCE LESSIG, FREE CULTURE 99 ("The fuzzy lines of the 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.") (discussing the ineffectiveness of the 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, 35 U.S.C. § 271(e), *compare* Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011) (finding no statutory experimental use), *with* Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348 (Fed. Cir. 2012) (finding statutory experimental use under factually similar circumstances).

[365] For a sampling of works, *see* James E. Bessen & Michael J. Meurer, *The Direct Costs from NPE Disputes*, 99 CORNELL L. REV. 387 (2014); Colleen V. Chien & Michael J. Guo, *Does the US Patent System Need a Patent Small Claims Proceeding?*, *available at* http://ssrn.com/abstract=2249896. For my own work on an approach to limiting litigation costs in certain circumstances, *see* Dmitry Karshtedt, *Contracting for a Return to the USPTO:* Inter Partes *Reexaminations as the Exclusive Outlet for Licensee Challenges to Patent Validity*, 51 IDEA 309, 331-32 (2011).

[366] *See* Judge J.T. Ellis, III, *Distortion of Patent Economics by Litigation Costs*, CASRIP pub. Ser. No. 5, *available at* https://www.law.washington.edu/CASRIP/Symposium/Number5/pub5atcl3.pdf. The validity of the patent can also be adjudicated via post-grant inter partes review in the PTO, but this forum is not available for determining infringement liability and

course settle or choose arbitration,[367] the very threat of the patent lawsuit creates opportunities for holdup and thus affects the value of the settlement or the decision whether or not to go to arbitration. The unpredictability of juries and potential exposure to a large amount of damages, even in lieu of an injunction, makes the ex post approach even more unattractive.[368] In addition, as argued by Alan Devlin, "[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."[369] In contrast, the proposed approach avoids the ex post determination of patent value during litigation.

2. Sui generis approaches

A few other approaches to limiting upstream inventions are worth noting. Particularly, some commentators have dealt with 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 the fields ranging from biotechnology to software,[370] while others have advocated compulsory

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remedies. *See* J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917, 952 (2011) (patent litigation "costs upwards of $15 billion per year to patentees and accused infringers").

[367] *See* 35 U.S.C. § 294 (2012).

[368] *See, e.g.*, FED. TRADE COMM'N, *The Evolving IP Marketplace, Aligning Patent Notice and Remedies with Competition* 161-62 (Mar. 2011), *available at* www.ftc.gov/os/2011/03/110307patentreport.pdf; *see also* LESSIG, supra note 364, at 99. *But see* Michael J. Mazzeo et al., *Excessive or Unpredictable? An Empirical Analysis of Patent Infringement Awards*, *available at* http://ssrn.com/abstract=1765891. *Cf.* Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985 (1999) (arguing that uncertainty in the type of remedy for patent infringement may be socially beneficial).

[369] Alan Devlin, *Restricting Experimental Use*, 32 HARV. J.L. & PUB POL'Y 599, 635 (2009) ("Indeterminate ex post interference in proprietary rights by the courts tends to inject further uncertainty into an already flawed system, to undermine efficient contractual exchange, and to endanger ex ante technological research."); *see* Richard A. Epstein, *Steady the Course: Property Rights in Genetic Material*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 168-79 (F. Scott Kieff ed. 2003) (highlighting problems with forced transfers of patent rights, such as compulsory licenses); *see also* Eisenberg, *supra* note 91, 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.").

[370] Julian D. Forman, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 681-82 (2002) (proposing this solution for ESTs); Holman & Munzer, *supra* note 92, at 810-20 (discussing a shortened patent term for ESTs and proposing a registration system). *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 of software). For an approach to software patent scope that can be

licensing for patents on certain types of technology[371] and proposed other limits on remedies for successful enforcement of such patents.[372] Implicitly or explicitly, these proposals may reflect the fact 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.

C. Toward a research patent right

1. Features of the research patent

Devlin has argued that "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 ante approaches] is to reduce the scope and duration of that protection ex ante through legislative fiat."[373] The Research Patent (RP) proposal adopts a form of this approach.[374] 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 treatment setting forth patent rights for such inventions. At a high level, any patent claim that passes the extant requirements of patentability at the PTO, but fails the completeness requirement, would not be invalidated but rather given a limited patent right in the form of an RP.

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.[375] Liability-rule protection of upstream patents makes sense because full rights in such patents appear to be associated with a high rate of market

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implemented under existing law, see Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L. REV. 1 (2001).

[371] 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 (2001) (proposing this solution for DNA sequences); Lopez-Beverage, *supra* note 103, at 90-91 (proposing this solution for ESTs).

