THE COMPLETENESS REQUIREMENT IN PATENT LAW

DMITRY KARSHTEDT

Abstract

This Article argues that courts have created a de facto extra-statutory patentability requirement, herein termed “the completeness requirement,” that bars patents on certain inventions whose chief value lies in facilitating downstream research. It explains that, although this requirement reflects the important policy reason of limiting unduly preemptive patent claims on “upstream,” building-block inventions, courts have failed to implement the requirement in a coherent and consistent way. For example, while patents on some upstream inventions are invalidated completely, other problematic patents are upheld—a result that is damaging to innovation policy. In addition, courts’ attempts to implement the completeness requirement under existing statutory provisions have led to controversial interpretations of established lines of cases, creating legitimacy costs.

The Article argues that these problems are best solved through legislation that would create an explicit new statutory requirement of completeness and shed the doctrinal baggage resulting from courts’ inconsistent efforts to prohibit upstream patents. In addition, the Article explores the possibility that patent claims that pass the existing requirements of patentability but fail the proposed statutory completeness requirement should not be invalidated completely. It suggests instead that such patents should be given limited patent protection in the form of what I term the Research Patent. The Research Patent would offer two benefits: it would provide the intellectual property incentives that are likely needed to develop and commercialize upstream inventions, and decrease the potential for stifling downstream innovation caused by granting full patent protection to such inventions.
Table of Contents

I. Introduction . . . 3

II. What Are Upstream Inventions? . . . 10
   A. Categories of upstream inventions . . . 10
   B. Overarching problems with patents on upstream inventions . . . 15

III. Contours of Patent law’s Completeness Requirement . . . 19
   A. Completeness doctrines . . . 19
      1. Utility . . . 19
      2. Written description . . . 20
      3. Patentable subject matter . . . 22
   B. A single requirement . . . 24

IV. Problems with Completeness Requirement’s Implementation . . . 25
   A. Utility . . . 25
   B. Written description . . . 28
   C. Patentable subject matter . . . 30
   D. Summary . . . 32

V. Toward a Unified Completeness Requirement . . . 32
   A. The completeness test . . . 32
   B. Implementation issues . . . 34
   C. Representative examples . . . 36
   D. The need for implementation through statutory change . . . 39

VI. The Research Patent Proposal . . . 43
   A. Do limited rights for incomplete patents make sense? . . . 43
   B. Prior proposals for limited rights in some upstream patents . . . 46
      1. Ex post approaches . . . 46
      2. Sui generis approaches . . . 48
   C. Toward a research patent . . . 49
      1. Features of the research patent . . . 49
      2. Challenges of the approach . . . 51

VII. Conclusion . . . 54
I. INTRODUCTION

Suppose that, after several years of working in the lab, a researcher discovers a novel way to make a certain type of a 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.  

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.” In contrast to earlier work, this approach treats the inflammation while avoiding “undesirable side effects such as upset stomach, irritation, ulcers, and bleeding.” 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,” including Celebrex and Vioxx. Realizing that a patent merely to a method of finding a drug might be of little commercial 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 amount of a particular chemical compound (called a “probe molecule”) in the human body. The inventors license the technology to a company, which designs a kit for optimizing the dosage and makes it commercially available. The invention is hailed as a significant development of “personalized medicine” to treat inflammatory bowel disease, and other researchers and doctors use the kit to make further discoveries. Again, unsatisfied to claim merely a kit, the inventors attempt to claim a general method of optimizing drug dosage based on the measured amount of the probe molecule in the body.

---

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 University of Rochester v. GD Searle & Co., Inc., 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…”).
All of these inventions required significant investments and constituted important research results, so it is difficult to fault the inventors for seeking valuable patent claims to protect them. But courts held that none of them could be patented. As to the first type of invention, the patent applicant did not show that the chemicals made with his process would be useful to ordinary consumers (e.g., as drugs) rather than to other researchers, and the Supreme Court ruled that the process therefore lacked “utility”, 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”; and as to the third, the Supreme Court held that the patent claims did not “confine their reach to particular applications of” the correlation discovered by the inventors, and the Supreme Court invalidated the claims as drawn to unpatentable subject matter as a “law of nature.”

This Article posits that the three lines of cases are best understood as testing the patent claims at issue against the same unwritten requirement of patent law, here termed the completeness requirement. The requirement is generally concerned with whether, taking into account the scope of the claim and the disclosures in the patent’s specification, the invention has reached the developmental stage at which a patent should be allowed. Completeness is critically important because patents on what amounts to

8 See Elizabeth A. Doherty, FINNEGAN—FULL DISCLOSURE, Biomarker and Personalized Medicine Patent Claims One Year After Mayo v. Prometheus, http://www.finngan.com/files/upload/Newsletters/Full_Disclosure2013/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.”).


10 University of Rochester v. GD Searle & Co., Inc., 358 F.3d 916, 927 (Fed. Cir. 2004).


12 Although this is not entirely clear from the opinion, colloquy during oral argument suggests that, if the claims made clear how the dosages should be adjusted to achieve an effective treatment, the patent would have been drawn to a particular downstream application and would perhaps not have been invalidated. See Oral Arg. Transcript, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012), p. 22 ll. 9–19 (Justice Kagan: Is there . . . a patent that Prometheus could have written that you think would have met the 101 test? Counsel for Mayo: Certainly. They could have said when you reach [a certain concentration of the probe molecule] . . . you adjust the dosage by 20 percent. That’s a treatment patent. Justice Kagan: So, if they had added a treatment protocol, that would have been a completely different case? Counsel for Mayo: Yes . . . .).

13 This is not to be confused with the notion of a completely conceived invention for the purpose of the on-sale 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.’”). I thank Janice Mueller for pointing out this issue.
basic research are thought disserve the utilitarian goals of patent law. Thus, patent-based mechanisms, if any, to incentivize creation and commercialization of basic research and to induce its disclosure are thought to be generally outweighed by the harmful effects of such patents on downstream innovation. Accordingly, the requirement appears to be designed to bar patents that are directed to foundational inventions that can serve as inputs into further inventive activity. Some courts and scholars speak of the policy of prohibiting “undue preemption” of downstream research through upstream patenting. But because it is sometimes difficult to measure preemption directly and to say how much preemption is “due,” courts solve the problem of upstream patenting by applying various tests that, in effect, separate patents on basic research, broadly understood, from those on applied research.

---


15 But see Tun-Jen Chiang, Competing Visions of Patentable Subject Matter, forthcoming 83 GEO. WASH. L. REV. (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 the courts have begun to depart from the utilitarian basis for rendering certain inventions unpatentable, this paper seeks to propose a mechanism for correcting this trend.

16 I generally refer to such inventions as “upstream” inventions.

17 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 . . .”).

18 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).

19 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012) (“[P]recedent] 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
This Article argues that recognizing completeness as a standalone requirement of patentability might aid in the development of a more rational framework of patent rights and remedies for inventions that are upstream in the research process. Once the three lines of cases are clearly understood to be facets of an overarching prohibition against patents on early-stage inventions that serve as foundational research inputs, one might more readily identify other problematic patents of this sort that courts have nonetheless allowed—or, conversely, identify patents that have been invalidated in error. For example, it is notable that, while courts sometimes reject patent claims to certain early-stage biotechnological and chemical inventions, they routinely permit claims to foundational inventions that might preempt many downstream research and development applications in fields such as scientific instrumentation. Broad, functionally drafted software claims that might block off development pathways have also generally escaped the scrutiny of the completeness cases, although this appears to be changing as courts have begun to apply the patentable subject matter requirement against software patents with increasing rigor.

There is nothing wrong with “technology-specific” standards in general, 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. And it may also stand to reason that, in certain fields, it is easier to tell than in others when a patent claim is directed to an invention that is at an early stage of development—and should therefore be a target for invalidation or rejection. Nevertheless, the bottom-line, utilitarian concern behind barring patents on upstream inventions is undue preemption of downstream research, no matter what the field. In line with this goal, a

(“[C]laims to research plans . . . impose costs on downstream research, discouraging later invention.”) (written description).


21 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 patents in the biomedical field that have been allowed. See infra notes 49-50 and accompanying text.


24 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 125-126 and accompanying text; see also Sean B. Seymore, Foresight Bias in Patent Law, forthcoming 90 NOTRE DAME L. REV. (2015), available at http://ssrn.com/abstract=2397466.


