

UPSTREAM INVENTIONS

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Abstract

One of patent law's most important goals is to grant legal rights that are properly calibrated to incentivize invention without unduly stifling innovation, and one of its greatest struggles is to provide the appropriate level of protection for foundational, widely applicable inventions. Although many scholars have addressed the law's difficulties with patents on such "upstream" inventions, a systematic treatment of upstream patents has proven elusive. This Article adds to the literature by identifying an as-yet unrecognized requirement of patentability, here termed "the completeness requirement," which courts have used to limit patent protection on some upstream inventions. The Article argues that, although policy justifications for the completeness requirement are generally sound, its judicial implementation has been subjective and inconsistent at best, and damaging to innovation policy at worst. It also explains that the remedy of completely invalidating or disallowing patents on upstream inventions is disproportionate to the perceived harm of such patents.

The Article proposes two improvements. First, it posits that decision-makers should abandon the current hodgepodge of doctrines that collectively house the completeness requirement, and calls for the creation of a new statutory provision that explicitly recognizes it as a condition of patentability. Making completeness a standalone requirement would help reduce the problems associated with courts' ad-hoc, technology-specific implementation of it. Second, the Article proposes the Research Patent—a new form of intellectual property protection for patent claims that meet established patentability requirements but fail completeness. Unlike a regular utility patent, the Research Patent would only permit its owner to pursue a claim for a limited amount of damages before a specialized tribunal. The Research Patent would offer two benefits: it would provide incentives for creating upstream inventions and decrease the potential for stifling downstream innovation caused by granting full patent protection to such inventions.

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I. INTRODUCTION

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

Or, consider a case where biomedical investigators discover that, by interfering with the function of a certain receptor in the human body, one could reduce "inflammation associated with diseases such as arthritis."² In contrast to earlier work, this approach treats the inflammation while avoiding "undesirable side effects such as upset stomach, irritation, ulcers, and bleeding."³ The discovery is highly valuable: as one commentator noted, "there is little question that this pioneering . . . work paved the way for a new generation of painkillers that would be easy on the stomach,"⁴ including Celebrex 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.⁵ The invention is hailed as a significant development of "personalized medicine" to treat inflammatory bowel disease,⁶ and other researchers and doctors use the kit to make further discoveries.⁷ Again, unsatisfied to claim merely a kit, the inventors attempt

¹ This is a stylized example describing an invention that would be held unpatentable in view of the holding in *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...").

⁵ See Product Description, *Prometheus Therapeutics and Diagnostics*, http://www.prometheuslabs.com/Resources/PTM/Thiopurine_Metabolites_Product_Detail.pdf

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

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

to claim a general method of optimizing drug dosage based on the measured amount of the probe molecule in the body.⁸

It would appear that the law should encourage the creation of these three inventions by allowing for valuable patents to protect them.⁹ But courts held that none of the inventions could be patented because each was incomplete in some way based on what the inventor claimed and disclosed. 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”;¹⁰ 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”;¹¹ 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,¹² and the Supreme Court invalidated the claims as drawn to an unpatentable “law of nature.”¹³ In all three cases, the courts relied on the same policy reasons to invalidate or reject the patent claims: they worried that patents on such early-stage, “upstream” inventions would over-reward their owners and unduly preempt too much downstream research.¹⁴ Although the courts

⁸ See Elizabeth A. Doherty, FINNEGAN—FULL DISCLOSURE, *Biomarker and Personalized Medicine Patent Claims One Year After Mayo v. Prometheus*, http://www.finnegan.com/files/upload/Newsletters/Full_Disclosure/2013/June/FullDisclosure_Jun13_5.html (June 2013) (“From [a patent] applicant’s point of view, . . . narrower claims may be very easy for a competitor to design around and thus of little commercial value.”).

⁹ Cf. 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 *Brenner v. Manson*, 383 U.S. 519, 535 (1966).

¹¹ *University of Rochester v. GD Searle & Co., Inc.*, 358 F.3d 916, 927 (Fed. Cir. 2004).

¹² *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302 (2012).

¹³ 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 . . .).

¹⁴ *Mayo*, 132 S. Ct. at 1294 (“[Precedent] warn[s] us against upholding patents that claim processes that too broadly preempt the use of a natural law.”); *Brenner*, 383 U.S. at 535 (“[T]here is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”); *Rochester*, 358 F.3d at 920 (explaining that courts should “ensure that the scope of the right to exclude . . . does

formally drew upon different provisions of the Patent Act in deciding that the three sets of claims were not patentable, this Article explains that all three cases tested the inventions against the same unwritten requirement of patent law. I call it the completeness requirement.