[372] *See* Cara Koss, *Oyster and 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); Mireles, *supra* note 103, at 194-234 (similar); *see also* Jerome 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 43-55 (Paul F. Uhlir ed. 2011); Michael J. Stimson, *Damages for Infringement of Research Tool Patents: The Reasonableness of Reach Through Royalties*, 2003 STAN. TECH. L. REV. 3 (proposing an approach to damages for infringement of research tool patents within the statutory reasonable royalty framework).

[373] Devlin, *supra* note 369, at 635.

[374] The shortened patent term suggestion would be unsuitable here because the holdup problem would remain. *See supra* notes 364-368 and accompanying text.

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

failure.[376] 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.[377]

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.[378] Damages caps are a familiar feature of tort reform efforts—for example, several states have instituted caps on compensation for medical malpractice.[379] If damages can be capped for physical injury, damage caps or scheduled damages for patent infringement also appear to be reasonable,[380] and will help mitigate holdup problems stemming from unpredictable jury verdicts.[381] The fact that, for many of the types of patents discussed in this Article, private arrangements such as patent pools have not succeeded underscores the potential value of a government-mandated liability-rule solution.[382]

A specialized tribunal would be needed to reduce the threat of holdup associated with the costs of patent litigation in district courts. One possibility is a specialized patent small claims court. Interestingly, such a tribunal has been proposed as part of recent efforts to reform the Patent Act in pursuit of the goal of reducing the incidence of nuisance-value

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[376] *See* FELDMAN, RETHINKING PATENT LAW, *supra* note 86, 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 195, 200-01 (F. Scott Kieff ed. 2003); Liivak, *supra* note 104, at 1372. *See generally* Ben Depoorter, *Property Rules, Liability Rules, and Patent Market Failure*, 1 ERASMUS L. REV. 59 (2008).

[377] *See* Daniel R. 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).

[378] This approach, of course, does not eliminate attorney 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 are expected to be much lower that the costs of litigating a regular patent in a district court.

[379] *See, e.g.*, Cal. Civ. Code § 3333.2 (2013); Colo. Rev. Stat. § 13-64-302 (2005); Fla. Stat. Ann. § 766.118 (2013). For a summary of malpractice cap statutes as well as an analysis and criticism, see Catherine M. Sharkey, *Unintended Consequences of Medical Malpractice Damages Caps*, 80 N.U.Y. L. REV. 391, 476 (2005).

[380] *Cf.* Samuel L. Bray, *Announcing Remedies*, 97 CORNELL. L. REV. 753 (2012) (arguing that scheduled damages reduce administrative costs and fosters 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 between venue, and other factors that open the legal system to manipulation).

[381] *See generally* Lemley & Shapiro, *supra* note 273.

[382] *Cf.* Bradley J. Levang, Comment, *Evaluating the Use of Patent Pools for Biotechnology: A Refutation to the USPTOs White Paper Concerning Biotechnology Patent Pools*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 229, 249-50 (2002); *see also* Scott Iyama, Comment, *The USPTO's Proposal of a Biological Research Tool Patent Doesn't Hold Water*, 57 STAN. L. REV. 1223 (2005). In contrast, patent pools and related private arrangements, such as standard-setting organizations, have been formed for certain standard-essential patents in the telecommunications field. *See* Lemley & Shapiro, *supra* note 273.

settlements.[383] The PTO has issued a request for comments,[384] and several suggestions for what form such a court might take have been put forward.[385] These proposals for reforming patent litigation have been criticized, however, because of the potential of small claims court proceedings to lead to the dilution of patent rights and the concern that mandatory litigation in such tribunals would violate the Seventh Amendment right to a jury.[386] In contrast, if a patent is designed by statute to come with a limited bundle of rights, these concerns are not present.

In keeping with the goal of facilitating low-cost resolutions of disputes over RPs, the tribunal would only be able to evaluate ordinary infringement and invalidity based on patents and written publications.[387] This approach avoids costly, discovery-intensive subjects like inequitable conduct and willfulness,[388] as well as non-prior art invalidity.[389] Reflecting the limited nature of the RP right, no claims for infringement under the doctrine of equivalents would be allowed.[390]

2. Challenges of the approach

The tentative RP proposal described herein is open to numerous objections.[391] The essence of some of them is that the RP game is not worth the candle—that the "coarse filter" approach of invalidating all incomplete patents would be more effective from the utilitarian perspective. Two of the possible difficulties include determining 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. In this Subpart, I briefly examine these objections.