26 See, e.g., See, e.g., Univ. of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1327 (Fed. Cir. 2004) (“The burden of [the Federal Circuit’s] recent written description cases has fallen on the biotech industry disproportionately . . . .”) (Linn,
potential improvement to the completeness requirement might be to get courts to look beyond certain life sciences patents that they have rejected for the reason of what I term incompleteness, and to scrutinize patents on upstream inventions more generally.\textsuperscript{27}

A better understanding of this requirement is also desirable because all three lines of completeness cases have been especially controversial, and have drawn a firestorm of academic (and judicial) criticism.\textsuperscript{28} It has been argued that some utility, written description, and patentable subject matter


cases reflect judicial subjectivity— or even bias. Although the presence of disagreement is not, in itself, a sign that there is a problem, it is worth noting that the three lines of cases underlying the completeness requirement have been described by some as not merely wrong, but somehow unprincipled. The project of better understanding the rationales underlying these cases and, and if needed, adjusting the legal rules where needed to fall in line with the rationales might help answer these critiques and enable the two sides of this debate to find middle ground.

Moreover, the recognition of the role of the completeness requirement might point to practical improvements in the functioning of patent law. One possible improvement is to codify the requirement so as to bring it into line with the core policy aim of limiting undue preemption of downstream research and development. Codification would help simplify and streamline the multiplicity of tests that have been developed under the doctrinally siloed enforcement of the completeness requirement. Although the requirement can, in principle, be improved by courts based on the existing patentability requirements, a statutory fix may be needed because the existing provisions come with a great deal of baggage. Much like the requirement of nonobviousness, which was judicially created but underwent codification and a course correction in 1952, the completeness requirement may benefit from codification and course correction today after years of

29 Kresh, supra note 28, 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 28; Seymore, Making Patents Useful, supra note 28, at 1077 (arguing that the utility requirement is arbitrary).
31 See, e.g., Pitlick, supra note 28, 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 28-30 and accompanying text.
32 Cf. 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, 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”).
33 See, e.g., Lemley et al., supra note 28; Yu, supra note 28, at 427-45.
34 See infra Part _.
35 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. of Kansas City, 383 U.S. 1, 15 n.7 (1966) (stating that “flash of creative genius” was only “a rhetorical embellishment”).
judicial experimentation. Although imminent Congressional intervention of this sort might seem unlikely in today’s political climate, that might change if the recent judicial developments in this area of patent law lead to widespread public dissatisfaction.

The proposed requirement would mandate explicitly that the invention, as claimed in a patent, cannot be directed to an object of basic research. Although basic research has proven difficult to define, work in the field of science studies provides one possible framework that courts can use. This framework focuses on the unpredictability associated with an invention and generality of that invention’s applications. Guided by these considerations, one possible test for implementing the completeness requirement might ask, based on claim scope and the disclosures in the specification, whether the claim at issue is directed primarily to an invention that sets the foundation for future research and development work, 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 new types of factual inquiries, it is hoped that it might also provide the significant benefits of making the completeness requirement more robust and transparent relative to its current implementation.

Another, more controversial suggestion for change in the 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 only comes with the remedy of a compulsory license. If the concern is that owners of upstream patents wield an undue degree of preemption, then the logical solution appears to be to weaken the available remedy until the patentee receives preemption that is due. Thus, even if utilitarian considerations suggest that upstream inventions should not be given full patent protection, partial patent protection might be justifiable on these grounds.

Of course, the U.S. Patent and Trademark Office (PTO) lacks the power to grant patents that come with a limited remedy. It is faced with only two choices—grant the full patent right, or none at all. Nevertheless, the power to give a third choice can be given with another statutory fix.

---

36 I thank Professor Rochelle Dreyfuss for drawing this analogy to my attention.
38 Id. at 204.
40 Unless the right amount of preemption is zero, which does not appear to be true in most circumstances. As I suggest infra in Subpart _, complete absence of patent protection for upstream invention might be problematic, and likely to result in underinvestment into important technologies and lack of valuable disclosures.
42 While the courts have the power to tailor remedies by granting or denying injunction and awarding a higher or lower amount of damages, see 35 U.S.C.
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. 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 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 explains judicial and scholarly concerns behind allowing patents on such inventions. Part III explains how the law currently deals with some of these inventions. This Part demonstrates 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 of implementing the completeness requirement, including the likely need for its codification. This Part puts also the codified completeness requirement into practice, testing how potential patent claims might fare under this requirement. Part VI explores the question whether some form of patent protection is likely needed to incentivize the creation of inventions that cannot be patented for failing the completeness requirement, provides suggestions for the structure of a partial patent right, 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. Several themes emerge from the cases and the literature,

§§ 283, 284 (2012), when it comes to patent validity, they can only uphold or invalidate patent claims. See id. § 282. Furthermore, in Subpart _, 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.


44 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 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 three examples discussed in the Introduction represent three forms of upstream inventions, which can be loosely categorized as research tools, hypotheses, 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 stemming from the fact that such patents might 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.45 Such inventions have been called “research tools”46 and “research intermediates.”47 One set of examples, discussed in the Introduction, includes chemical compounds not having a known end use and methods of making such compounds.48 Another group of patents generally thought of as belonging to the “research tool” category includes 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) from a small sample—and it has numerous applications ranging from paternity testing to the diagnosis of cancers and detection of viruses.49 Human embryonic stem cells exemplify still another set of broadly applicable research-tool inventions.50

Research tools and intermediates are not limited to biological and chemical materials—the microscope51 may be the archetypal “invention the

However, the same computer chip might be an upstream invention relative to a device that uses the chip, such as cellular phone.”).

45 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.”).
46 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 28, at 1302-03; Strandburg, supra note 45, 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.”).
47 In re Fisher, 421 F.3d 1365, 1373 (Fed. Cir. 2005); see also infra notes 169-173 and accompanying text (exploring the difference between research intermediates and research tools).
48 See supra note 1 and accompanying text.
49 See Mueller, supra note 46, at 12-13 (describing patents on PCR methods).
50 Id. at 13; see also Peter Yun-Hyong Lee, Inventing the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine To Constrain Patents on Biotechnology Research Tools, 19 HARV. J.L. & TECH. 79, 106-08 (2005).
51 See Fisher, 421 F.3d at 1380 (Rader, J., dissenting).
primary function of which is to facilitate scientific and technological progress." Specifically, consider the atomic force microscope. This device enables, among other things, the observation of very small objects at high resolution. The atomic force microscope is considered a building-block technology that can serve as an input into many areas of downstream research, such as nanotechnology.

A second category of upstream inventions has been variously characterized as a “wish,” a “research plan,” “a hypothesis,” and so on. Like 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. One upstream invention of this sort discussed in the Introduction—which some courts and commentators argue should not even be called an invention—is a method of treatment of a health condition based on the identification of a target of drug action in the human body. Although the discoverers of the target might have developed and described search methods for finding the drug that would treat the condition, they have not identified any specific drug having the capacity to do so.

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. If the Wrights

52 Strandburg, supra note 45, at 123
55 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.”).
56 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, some examples of end products 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).
57 University of Rochester v. GD Searle & Co., Inc., 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).
58 See supra notes 2-4 and accompanying text.
59 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 patent claim would likely not be worth very much because of the large number of possible design-aroinds. 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 271 and accompanying text.
60 See What Did the Wright Brothers Invent, Wright Brothers Airplane Company, http://www.wright-
had not described how to actually build a plane, but only provided a roadmap for doing so using 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. A more modern version of what could be described a “hypothesis”-type invention is a functionally claimed software patent. The concern is related: some software claims appear to appropriate the problem to be solved rather than any specific way of implementing a solution.

Yet a third category of upstream inventions relates to the workings of the natural world and other fundamental principles. Commentators and courts have denominated such inventions “law[s]” or “products” of nature, “natural phenomena,” “scientific truths,” “concepts,” “abstract ideas,” “formulas,” or by some other similar label. This facet of upstream-ness has a rich historical pedigree, harkening back to the distinction between patentable “industrial property” and unpatentable

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).

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 their own implementation of the three-axis principle did not really work well. See MALCOLM J. ABZUG & 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.


Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013).

Id. at 2111.


Id. (citation omitted)

Id. at 3233.