This Article shows that, while the completeness requirement reflects sound policy, it is problematic in its current form. First, the completeness requirement as implemented by courts is subjective and inconsistent,¹⁵ picking out certain inventions and certain technology areas for unfavorable treatment.¹⁶ Indeed, patent law routinely allows claims to upstream inventions in fields such as software and scientific instrumentation, but enforces the completeness requirement rigorously against some types of biotechnological and chemical inventions.¹⁷ As a result, the policy goals of the completeness requirement are implemented only erratically. Second, by prohibiting patents on certain classes of upstream inventions, completeness cases clash with other patent law doctrines, which generally exhibit a strong preference for early patenting and early disclosure.¹⁸ This Article argues that this tension creates serious practical problems.¹⁹ Third, the remedy imposed for noncompliance with the completeness requirement—outright invalidation of the upstream patent claims—is harsh and disproportionate.²⁰ If the concern is that the amount of preemption is *undue*, then the logical solution is to weaken the available remedy until the patentee receives preemption that is *due*.²¹ However, the U.S. Patent and Trademark Office

not over-reach the scope of the inventor’s contribution to the field of art”) (quoting *Reffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000)).

¹⁵ 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, J., dissenting from the order denying rehearing en banc); Joshua Kresh, *Patent Eligibility After Mayo: How Did We Get Here and Where Do We Go?*, 22 FED. CIR. B.J. 521, 540 (2013) (“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.”); Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1077 (2014) (arguing that the utility requirement is arbitrary).

¹⁶ See *infra* Subpart V.A.

¹⁷ See Dan Burk, *The Problem of Process in Biotechnology*, 43 HOUS. L. REV. 563, 581 (2006); 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). See generally Dan Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002). To be sure, there are some upstream patents in the biomedical field that have been allowed. See *infra* notes 39-40 and accompanying text. 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 161-162 and accompanying text.

¹⁸ See generally John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 453 (2004).

¹⁹ See *infra* Subpart III.C.

²⁰ See *infra* Subpart V.B.

²¹ Unless the right amount of preemption is zero, which does not appear to be true in most circumstances. As I make clear in Subpart III.C, complete absence of patent

(PTO) lacks the power to grant patents that come with a limited remedy.²² It is faced with only two choices—grant the full patent right, or none at all.²³

This Article provides a proposal that addresses all three problems.²⁴ First, it abrogates the holdings of the troublesome completeness cases by statute. Second, it replaces the judicially created completeness requirement with a statutory test for completeness that is intended to apply broadly across technology areas and invention types. Third, it sets forth a novel Research Patent (RP) right to protect inventions that meet the standard conditions of patentability, but fail the newly proposed statutory requirement of completeness. Unlike a regular utility patent, the RP would only entitle its owner to negotiate a royalty for the use of the subject technology with the potential users. Failing that, the RP owner could pursue a claim in a specialized tribunal for a limited amount of damages.²⁵ The RP framework is intended to provide incentives for creating upstream inventions and encouraging their dissemination. At the same time, the limited nature of the RP right would help reduce the potential for holdup of downstream research that the threat of a patent infringement lawsuit can create. Indeed, avoidance of costly litigation to determine the scope and value of the patent right is a major advantage of the proposed regime over *ex post* solutions such as infringement exemptions and the tailoring of remedies at the district courts.²⁶

The test for determining whether an invention is incomplete draws partly upon the reasoning of the completeness cases, but calls for factual inquiries in place of subjective judicial determinations. It relies on the following two factors: (1) whether, according to a person of ordinary skill in the art, the claimed invention is likely to cover many significant uses that are presently unknown, i.e., have not been invented;²⁷ and (2) whether a person of ordinary skill in the art would recognize that the claimed invention has the features of a hypothesis or a conjecture.²⁸ More generally, the proposed new doctrinal home for completeness is designed to shed the baggage of the “I

protection for upstream invention is problematic, and likely to result in underinvestment into important technologies.

²² 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. §§ 283, 284 (2012), when it comes to patent *validity*, they (like the PTO) can only uphold or invalidate patent claims. *See id.* § 282. Furthermore, in Subpart VI.A, I explain that it is costly to wait until litigation to determine the value of a patent, and in Part VII I propose a patent right that comes with a limited remedy *ex ante*.

²³ The lack of *ex ante* intermediate solutions in patent law gives rise to what are called “uniformity costs.” *See* Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845, 871-75 (2006).

²⁴ *See infra* Part VII.

²⁵ *See infra* Subpart VII.C.

²⁶ *See infra* Part VI. Federal district courts have exclusive jurisdiction over patent infringement cases. *See* 28 U.S.C. § 1338 (2012).