Whatever numbers are chosen, scheduled damages will be certainly inaccurate as estimates of patent value for a number of reasons—for example, because of the differences in value of patents from one technology to another and the variance in how extensively various infringers might use the technology. Nonetheless, the scheduling approach has the advantage of sidestepping the notoriously difficult problem of litigation-forced valuation

[383] *See, e.g.*, Chien & Guo, *supra* note 365.
[384] *See Request for Comments on a Patent Small Claims Proceeding in the United States*, 77 Fed. Reg. 7480 (2012).
[385] *See, e.g.*, *supra* note 383 & *infra* note 388.
[386] *See generally* Robert P. Greenspoon, *Is the United States Finally Ready for a Patent Small Claims Court?*, 10 MINN. J.L. SCI. & TECH. 549 (2009).
[387] Moreover, in order to encourage the limited validity challenges, claim amendments would not be allowed.
[388] *See Comments of Michael Risch in Response to PTO Request for Comments on Patent Small Claims*, Docket No. PTO-P-2012-0050, http://www.uspto.gov/ip/global/patents/comments/comments_to_us_pto_re_patent_small_claims.pdf; *see also* Karshtedt, *supra* note 365.
[389] Indeed, non-prior-art based challenges at the Patent Trial and Appeal Board are already disallowed during inter partes review of issued patents. *See* 35 U.S.C. § 311(b) (2012).
[390] *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997).
[391] The RP proposal will be worked out further and objections examined in greater detail in a separate article. Besides the objections discussed in this Subpart, such a system may perhaps be challenged on constitutional grounds. *See supra* note 182.

of patents by courts,[392] which have often questioned their own competence to gauge patent damages.[393]

In addition, at least extent of the infringement might be taken into account in some way under the scheduling approach.[394] For example, damages under an RP claim 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 claim based on whether the infringer's use of the claimed invention is "maximum," "medium," or "small" according to some preset schedule.[395]

Moreover, the scheduling approach shifts the focus from measuring the damages for any particular act of infringement to rewarding the RP owner for how broadly the technology is used—and it is easier to quantify the *number* of infringers than the *value* of any particular infringement.[396] Even if the amount of scheduled damages is small, the size of recovery from any individual user would encourage the RP owner to search out as many downstream users as possible to obtain adequate compensation.[397] This

[392] Indeed, the valuation problem is one of the common objections to compulsory licensing of issued patents. *See* Epstein, *supra* note 369.

[393] *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 rather than those of a judge").

[394] Relatedly, the claims would follow the rules of res judicata—all the available claims should be brought at once—and the same party in interest would not be able to bring multiple, successive claims against a given user of the technology within three years. Finally, the plaintiff would be able to recover only once from a given user for a particular portfolio (i.e., a group patents that are a part of the same patent family or are directed to closely similar technology).

[395] The overall approach resembles the determination of copyright royalties for song covers, but with more rigid "scheduling" awards. *Cf.* Sandra Schmieder, *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 done for covers of copyrighted songs. As the experience with copyright royalty panels has shown, this system has generally functioned well and even had the effect of promoting private negotiation. *See* Daniel R. Cahoy, *Breaking Patents*, 32 MICH. J. INT'L L. 461, 499 (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). Whatever one thinks of Copyright Royalty Boards, the market failure problem with upstream patents would seem more acute than that with cover songs. *See supra* notes 376-382 and accompanying text. But patents will surely present greater valuation difficulties.

[396] Consistent with this approach, sublicensing of the right to use the RP subject matter by the infringer to another party would not be allowed.

[397] Indeed, "[if you create enough certainty in the commercial and regulatory landscape, a private market will fill in the spaces unless impeded by some other

approach encourages the spreading of liability rather than a focus on a few "deep pockets" infringers in an effort to obtain large damages or an injunction,[398] which is a strategy that can be pursued with regular utility patents.[399] Thus, RP owners may still recoup their research and development costs if the subject matter of the RP is broadly applicable. Finally, while investigating potential infringers before the claim is brought can be costly, the RP owner can likely obtain economies of scale in its pre-claim investigations after identifying the first few suspected downstream infringers and proving that they infringe.