Cf. Le Roy v. Tatham, 55 U.S. 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 28, at 1340-43; Yu, supra note 28, at 423-24.
“scientific property” in the early international patent regimes. As we have seen, the Supreme Court described as a law 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 amount of a probe molecule in the body. Assuming the Supreme Court’s analysis was correct, it is difficult to think of a stronger example of a claim to a discovery “at the beginning of the development chain” than a law of nature. Other examples in this general category include inventions as diverse as isolated human genetic material, a method of communicating at a distance using electromagnetism, a method of data processing, and the concept of risk hedging. Upstream inventions of the “fundamental principle” kind, like upstream inventions of the research tool and research plan kind, 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,” which fairly places it into the third category as well. Or, it could also be that at least some inventions in the first category belong in the third category. Peter Lee described stem cells as “research tools,” yet Allen Yu argued that they are also like natural phenomena in that isolated stem cells “faithfully preserve the pluripotent properties of stem cells as found in nature.” 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 viewed as “research tools,” they would probably be unpatentable under his framework as basic tools of scientific and technological work. 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. 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

The patents described in this Part are all problematic because of their upstream-ness, which is correlated with the potential to impose

---

72 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1298 (2012); see supra notes 5-7 and accompanying text.
73 Lee, supra note 50, at 81.
75 ROBIN C. FELDMAN, RETHINKING PATENT LAW 100 (2012); see also id. at 122.
76 See Yu, supra note 28, at 433.
77 Id. at 431, 433.
78 In other words, because they are artifacts of basic research.
intolerable costs on downstream research and development.\textsuperscript{79} For example, the concern behind allowing a patent on a chemical compound without an identified end use in the hands of the general public is that a subsequent researcher who does the work of discovering such a use—for example, biological activity against cancer cells—will be beholden to the owner of the patent on the compounds.\textsuperscript{80} 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.\textsuperscript{81} Faced with this prospect, the follow-on researcher might decide to forgo investigation of a certain type of a chemical structure during the life of the patent, which could mean that society would lose out on promising drug candidates.\textsuperscript{82} Similar arguments have been made about other “research tool” patents, like stem cells.\textsuperscript{83}

The upshot of the critiques is that “whereas most patents cover the \textit{outputs} of scientific investigation, patents on research tools cover the \textit{inputs} of that investigation.”\textsuperscript{84} 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.”\textsuperscript{85} Analogous critiques have


\textsuperscript{82} DAN L. BURK & MARK A. LEMLEY, \textit{THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT} 111 (2009) (“[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.”).

\textsuperscript{83} See supra note 50 and accompanying text.

\textsuperscript{84} Lee, supra note 50, at 81 (emphasis is original); see also Mueller, supra note 46, at 4 (“[T]he dispute stems from the broad rights conferred by the patents covering [PCR] tools.”).

\textsuperscript{85} Lee, supra note 50, at 81.
been made against research-plan patents in biotechnology, functionally claimed software patents, and patents inventions that are characterized as fundamental principles. Scholars and courts describe them as “bottleneck” patents that are thought to stifle innovation. To prevent such unduly preemptive patents, commentators have exhorted courts to apply the rules that prohibit them more stringently or praised them for already doing so.

Although many upstream patents might not end up having valuable applications, some critics of such patents find the uncertainty to be highly problematic in itself. They contend that, if the patent on an invention early

---

87 Lemley, supra note 21, at 964 (arguing that allowing functional claims in software field ignores the principle that “patents spur competition by preventing direct imitation while leaving open avenues for alternative development”).
88 Alan Devlin, supra note 14, 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.”).
89 Mayo, 132 S. Ct. at 1301 (addressing “a danger that the grant of patents that tie up [the use of basic tools of scientific and technological work] will inhibit future innovation premised upon them”); see also, e.g., Jakas, supra note 56, 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 86, at 1269; Sarnoff, supra note 41.
91 See, e.g., Statement of Dr. Harold Varmus on Gene Patents and Other Genomic Inventions, Hearing Before the Subcommittee on Courts and Intellectual Property of the Committee 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.”).
in the development process turns out to be highly valuable, its owners might reap enormous benefits—likely out of proportion to their contribution—if they enter into a so-called reach-through royalty arrangement with the downstream users. Commentators fear that such licenses might permit the owners “to leverage its proprietary position in upstream research tools into a broad veto right over downstream research and product development.”

Overbreadth and uncertainty concerns are closely related—indeed, claims having uncertain applications are thought to be problematic mainly because of their potential to be overbroad. Thus, patents on upstream inventions might dominate and preempt entire fields of research, cover unpredictable, transformative applications, and may also massively over-reward their owners. 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.”

* * *

92 See infra note 288 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.

93 Heller & Eisenberg, supra note 79, at 699; see also Strandburg, supra note 45, 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.”).

94 But this not always the case—the utility requirement can bar claims that are narrow, and so can the patentable subject matter requirement. As I make clear infra at Part _, the problem is not breadth but a patent on a research input.

95 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.”).

96 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].”).

97 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)).

98 Wang, supra note 79, 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 79, 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.
Although the critiques common to upstream patents might suggest that they 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 evaluate the three types of claims loosely track the distinction between research tool patents, research plan/hypothesis patents, and fundamental principles patents. In spite of the multiplicity of the 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 upstream patents—the artifacts of basic research.

I believe that there are benefits to the observation that the three lines of doctrine are explained by the principle of completeness. This approach may provide a route to simplifying and streamlining the tests, some of which might seem overly essentialist and formalistic, and to focus on the core policy aims of the doctrine. Indeed, the fact that some of the patents on upstream inventions discussed in the previous section (chemical intermediates, methods of treatment based on a newly identified target, natural correlations) have been invalidated, while others (stem cells, atomic force microscopes, functionally claimed software inventions) have not, suggests that the current approach may be inconsistent. The holistic completeness framework might help address whether or not there is a principled distinction between the patents that failed and those that did not, and point to corrections in the ways that courts approach upstream patents. Furthermore, as suggested in the Introduction, the recognition of the requirement might help understand and respond to critiques of the cases discussed in the Parts that follow, and generate broader ideas for reform. Possible reforms are discussed in the last two Parts of the Article. The two Parts that follow discuss the three lines of cases, explains how they function as a single, unwritten requirement of patentability, and critically evaluate the courts’ current approach to upstream patenting.

III. CONTOURS OF PATENT LAW’S COMPLETENESS REQUIREMENT

A. Completeness doctrines

1. Utility

99 See infra Part III.
100 Cf. Laakmann, supra note 32, at 60 & n.108.
101 Although this may be changing for software inventions. See supra note 22 and accompanying text.
102 Of course, some of this could be a consequence of litigation strategy—some of these patents may not have been invalidated because they were never challenged in this manner.
One way that patent law polices completeness is via the utility requirement. The modern utility doctrine took shape in the case of *Brenner v. Manson*. At issue was a patent application directed to a process of making chemical compounds falling within a larger class of molecules called steroids. Expecting the Supreme Court’s hostility to an older doctrine that chemical compounds had “inherent” utility, 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 compounds that were used to fight cancer. 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.”

The Supreme Court rejected the patent application because the claimed process was not “refined and developed to . . . where specific benefit exists in currently available form.” 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.” 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. As one commentator aptly noted, *Brenner* “seem[ed] effectively to exclude research chemists from the class of people for whom an invention may be useful.”

Although it has been argued that the utility requirement became “minimal” under the Federal Circuit’s interpretation of *Brenner*, recent

---

103 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.
105 Id. at 520-22.
106 The inherent utility doctrine derives from the realization 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).
107 Id. at 530-31.
108 Id. at 532 (emphasis added).
109 Id. at 534.
110 Id. at 529, 535.
112 Lopez-Beverage, *supra* note 90, 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
cases show that the basic rule that the inventor must demonstrate a downstream consumer use has not been abandoned. Applying Brenner, the Federal Circuit in In re Fisher rejected claims to so-called “expressed sequence tags” (ESTs), which are a class of chemical compounds made from the same building blocks as deoxyribonucleic acid (DNA) and are of interest to researchers as tools for identifying and studying genes. The court held that ESTs lacked utility because they are “no more than research intermediates.” 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 that claimed invention has a significant and presently available benefit to the public.” As in Brenner, research utility did not render the inventions complete enough to be patentable. Thus, courts continue to rely on utility as a “policy lever” to prohibit “premature [patent] filing[s]” on chemical and biotechnological inventions.

2. Written description

The written description doctrine provides another line of attack, of more recent vintage than utility, against patents on upstream inventions. 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 claims that describe chemical compounds in terms of their beneficial function but fail to provide any chemical structures that could be used by consumers as drugs.

For example, in University of Rochester v. G.D. Searle & Co., the patentee claimed a method reducing inflammation using “a non-steroidal compound that selectively inhibits activity” of a certain gene. The patentee disclosed experiments for finding compounds that would perform 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). 421 F.3d 1365, 1367-69, 1378 (Fed. Cir. 2005); see also id. at 1379-80 (Rader, J., dissenting). 114 Id. at 1373. 115 Id. at 1376. 116 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))). 117 See generally Burk & Lemley, supra note 23. 118 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). 119 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.” 120 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). 121 358 F.3d 916, 918 (Fed. Cir. 2004) (quoting U.S. Pat. No. 6,048,850, claim 1).
the claimed inhibiting function, but did not actually provide any examples.122 The Federal Circuit agreed with the defendants 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.123 For the invention to be complete, the court required a chemical structure, not merely a “search method.”124 The court rejected the plaintiff’s argument that identifying a biological target and providing a roadmap for finding drugs that act on that target might reasonably entitle the inventors to reap a benefit once such drugs are found.125 After citing Brenner—a utility case—it even suggested that the patentees did not invent the claimed methods at all.126

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.”127 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.”128 The court further stated that patent law is directed to inventions “with a practical use” rather than “basic research.”129 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.”130 The familiar policy concern behind this result is that “claims to research plans . . . impose costs on downstream research, discouraging later invention”131 by “attempt[ing] to preempt the future before it has arrived.”132

---

122 See id. 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).
123 Id. at 927, 929.
124 Id. at 930 n.10.
125 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 332 and accompanying text.
126 Rochester, 358 F.3d at 930 n.10 (quoting Brenner v. Manson, 383 U.S. 519, 536 (1966)).
127 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc).
128 Id.
129 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.
130 Ariad, 598 F.3d at 1359 (Newman, J., additional views).
131 Id. at 1353.
132 Id. (alterations and internal quotation marks omitted) (emphasis added).
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 invention 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”133 that places certain claims outside the category of patentable subject matter. This exception bar patents to natural phenomena, laws of nature, and abstract ideas.134 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.”135 In Benson, the Court concluded that a claim to a method of converting binary-coded (BCD) numbers into pure binary numbers was unpatentable because it was drawn to “an idea.”136 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.”137 As with utility and written description cases discussed in the previous two Subparts, the fact that the patent was directed to a basic discovery—in Benson, an algorithm—was the reason for holding the claim unpatentable. Once again, preemption of downstream uses was an important policy driver behind this result.138

A recent patentable subject matter case, Mayo Collaborative Services v. Prometheus Laboratories, Inc.,139 further demonstrates how the patentable subject matter doctrine functions to bar patents on inventions that are thought by courts to be too upstream. The 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’

134 Id.
136 Benson, 63 U.S. at 71.
137 Id. at 71-72.
138 Cf. Chisum, supra note 39, at 20-21 (noting this similarity between the abstract ideas exception and the Ariad form of the written description requirement). But see Strandburg, supra note 28, at 594 (arguing that “[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).
139 132 S. Ct. 1289 (2012).
concern”—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 an amount of a certain chemical in the body—the probe molecule discussed in the Introduction—and effectiveness of a drug used to treat gastrointestinal disorders. 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 than simply state the law of nature while adding the words ‘apply it,’” and invalidated the patent because the claims at issue were not sufficiently limited. Echoing the rhetoric of other completeness decisions, the Court heavily relied on the preemption rationale for invalidating the claims for being unacceptably 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.

In another recent pronouncement on patentable subject matter, Association for Molecular Pathology v. Myriad Genetics, Inc., the Supreme Court explained how the prohibition against basic research functions in a “product of nature” case. 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” rather than “new applications of knowledge about” these genes. In other words, these claims were invalidated because the patentee claimed the basic tool of a product of nature itself, rather than its downstream use.

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.”

B. A single requirement

---

140 Id. at 1303.
141 See supra notes 5-8 and accompanying text.
142 Id. at 1295.
143 Id. at 1294.
144 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1301-02 (2012); see supra notes 95-97 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.”).
145 133 S. Ct. 2107 (2013).
146 Id. at 2116.
147 Id. at 2120 (emphasis in original).
148 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 AMP: “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 AMP: “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.”).
The similarities across utility, written description, and patentable subject matter doctrines are notable. The inventors in all of these cases have discovered something that is valuable and was previously unknown—a new chemical compound, a new biological target of drug action, and a natural product or a novel correlation. Nevertheless, these inventors were not allowed to capture the value from their respective inventions’ downstream applications. In the utility cases, the patents did not demonstrate a downstream, consumer use in the patent’s specification, and the invention was deemed not useful within the meaning of § 101. In the written description cases, the patents failed because the inventions were claimed in functional terms based on a target of drug action and did not provide any examples of drugs that would perform the function. And in the patentable subject matter cases, the claims were ostensibly so broad that they captured a fundamental principle or a natural law rather than an application. In every case, the claim, or the specification, or both suggested that the patented (or would-be patented) inventions were in some way artifacts of basic research. This is the completeness requirement at work.

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 compensation for its successful conclusion.” 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.” And in Mayo (a patentable subject matter case), the

---

150 Chisum, supra note 39, 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 91, at 1373 n.206 (noting “a curious, relatively unexplored kinship between many § 101 and § 112 cases”).

151 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 28, 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 28, at 64 n.35 (quoting In re Rasmussen, 650 F.2d 1212, 1214-15 (C.C.P.A. 1981)).


153 “Specification” is a term colloquially used to refer to the part of the patent document other than the claims. Although the proper name for it is “written description,” I use “specification” to be consistent with common usage.

154 894 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 28, at 209-11.
Supreme Court invalidated claims that “tie[d] up too much future use of laws of nature” by allowing its owner to appropriate “basic tools of scientific and technological work.” The three lines of cases therefore serve the same policy goal of limiting undue preemption of downstream research.

Courts do not like patents on upstream inventions, and, in the absence of a unified statutory prohibition against the patenting of basic research inputs, they have used three distinct doctrinal sources to invalidate claims that are drawn to them. This approach has put pressure on the statutory provisions used to implement completeness, and, in the views of some, has raised the specter of judicial overreaching. I believe that explicitly recognizing these cases as facets of the same requirement—the completeness requirement—might relieve some of that pressure and help clarify, and perhaps improve, the ways in which patent law polices claims on basic research. The next Part discusses the critiques of the completeness cases in more detail.

IV. PROBLEMS WITH COMPLETENESS REQUIREMENT’S IMPLEMENTATION

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.” The invention at issue in Brenner was a method for making chemical compounds. To say that such an invention is not “useful” in the ordinary sense of that word defies common sense, as numerous commentators have observed. Indeed, while

---

156 Id. at 1293 (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).
157 It has been argued that this prohibition has constitutional underpinnings. See Liivak, supra note 57. 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.
159 See supra notes 29-31; see also infra note 201 and accompanying text.
courts and the PTO have applied the utility requirement quite rigorously in the serious and generally useful fields of chemistry of biotechnology, the PTO has been granting patents on silly, ridiculous, and plain useless inventions without issuing § 101 utility rejections. In a recent critique that puts these problems into sharp focus, Sean Seymore has argued that the utility requirement is highly subjective, reflecting “a bias against granting patentability for certain types of inventions.” To be sure, results of the utility cases may be defensible as policy judgments that certain inventions in the chemical arts are too upstream to be patentable. But whether or not these judgments are correct, the distinctions made under the utility doctrine have put a great deal of weight for the word “useful.” Accordingly, there must at least be a nontrivial legitimacy cost associated with the way that courts have implemented the utility requirement.

Several scholars have provided policy justifications for the distinctions made by the current utility regime. For example, John Duffy contends that it makes sense to allow patents on research tools such as microscopes but to reject patents on chemical and biochemical research intermediates such as ESTs and molecules having and unknown end use. He argues that patents on chemical intermediates are rejected, while patents on microscopes are allowed, because the former, but not the latter, would generate the undesirable “mutually blocking patents” scenario. Thus, Duffy finds it problematic that—because of overlapping patent rights—a downstream researcher could practice his or her patented inventions created

---

164 See Burk & Lemley, The Patent Crisis, supra note 82, at 111 (“The only exceptions to the effective elimination of the utility requirement in patent law are in the fields of biology and chemistry.”).
165 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 14, 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.
166 Seymore, supra note 28, at 1050.
167 Cf. Burk, supra note 20, 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”).
170 Duffy, supra note 169, at 246-47.
171 Id.
with the aid of ESTs only with the permission of the patent owner. Research tools are patentable because they have “broad 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.” As Duffy notes, “research facilitated by a microscope is not a step in refining a microscope.”

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. Mutually blocking patents are routine in patent law. Indeed, the Patent Act expressly contemplates patents for new uses or known things, and this is not prohibited even when the known thing is itself patented. Moreover, an entity can be an object of research even though it has a known use. As stated in an old opinion, “a patentee is entitled to every use of which his invention is susceptible, whether such use be known or unknown to him.” The critical policy concern behind the completeness requirement is not the presence of mutually blocking patents, but preemption of downstream research, patented or not, due to the bottleneck of a research tool patent or another sort of upstream patent. 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.

Given these policy considerations, it is difficult to explain why the completeness cases pick out ESTs over microscopes. 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 stimulate (and, if patented, to block) further research and development activity. The utility requirement is on the right track in

---

172 Id.
173 Id. Interestingly, 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. See Seymour, Foresight Bias, supra note 24.
175 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”).
176 In re Thuau, 135 F.2d 344, 347 (C.C.P.A. 1943).
177 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 ESTs 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 90, at 47-48, 73-75.
178 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 169, at 246. But the result of Brenner is directly contrary to this observation because that case involved with a
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, but the case law has, at the very least, failed to capture the full range of such inputs.