The line-drawing between completely unpatentable inventions and those that qualify for an RP also presents very difficult questions. As an initial matter, § 101 limits patentable subject matter categories to "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,"[400] and claims directed to subject matter outside of these prohibited categories would not be entitled even to an RP. In addition, even if a claim is nominally fits into an allowable statutory category, long-standing precedent prohibits patents that are manifestly directed to[401] abstract ideas, natural laws, formulae, or natural phenomena—say, "a method of calculating energy from mass, the method comprising multiplying the mass by the square of the speed of light."[402] Deciding whether claims of this sort should be excluded, as opposed to given an RP, however, would be challenging. The analytical approach would require a decision-maker to identify claims to "relatively 'pure' abstract ideas, natural laws, and natural phenomena"[403]—claims that simply state a fundamental discovery and do not purport to apply it outside the realm of pure science—and differentiate them from claims that are not as "purely" or "manifestly" within these categories. Although this distinction can be difficult to make,[404] scholars

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barrier." Cahoy, *supra* note 395, at 506; *see* Dreyfuss, *supra* note 376, at 201("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).

[398] For another proposal for dealing with this problem, see Bernard Chao, *The Case for Contribution in Patent Law*, 80 U. CIN. L. REV. 113 (2011).

[399] 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 a large amount of resources for litigation will likely, all things being equal, choose a deep-pockets target.

[400] 35 U.S.C. § 101 (2012).

[401] Rather than being an "inventive application" of or "markedly different" from such artifacts, which are the tests elaborated in recent cases expanding the scope of patentable subjectable matter exclusion. *See supra* notes 235-236 and accompanying text.

[402] *See* Parker v. Flook, 437 U.S. 584, 595 (1978) ("[I]f a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.") (quotation marks omitted); *see also* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980); Brief for the United States as Amicus Curiae Supporting Neither Party, 2011 WL 4040414, at *12-13, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); *supra* note 79 and accompanying text.

[403] Sichelman, *supra* note 240, at 370.

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

have suggested approaches to identifying "embryonic" patents that might be distinguishable from pure ideas and laws of nature.[405]

Perhaps, one way that embryonic inventions can be distinguished from pure ideas in that the former, as claimed, provide a roadmap for useful 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 for carrying out the claimed functions. Applications of this sort should perhaps be sufficient to allow the invention to pass the initial hurdle of patent-eligibility. While all of these invention types may be validly viewed as upstream in the research process, all involve more than mere ideas or statements of a scientific principle.

In contrast, true hypotheses (i.e., 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 RP scheme.[406] Under the current regime, such claims can be rejected for lack of credible or operable utility under § 101,[407] for lack of enablement under § 112,[408] or under both provisions. I do not purport to propose any changes to this area of patent law—inventions that are completely inoperative and unenabled or should not qualify even for limited patent protection.[409] And other requirements of patentability, such as novelty[410] and

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[405] *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. *Id.* 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 231, at 68 (describing this approach); *cf.* Bar-Gill & Parchomovsky, *supra*, at 426 (arguing that the "make love not war" idea is not entitled to any intellectual property protection).

[406] This is in contrast to claims invalidated in, for example, University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 919 (Fed. Cir. 2004), where the claimed invention surely had a credible scientific basis. Indeed, the *Rochester* disclosure by hypothesis provided a roadmap for finding compounds that would perform the claimed methods of treatment—if it did not, the claims would not have been enabled and resort to written description would have been unnecessary. *See supra* notes 139-145 and accompanying text.

[407] *See, e.g.*, *In re* Swartz, 232 F.3d 862 (Fed. Cir. 2000). *See generally* Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1492 (2011).

[408] *See, e.g.*, Rasmusson v. Smithkline Beecham Corp., 413 F.3d 1318 (Fed. Cir. 2005).

[409] To be sure, the enablement requirement sometimes may function as a completeness requirement. *Cf. supra* notes 321-326 and accompanying text. 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.

[410] *See* Dan L. Burk, *Anticipating Patentable Subject Matter*, 65 STAN. L. REV. ONLINE 109 (2013); *see also* Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373 (Fed. Cir. 2003); In re Cruciferous Sprout Litig., 301 F.3d 1343 (Fed. Cir. 2002).

nonobviousness,[411] will continue to serve as backstops against many socially harmful patents. These requirements would ensure that Research Patents are awarded only to inventions that have some demonstrable technical merit and improve upon the prior art.

VII. 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 recently in the 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 extant requirements of patentability but fail completeness. I justify these proposals on utilitarian grounds.

[411] *See In re* Fisher, 421 F.3d 1365, 1382 (Fed. Cir. 2005) (Rader, J., dissenting). Arguably, ESTs would not have been adjudged obvious under the reasoning of *In re* Kubin, 561 F.3d 151 (Fed. Cir. 2009). *See* Mark D. Janis, *Tuning the Obviousness Inquiry After* KSR, 7 WASH. J.L. TECH. & ARTS 335, 337-40 (2012); 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 (2007) (explaining how the obviousness requirement could be used to limit other upstream patents in the biotechnology field).