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.179 Echoing the complaints about the utility requirement, the written description line of cases exemplified by Rochester has been thought to be problematic as a matter of doctrinal development,180 and to impose heightened disclosure requirements on biotechnology inventions.181 Unlike the utility requirement, which has only been applied against chemical and biochemical patents, the written description requirement has appeared in other areas of technology.182 But, outside of the biotechnology field, patent claims are only rarely invalidated under the

---


180 See, e.g., Pitlick, supra note 28. But cf. supra note 151 (discussing uncontroversial aspects of the written description requirement).

181 See, e.g., Univ. of Rochester v. G.D. Searle & Co., Inc., 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., 325 F.3d 956, 976 (Rader, J., dissenting from the order denying rehearing en banc); BURK & LEMLEY, THE PATENT CRISIS, supra note 82, 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 125, 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 26, at 4 (describing the written description requirement as “a ‘super-enablement’ requirement specifically targeting biotechnology and substantially restricting the patentability of biotechnology-related inventions”).

182 See, e.g., In re Katz Interactive Call Processing Patent Litig., 639 F.3d 1303, 1319-20 (Fed. Cir. 2011) (affirming invalidation of method claims steps 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).
written description requirement for being directed to a research plan. \(^{183}\) Although one reason for such an outcome could be that patentees do not often draft research-plan claims in other fields, this does not seem to be the case in practice. Functionally drafted software claims that are directed to “a problem to be solved,” \(^{184}\) a deficiency that is arguably similar to that of research-plan biotechnology claims, \(^{185}\) appear to be common, but they have not been eliminated by the written description requirement. \(^{186}\)

To be fair, the modern written description requirement has been accepted to a large majority of Federal Circuit judges, and several scholars have provided justifications for the ways in which the written description requirement is applied. \(^{187}\) 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. \(^{188}\) Nonetheless, the rhetoric of the cases seems also to be consistent with the conclusion that words like “invent” or “possess” are, in the end, labels for the policy judgment that the inventions at issue are not sufficiently developed to warrant a claim that captures valuable downstream applications made possible thanks to those inventions. \(^{189}\)

As with 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 legitimacy of the patent system might be bolstered if we openly admit that it is the prohibition against the patenting of basic research—the completeness requirement—that is doing the work in these cases. As it stands now, critiques of the written description requirement as somewhat capricious continue unabated in spite of its judicial acceptance. \(^{190}\)

---

\(^{183}\) See Comments of Michael Risch, supra note 62. Indeed, the specific approach of rejecting claims for lack of written description due to inadequate structure in the claims seems to be limited to the biochemical cases.

\(^{184}\) See supra note 62 and accompanying text.

\(^{185}\) 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).

\(^{186}\) It appears, though, that courts have started invalidating such claims via § 101. See supra note 22 and accompanying text. This phenomenon might lend further support to the notion that these are all facets of the same requirement of patentability.

\(^{187}\) For some defenses of the written description requirement, see Jakas, supra note 56; Liivak, supra note 57; 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.

\(^{188}\) Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351, 1355 (Fed. Cir. 2010) (en banc).

\(^{189}\) See, e.g., FELDMAN, RETHINKING PATENT LAW, supra note 75, 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.”); see also supra notes 2-4 and accompanying text.

\(^{190}\) See supra note 179 and accompanying text.
C. Patentable subject matter

The jurisprudence of § 101 patentable subject matter exclusions have also been a subject of numerous critiques. Unlike utility and written description, the complaints here are not only about questionable doctrinal development or a disproportionate burdens some particular industry or patent type, 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 serves utilitarian goals of patent law is well-established. The problem is that the Supreme Court has steadfastly refused to provide any clear standards for identifying what should be excluded from patentability on this ground—in other words, it has not explained how to identify patents that belong to these categories. In an article on the abstract idea exclusion, Kevin Collins criticized the Court for “an open embrace of an ‘I know it when I see it’ jurisprudence” that “offers no prospective guidance for the patent community,” and a district court recently joined in that criticism. A similar critique has been lodged about the Supreme Court’s laws-of-nature and products-of-nature jurisprudence.

Even if an abstract idea or a natural phenomenon were to be well-defined, it is difficult to know what it takes to render these unpatentable concepts into patentable inventions. In particular, the Court in Mayo did not clarify the line between an unpatentable “conventional” application of an idea or law and a patentable “inventive” application. 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. For example, the Court in Association for Molecular Pathology v. Myriad

---

191 See supra note 14 and accompanying text.
196 Kresh, supra note 28, 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, 132 S. Ct. at 1294-95)).
Genetics, Inc. invalidated the claims to molecules excised from naturally occurring DNA under this exception 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.198 This distinction, while perhaps justifiable as a pragmatic result that gives something to both sides, is unpersuasive.199

The Supreme Court’s patentable subject matter jurisprudence is so murky that making the doctrine more reasoned and systematic has been a goal of many scholarly projects.200 Yet in spite of all the work that has been done in this area, patentable subject matter jurisprudence continues to be a struggle. Furthermore, similarly to the utility and written description cases, patentable subject matter decisions have been criticized as instances of judicial overreaching and subjectivity, raising the specter of legitimacy.201 And even scholars who are generally sympathetic to these cases have been critical of the Court’s analytical approach and advocated for improvements.202 Although the goal to eliminate patents on “basic tools” 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 claim to a basic tool looks like.

D. Summary

Across doctrines, there is an overarching concern about the patenting of upstream, research-input inventions. That concern is justifiable—basic research includes those inventions that may be likely to be produced without a patent incentive203 and whose patenting could have particularly chilling impact on downstream research. In the absence of conclusive empirical tests for measuring excessive monopoly costs of patents and a clear way of answering how much preemption a patentee is due to exercise, courts’ approach to eliminating socially harmful patents by the indirect means of prohibiting claims to claims that qualify as “basic research” appears sensible.204

---

198 Id. at 2118.
200 See, e.g., Chao, supra note 28; Collins, supra note 193; Lemley at al., Life After Bilski, supra note 28; Stramburg, supra note 28; 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 (proposing a “technological arts” approach to patentable subject matter derived from common law).
201 See, e.g., Kresh, supra note 28; Oppenheimer, supra note 29; 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 177, at 360 (arguing that the patentable subject matter requirement is coherent and rooted in historical case law); Sarnoff, supra note 41 (similar); Menell, supra note 200.
202 See, e.g., Sarnoff, supra note 41.
203 See supra note 14 and accompanying text.
204 See supra notes 18-19 and accompanying text.
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 state of affairs remains less than satisfying. The tests under utility and written description have been criticized as anomalous, and they appear to invalidate certain some patents but not others using justifications that are at best controversial. And patentable subject matter jurisprudence fails to provide any clear tests altogether.

The completeness requirement pervades the patent law and has real force, but its implementation has faltered. This implementation has led to a supervening requirement for patentability that, in the current form, can be difficult to define apart from the facts of the specific cases in which it is applied. 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 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 test reflects the policy concerns addressed in the cases, but it is designed to prompt the courts to face the question of whether a claim is directed to an artifact of basic research squarely, rather than through tests like “possession” or labels like “abstract idea.” Although the definition of basic research has generally been considered elusive, work by Jane Calvert, a scholar in the field of science and technology studies, has identified two major ways in which scientists and policymakers understand the term—epistemologically and intentionally. 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 this definition “can mean that if the same research is done with different intentions, it is classified differently.” The intentional definition is simply too subjective and malleable to serve as a basis for a legal test. In contrast, the epistemological definition of basic research is more stable and more capable

---

205 See, e.g., Collins, supra note 193, 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 Gottschalk); 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”).

206 Calvert, supra note 37, at 204.

207 Id.
of objective evaluation. The epistemological features associated with basic research are unpredictability and generality. Both of these factors are markers of possible effects of an upstream patent claim on future innovation—unpredictability relates to the kind of research that could “produce radical innovations,” and generality relates to the notion that “solving a general problem will potentially help solve a wide range of other problems.”

The proposed test unifies these characteristics and addresses in a broad way the policy concerns of the completeness cases. The test asks, based on claim scope and the disclosures in the specification, whether the claim at issue is directed primarily to an invention that sets the foundation for future research and development work, and whether the developmental stage of the claimed invention is such that the claim has the potential to cover many unforeseeable, transformative applications. The test would foster a fact-intensive inquiry of the sort that courts and the PTO undertake in their enablement and nonobviousness analyses, where the ultimate questions of law are resolved based on subsidiary facts. Based on these considerations, the PTO (or a court, when the validity of a patent on the ground of completeness is tested in litigation) can decide if a claim is complete, assuming that other requirements of patentability have been met. As with enablement and nonobviousness, and as is generally the case with validity doctrines, completeness should be assessed at the time of filing rather than the time of litigation.

Although one result of applying the test would be to invalidate claims that are very broad, mere narrowness of the claim will not always provide a way of escaping incompleteness. In so doing, the test borrows from the collected wisdom of the completeness cases—some of which would invalidate even seemingly narrow claims due to their upstream nature. 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 left open in spite of the patent, the claims will be more likely to pass the test than if it fails to do so. Furthermore, if the specification tends to show that the invention works in predictable ways, such as by

---

208 Id.
209 Suppurt V.D., infra, explains that this test is best implemented through statutory change.
211 Cf. Chisum, supra note 39, 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.”); see also Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012) (“[T]he 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.”).

214 See, e.g., Duffy, supra note 169, at 239-40 (discussing the failure to patent Georges Kohler and Cesar Milstein’s work on monoclonal antibodies due to failure of a government agency to recognize the commercial potential of this technology). Even so, these researchers themselves apparently recognized the transformative nature of their invention. See id.


218 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
was immediately clear (and early, upstream patents were obtained for all those inventions). The first few ESTs may not have been immediately recognized as transformative, but by the time the “gold rush” to patent newly discovered ESTs began, their potential was clear as well.219 For software patents, although the number and variety of downstream applications may sometimes be difficult to predict, the broad functional language of some software claims may, on its face, provide a clue that the claim is directed to an input into further development and is therefore incomplete.220 It is, of course, inevitable that the PTO and courts will make mistakes in the application of the proposed test, leading to erroneous results. But there is no reason to believe that the contemplated completeness inquiries would be more difficult for the PTO and courts to undertake and apply than the tests under the current completeness doctrine, or under other patentability requirements like enablement and nonobviousness.

More specifically, to avoid rejections based on incompleteness, patent applicants may be tempted to downplay the potentially transformative or widely applicable nature of their inventions, or patent examiners may fail to recognize these characteristics. This, however, is a systemic issue in the ex parte patent prosecution process, and it affects all the patentability requirements. For example, to overcome an obviousness rejection, an applicant might submit self-serving “evidence” of unexpected results,221 and a PTO examiner might err by viewing that evidence as persuasive. One possible remedy is invalidation of the patent, if improvidently granted in spite of incompleteness, during post-grant review,222 inter partes review,223 or in district court litigation.224 In cases of serious misconduct, a charge of inequitable conduct—which would render the regular patent unenforceable if successful—might be a possibility.225 These prospects might deter some of the self-serving behavior and induce applicants to introduce new claims during prosecution that would comply with the requirement. Another check is the doctrine of prosecution 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 accordingly narrowed.226 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’ desire to develop the invention’s applications during the life of the patent.227

---

219 See Robert Cook-Deegan & Christopher Heaney, Patents in Genomics and Human Genetics, ANN. REV. GENOMICS HUM. GENET. 382, 399-400 (2010).
220 See supra note 62 and accompanying text.
223 Id. § 311.
224 Id. § 282.
226 Omega Eng’g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-36 (Fed. Cir. 2003).
227 Cf. O’Toole, supra note 213 (listing examples).
Measuring completeness at the time of the filing presents its own set of issues. For example, there may be cases where a patented invention, contrary to expectations, turns out to be foundational and transformative at some point after the patent 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 surprisingly turned out to be a basic research input is the result contemplated under the proposed scheme. 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 the patent that would punish the inventor for the patent’s unexpectedly broad applicability.\(^\text{228}\) 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 post-filing “book of wisdom” that might cast doubt on the claim that the claim’s broad-reaching nature was actually unpredictable.\(^\text{229}\)

Finally, although the proposed test would add administrative costs associated with the factual inquiries into whether the claim is directed to an artifact of basic research, these costs may well be balanced out by the increased sense of legitimacy and decreased controversy associated with the integrated completeness requirement. The value of the test is that it supplements judicial intuitions—some of which may well evince “foresight bias” and over pessimism about the impact of certain patents on downstream research\(^\text{230}\)—with expert input and a general framework for evaluating claim completeness. Accordingly, the test might lead to a more comprehensive and consistent treatment of the patenting of upstream inventions based on a variety of evidence. To be sure, some cases may present circumstances in which a decision-maker might determine that a patent claim is incomplete based only on the information in the patent itself. As a general matter, however, extrinsic fact findings 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 currently fail utility, written description, and section 101 patentable subject matter requirements would be found


\(^{230}\) Seymore, *Foresight Bias*, supra note 24, 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.).
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 for a framework
that may be more transparent and consistent than that which is currently
available, the completeness test might lead to a more textured analysis than
what has come out of 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 some of the patents at issue in the completeness
cases might have fared under the requirement—and how some hypothetical
patents might do.

For example, a chemical compound whose only utility is that as an
object of future research might fail under the unpredictability/generality
framework because that compound could be a cancer drug, a lubricant, a
fuel, and who knows what else. 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 does not cover transformative and
unpredictable downstream applications—but only uses of the compounds as
intermediates in connection with a particular, known class of drugs.

Although such an invention might set the foundation for some amount of
future research, the research area to which it drawn is so narrowly
circumscribed that an ordinary artisan would probably not view the claim
as directed to a fundamental research input or to be a major impediment to a
future work. In contrast, if a patent that reveals a utility for a chemical
compound that is substantial and specific within the meaning of the current
law, yet only trivial, the claim to the compound might fail the
completeness requirement.

The claims at issue in some of the written description cases—for
example, methods of treatment without a showing of any specific drugs—
would still be likely to be invalidated. These claims are often drafted in

---

231 This observation might suggest that many “product” claims, such as claims to
chemical compositions, may be entitled only to an RP. 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 is
expands over time, see Collins, supra note 174, 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
Professor Joshua Sarnoff for bringing this issue to my attention.

232 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

233 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.

234 Seymore, Foresight Bias, supra note 24, at *46; see also In re Kirk, 376 F.2d

235 Or, a showing of very few drug examples. See supra notes 56 & 120 and
accompanying text.
functional terms—in terms of an effect on a biological target—and leave open a large number of avenues for implementation. Because they threaten research and development pathways involving the synthesis and study of the drug candidates, such claims are likely to fail under the unpredictability/generality criteria absent a contrary showing in the patent’s specification. 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 its broad applicability of this sort of an invention at the time of filing. Stem cells would be subject to completeness scrutiny for similar reasons.

Moreover, the completeness requirement would affect various patent claims outside of the chemistry and biotechnology fields. 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 such patents seem, broadly speaking, to be directed to a problem to be solved rather than to a solution. This critique is quite similar to the critiques that have been directed to functionally drafted claims in the area of biotechnology, which suggests that certain software and business method claims should be scrutinized for completeness as well. Claims to general concepts such as the hedging of risk, unconstrained by any methods of implementation, are problematic for similar reasons as the functional biotechnology claims—indeed, some of the claims one encounters in these fields are broad that they might fail the completeness requirement no matter what the specification says. Scientific instrument inventions provide another illustration of how the completeness requirement might be applied. Claims to some machines, like the atomic force microscope, that would be expected to be used primarily in further research and to have many unforeseeable downstream applications, might fail the completeness requirement. Claims to others, perhaps gold metal detectors, would probably pass the requirement because of their narrowly defined utility.

Two final illustrations of the work of the proposed completeness requirement are based on recent, controversial Supreme Court cases in the

---

236 See supra notes 56-59 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 Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc)).

237 See supra Subpart IV.B.

238 See supra note 49 and accompanying text. I recognize that there is a level-of-generality problem lurking 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.

239 See supra notes 50 and accompanying text

240 See Lemley, supra note 21; see also supra note 62 and accompanying text.

241 See supra notes 179-183 and accompanying text.
life sciences area. One example relates to the patentability of DNA molecules at issue in Association for Molecular Pathology v. Myriad Genetics, Inc. 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. Under the proposed framework, however, both types of molecules would likely fail the completeness requirement due to the many downstream applications of the claimed genetic material. The incompleteness on analysis is agnostic to whether the previously unknown material is “natural” or not, for a focus in natural-ness would threaten to undermine the utilitarian grounding of the test. Rather, it focuses on the invention’s developmental stage, as viewed through the lens of the unpredictability/generality framework.

In contrast, the patent at issue in Mayo Collaborative Services v. Prometheus Laboratories, Inc. would probably pass the completeness test. The claims at issue were directed to administering a probe molecule along with a drug to a patient and deciding, based on the amount of the probe molecule measured after the administration, whether to increase or decrease the dosage of the drug. Although the Supreme Court was concerned that this claim would preempt all uses of the correlation between the amount of the probe molecule 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. 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. Thus, the unpredictability/generality 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.

D. The Need for Implementation by Statutory Change

---

242 133 S. Ct. 2107 (2013).
243 Id. at 2118; see supra note 199 and accompanying text.
245 Cf. Yu, supra note 28, 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 14, at 1716-18 (explaining patentable subject matter exclusions in utilitarian terms). But cf. Chiang, supra note 15, at *18-25 (arguing that the justification for the result in Myriad might be nonutilitarian).
247 Id. at 1295-97.
248 See Dreyfuss & Evans, supra note 212, at 1360-61 (“[T]here are arguably other ways to achieve the goals of the [Mayo] patent.”).
249 Cf. id.
250 See supra notes 193-197 and accompanying text.
Proposals for reforming how law treats 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 claim scope restrictions imposed by § 112. 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 basic for distinguishing technological from non-technological innovations. And Sean Seymore proposes that some of the concerns that courts currently address under the utility requirement should be addressed via the enablement and nonobviousness requirements. Similarly, it may be possible to implement the completeness requirement via one of the extant patentability requirements. Nonetheless, I believe that approach relying on one of the existing patentability requirements would be problematic.

Although the enablement requirement might seem to be a good candidate for enforcing completeness because of its focus on overclaiming, I believe that 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 could practice the full scope of the claim based on the disclosures in the specification without undue experimentation at the time of patent filing. The timing aspect of the requirement generally means that claims can cover after-arising technology without an enablement violation. Indeed, while the enablement requirement helps ensure that there is a reasonable correlation between what is claimed and what is disclosed in the patent. 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.

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. Section 101 patentable subject matter jurisprudence is already highly controversial and carries with it a great deal of baggage that would be challenging to leave behind. In addition, it would be difficult to square the language of the statute, which allows a patent on any “process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,”260 with prohibition of patents on 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 patenting of basic research. The word “new” has most often been used to support a distinction between patentable “inventions” and unpatentable “discoveries,”261 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 controversial interpretation of “useful.”262 Thus, an approach relying on the word “useful” 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—the first one, of course, is the challenge of getting the proposal through Congress. Given the current focus on procedural patent reform, this sort of a substantive 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 according to some commentators.263 For example, the 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-type patents on inventions that might not necessarily be directed to foundational inputs into future research and development.264 If consensus develops that a test for separating useful from harmful patents is required that is different from what courts currently offer,

259 See, e.g., Sitrick v. Dreamworks, LLC, 516 F.3d 993 (Fed. Cir. 2008).
261 See, e.g., Demaine & Fellmeth, supra note 177, at 345-49.
262 See supra Subpart IV.A.
perhaps a codification of the completeness requirement—with modifications that bring it into line with the patent law’s utilitarian goals—might become a possibility. Although completeness reflects crucially important policies, the court’s current implementation of this requirement may be nearing its “flash of creative genius” moment, and codification and course correction might be in order. In addition, the codification will help reduce the legitimacy costs of the current implementation of the completeness requirement.

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 unpredictability/generality framework introduced above provides one way of implementing the requirement, but perhaps other tests could be developed. In addition, just as the codified obviousness 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,” 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 specifying that

A patent claim should not be denied solely on the basis that the claimed invention has only research utility. A patent claim should not be denied solely on the basis that the specification does not provide a sufficient number of chemical, physical, or algorithmic structures for carrying out the claimed result, unless drafted in means-plus-function format. A patent claim should not be denied because 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.

The purpose of this statutory structure is to replace the extant test 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 “basic research.” The proposed requirement also leaves room for technology-specific standards, which may be appropriate in some scenarios. But I believe that the new statutory provision, along with the unpredictability/generality framework suggested for its implementation, would have the effect of pressing the “reset” button on the existing doctrine and lead to fresh approaches. In addition, with the completeness requirement having been unified under a single statutory provision, precedent will apply to all types of upstream patents. As a result, a more coherent body of law governing these sorts of patents may develop.

VI. THE RESEARCH PATENT PROPOSAL

A. Do limited rights for incomplete patents make sense?

265 See supra note 35 and accompanying test.
266 Id.
267 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.
The foregoing Part assumes that artifacts of basic research should be unpatentable. This Part questions this assumption and suggests 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 preemption that is due.

The undue preemption concern arises for many reasons. First, as discussed extensively in the previous Parts, 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. 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.

One powerful explanation for certain bright-line exclusions from patentability, as now implemented under the aegis of § 101, is that they can 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. 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 and the courts can either allow a full patent right or entirely invalidate or reject the claim, without the option of an in between solution. The all-or-nothing approach with respect to any given claim is

---


269 Cf. Devlin, supra note 14, 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.”).

270 Golden, supra note 193, at 1066-70.

271 Patent law does permit tailoring of rights to some degree by allowing the inventor to vary the scope of the patent claims. But 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 28, 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 59, at 161 (“The written description requirement only allows very narrow patents, so narrow and easily dodged as to be almost worthless.”). Cf. Benjamin N. Roin, Solving the Problem of New Uses, available at http://papers.ssrn.com/abstract=2337821 (describing a particular type of patentable but effectively valueless claims); see also Rai, supra note 79, 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
one of the patent system’s imperfections, resulting in what Michael Carroll terms “uniformity costs.”

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 way, however, would 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 is required for their creation and commercialization.

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. One of the arguments advanced in favor of Bayh-Dole was that, even if the 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. The Bayh-Dole regime has not, of course, escaped criticism, but it is thought to make some sense for commercialization of upstream inventions in the biotechnology industry.

will be relatively low. Where transaction and creativity costs are low relative to invention costs, patent protection is probably desirable.”).


274 See 35 U.S.C. § 200 et seq. Although this argument was rejected in University of Rochester v. GD Searle & Co., Inc. 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. 358 F.3d 916, 929 (Fed. Cir. 2004). See infra notes 127-132 & 187-190 and accompanying text.

275 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.”).

276 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).

277 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
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.278

A patent right would also provide a mechanism for the 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.”279 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”280 and aid in “achieving and publicizing basic research.”281 Even if such patents might not always be widely read,282 the patenting might facilitate peripheral disclosures that would help spread useful information.283 In addition, if the completeness test incorporates information-forcing mechanisms that may induce patentees to inform the public about the applicability of the invention and suggest approaches to designing around the claims, the patent disclosures might become quite socially valuable.284

B. Prior proposals for limited rights in some upstream patents

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 enforcement of some of these sorts of patents. One type of a solution preserves the validity of upstream patents but provides for a revival of a personal

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)). 278 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).

280 Brenner v. Manson, 383 U.S. 519, 539 (1966) (Harlan, J., dissenting)
281 Id. Several scholars have argued that patents fail at their teaching function. See, e.g., Holbrook, supra note 28, 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 278; see also Lisa Larrimore Ouellette, Do Patents Disclose Useful Information?, 25 Harv. J.L. & Tech. 531 (2012).
283 Rantanen, supra note 278.
284 See supra notes 211-212 and accompanying test.
“experimental use”\textsuperscript{285} 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.\textsuperscript{286} Conceptually related to the experimental use exemption are proposals that entail expanding the so-called reverse doctrine of equivalents,\textsuperscript{287} 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” licensing fees.\textsuperscript{288} Generalizing from 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\textsuperscript{289} can account for implications of technological unpredictability—such as uncertain value and applicability of upstream

\textsuperscript{285} 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(c)(1) (2012) (providing a form of experimental use defense under narrow circumstances).

\textsuperscript{286} 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 46, at 36-37; Strandburg, supra note 45, 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 45, at 119-38.

\textsuperscript{287} See Koneru, supra note 163, at 663-65; Lemley, supra note 213, 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 81, at 860-68; see also Chisum, note 39, 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 Robert Merges, Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents, 62 TENN. L. REV. 75 (1994). Although academic literature often discusses the reverse doctrine of equivalents in the context of “blocking” patents, see supra notes 169-173, the application of the doctrine is not limited to those circumstances.

\textsuperscript{288} See Robin C. Feldman, The Insufficiency of Antitrust Analysis for Patent Misuse, 55 HASTINGS L.J. 399, 441 (2003) (“[S]ome patent holders have charged royalties measured as a percentage of the final product created through a process which included using the research tool. . . . [S]uch payments provide revenues from any downstream commercial products to those who own intellectual property that may now be of uncertain value or utility.”); see Bayer AG v. Housey Pharm., Inc., 228 F. Supp. 2d 467 (D. Del. 2002).

inventions. 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.

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. 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. Expenses associated with patent litigation, which sorts out whether a user is liable for infringing a valid patent and what the infringement remedies should be, are thought to distort patent value. Although the parties can of course settle or choose arbitration, 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.

---

290 Id. at 274-79.
291 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).
292 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).


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.”

2. Sui generis approaches

A few other approaches to limiting upstream inventions are worth noting. Particularly, some commentators have tackled 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 certain upstream inventions, while others advocated compulsory licensing for their use and proposed other limits on remedies for successful enforcement of such patents. Implicitly or explicitly, these proposals may be motivated by the concern that the completeness requirement in its current form may not 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.


297 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 79, 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.”).


299 Lopez-Beverage, supra note 90, at 90-91 (proposing this solution for ESTs).

300 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); Mireles, supra note 90, 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).
C. Toward a research patent

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.” The RP proposal adopts this approach. 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 of such patents. At a high level, any patent claim passes extant requirements of patentability at the PTO but fails the completeness requirement would not be invalidated but rather entitled to some form of a limited patent, herein called the Research Patent (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. Liability-rule protection of upstream patents makes sense because full rights in such patents appear to be associated with a high rate of market failure. 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. 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. Damages caps are a familiar feature of tort reform efforts—for example, several states put caps on compensation for medical malpractice. If damages can be capped for physical injury, damage caps or scheduled damages for patent

301 Devlin, supra note 297, at 635.
302 Thus, the RPs 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. A patent with a shorter term is still susceptible to holdup problems. Cf. Mark D. Janis, Second Tier Patent Protection, 40 HARVARD INT’L L.J. 151, 218 (1999) (“Current property rights regimes are not the answer for protecting subpatentable innovation.”).
303 See FELDMAN, RETHINKING PATENT LAW, supra note 75, 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 91, at 1372. See generally Ben Depoorter, Property Rules, Liability Rules, and Patent Market Failure, 1 ERASMUS L. REV. 59 (2008).
305 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 than the costs of litigating a regular patent in a district court.
infringement also appear to be reasonable, and will help mitigate holdup stemming unpredictable jury verdicts. 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 plausibility of a government-mandated liability-rule solution.

A specialized tribunal would be needed to reduce the threat of holdup associated with the costs of district court litigation. One possibility is a specialized patent small claims court. Interestingly, such a court has been proposed as part of recent efforts to reform the Patent Act, as part of the goal of reducing the incidence of nuisance-value settlements. The PTO has issued a request for comments, and several suggestions for what form such a court might take have been put forward by practitioners and scholars. To be sure, these proposals have been criticized as a general approach to reforming patent litigation because of their potential to dilute patent rights and the fear that a small claims court might violate the Seventh Amendment right to a jury. In contrast, if a patent right is designed by statute to come with a limited bundle of rights, these concerns are not present.

In keeping with the goal of facilitating a low-cost resolution of disputes over RPs, the tribunal would only be able to evaluate ordinary infringement and invalidity based on patents and written publications. This approach avoids costly, discovery-intensive subjects like inequitable conduct and willfulness, as well as non-prior art invalidity. Reflecting

307 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).


309 Cf. Bradley J. Levang, Comment, Evaluating the Use of Patent Pools for Biotechnology: A Refutation to the USPTO’s 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 telecommunications field. See generally Lemley & Shapiro, supra note 308.

310 See, e.g., Chien & Guo, supra note 293.


312 See, e.g., supra note 310 & infra note 315.


314 Moreover, in order to encourage the limited validity challenges, claim amendments will not be allowed.


316 Indeed, non-prior-art based challenges at the PTAB are already disallowed under the inter partes review statutes. See 35 U.S.C. § 311(b) (2012).
the limited nature of the RP right, no claims for infringement under the doctrine of equivalents would be allowed. 317

2. Challenges of the approach

The tentative RP proposal described herein is open to numerous objections. 318 The essence of some of these objections is that the RP game is not worth the candle—that the “course filter” approach of invalidating all incomplete patents would work better. 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 subjects of an RP. In this subpart, I briefly examine these objections.

Whatever numbers are chosen, scheduled damages will certainly inaccurate as estimates of patent value for a number of reasons—for example, because of the differences in the value of patents from one technology to another and the difference between how extensively various infringers might use the technology. Nonetheless, the scheduling approach sidesteps the notoriously difficult problem of valuation of patents by courts. 319 Indeed, courts have often questioned their own competence to gauge patent damages, 320 and proposals to put the measurement into the hands of administrative agencies are open to the same critiques.

In addition, at least extent of the infringement might be taken into account in some way under the scheduling approach. 321 For example, damages under an RP claim might be limited to amount X for a “micro entity” infringer, amount 2X for a “small entity,” and 4X for a “large entity entity.” Within these categories, the small claims adjudicator would be able to further adjust the claim based on whether the infringer’s use of the claimed invention is “maximum,” “medium,” or “small” according to some preset schedule. 322

318 I will work out the proposal and examine the objections in more detail in a separate article. Besides the objections discussed in this Subpart, such a system may be challenged on constitutional grounds. See supra note 157
319 Indeed, the valuation problem is one of the common objections to compulsory licensing of issued patents. See Epstein, supra note 297.
320 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”).
321 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 familially related or are directed to closely similar technology).
322 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 or PTAB could be empowered to set the royalty for each particular invention as done for covers of
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.\textsuperscript{325} Even if the amount of scheduled damages might be 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.\textsuperscript{324} This approach encourages the spreading of liability rather than focusing on a few “deep pockets” infringers in an effort to obtain large damages or an injunction, which is a strategy that can be pursued with regular utility patents.\textsuperscript{325} 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 downstream infringers and proving the infringements.

The line-drawing between completely unpatentable inventions and those that qualify for an RP also presents very difficult questions. As an initial matter, section 101 limits patentable subject matter categories to “process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,”\textsuperscript{326} and claims directed subject matter outside of these prohibited categories would not be entitled even to an RP. In addition, even if a claim is nominally drawn to a statutory category, long-standing precedent prohibits patent claims that are manifestly directed to\textsuperscript{327} 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 seems more acute than that with cover songs. See supra notes 303-309 and accompanying text.

\textsuperscript{323} Consistent with this approach, sublicensing of the right to use the RP subject matter by the “infringer” to another party would not be allowed.

\textsuperscript{324} Indeed, “[i]f you create enough certainty in the commercial and regulatory landscape, a private market will fill in the spaces unless impeded by some other barrier.” Cahoy, supra note 322, at 506; see Dreyfuss, supra note 303, 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).

\textsuperscript{325} 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.

\textsuperscript{326} 35 U.S.C. § 101.

\textsuperscript{327} Rather than being an “inventive application” of or “markedly different” from such artifacts, which are the tests developed in recent cases expanding the scope of patentable subjectable matter exclusion.
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.”328 Indeed, exclusion of such discoveries from patentability has a long history.329 Deciding whether claims of this sort should be excluded, as opposed to given an RP, however, would require a decision-maker to identify claims to “relatively ‘pure’ abstract ideas, natural laws, and natural phenomena”—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 is tricky, scholars have suggested approaches to identifying “embryonic” patents that might be distinguishable from pure ideas and laws of nature.330

Perhaps, one way that that embryonic inventions can be distinguished from pure ideas in that the former, as claimed, provide a concrete roadmap for useful applications in the hands of downstream researchers. Thus, the three of the inventions discussed in this article can (1) be used to make new chemical compounds; (2) guide experiments for discovering valuable drugs; and (3) point to steps in the development of diagnostic tests. Applications of this sort should be sufficient to allow the invention to pass the initial hurdle of patent-eligibility. While all of these inventions 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.332 Under the current regime, such claims can be rejected for lack of credible or operable utility under § 101.333 I do not purport to propose any

328 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).

329 See supra note 71 and accompanying text.

330 Sichelman, supra note 201, at 370.

331 Duffy, supra note 169; cf. Oren Bar-Gill & Gideon Parchomovsky, A Marketplace for Ideas?, 84 TEX. L. REV. 395, 402 (2005). These authors do suggest treating ideas and embryonic invention 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 193, 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).

332 This is in contrast to claims invalidated in, for example, the Rochester case, 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.

changes to this area of patent law—inventions that are completely inoperative or should not qualify even for limited patent protection. And other requirements of patentability, such as novelty and nonobviousness, will continue to serve as a backstop.

VII. CONCLUSION

Patents on upstream, basic-research inventions have created problems for the law. Courts have had trouble developing a coherent body of doctrine for curbing unduly preemptive patents on upstream inventions. Concerns over upstream patenting have produced many controversial cases implementing the utility, written description, and patentable subject matter requirements—a controversy that is particularly acute today in the patentable subject matter context. I argue that these cases are best explained by supervening, unwritten requirement of patentability I call completeness, and explain 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 and fail completeness. These proposals are justified mainly on utilitarian grounds.

334 To be sure, the enablement requirement sometimes may function as a completeness requirement. Cf. supra notes 254-259 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.