²⁷ *Cf.* *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972); *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966); *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005); *see* Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315 (2011).

²⁸ *Cf.* *Ariad Pharm., Inc. v. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344-45 (Fed. Cir. 2010) (en banc). A person of ordinary skill in the art is a theoretical construct, like “the reasonable person” in tort law, from whose perspective factual questions are evaluated. *See* Mark D. Janis & Timothy R. Holbrook, *Patent Law’s Audience*, 97 MINN. L. REV. 72, 99 (2012).

know it when I see it” approach that often characterizes completeness cases,²⁹ and to generalize the completeness requirement’s application. Although some inventions that are presently unpatentable may qualify for RP, the effect of the RP regime would not necessarily be an overall expansion of patent rights. For example, certain types of “research tool” and software patents would likely become downgraded to RPs under the proposed scheme.³⁰

This Article is not the first to notice problems with the completeness cases. All three sets of doctrines have attracted a great deal of controversy and scholarly interest, and drawn a firestorm of academic (and judicial) criticism.³¹ But this Article is the first to present these disparate rules as facets of a single, unwritten underlying requirement, answering to the same policy concerns. Moreover, this Article provides a novel, holistic, and workable solution that addresses the important policy considerations behind these cases, but minimizes the problems that they have created. At the PTO, the RP regime would be far less challenging to administer than the rights under many of the tailored exclusivity regimes proposed by other scholars³²

²⁹ See *infra* Part V.B.

³⁰ See *infra* Part VII.B.2.

³¹ Given the high volume of work in these areas, I provide only a small sampling. Utility: Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195; Seymore, *supra* note 15; see also Joshua D. Sarnoff & Christopher M. Holman, *Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents*, 23 BERKELEY TECH. L.J. 1299, 1338–40 (2008). Written Description: Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 161–63 (2006); Mark D. Janis, *On Courts Herding Cats: Contending with the “Written Description” Requirement (and Other Unruly Patent Disclosure Doctrines)*, 2 WASH U. J.L. & POL’Y 55 (2000); Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998). Patentable subject matter: Bernard Chao, *Moderating Mayo*, 107 NW. U. L. REV. 423 (2012); Kresh, *supra* note 15; Mark A. Lemley et al., *Life After Bilski*, *supra* note 27; Katherine J. Strandburg, *Much Ado About Preemption*, 50 HOUS. L. REV. 563 (2012); Allen K. Yu, *Within Subject Matter Eligibility—A Disease and a Cure*, 84 S. CAL. L. REV. 387 (2011). There are also some notable judicial critiques. Utility: *In re Fisher*, 421 F.3d 1365, 1380 (Rader, J., dissenting); *In re Kirk*, 376 F.2d 936, 957 (C.C.P.A. 1967) (Rich, J., dissenting). Written description: *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1361 (Fed. Cir. 2010) (en banc) (Rader, J., dissenting); *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 375 F.3d 1303, 1307, 1315–21 (Fed. Cir. 2004) (Rader, J., dissenting from the order denying rehearing en banc) (criticizing the Federal Circuit’s written description requirement and collecting articles critical of the requirement). Patentable subject matter exclusions: *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1292 (Fed. Cir. 2013) (en banc) (Rader, C.J., concurring-in-part and dissenting-in-part), *aff’d*, 134 S. Ct. 2347 (2014); *In re Bilski*, 545 F.3d 943, 976 (Fed. Cir. 2008) (en banc) (Newman, J., dissenting).

³² See, e.g., Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 HARV. L. REV. 1362 (2011); Michael Abramowicz & John F. Duffy, *Intellectual Property for Market Experimentation*, 83 N.Y.U. L. REV. 337 (2008); Gideon Parchomovsky & Michael Mattioli, *Partial Patents*, 111 COLUM. L. REV. 207 (2011); Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on the Time-to-Market of Inventions*, 61 UCLA L. REV. 672 (2014); Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341 (2010). Cf. Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic*

because completeness inquiries entail the sorts of determinations that the agency already makes.³³ Just like regular patents, the RPs will have claims—indeed, the only difference from the current patentability framework is the additional condition of completeness. If, along with the other requirements of patentability, a claim meets the completeness requirement, a regular patent will be awarded. But if the PTO decides that the patent claim lacks completeness, the applicant will receive only an RP.

The rest of this Article proceeds as follows. Part II attempts to define upstream inventions. Part III presents arguments for and against allowing patents on such inventions and concludes that some form of patent protection is likely needed to incentivize their creation. Part IV explains how the law currently deals with such inventions. This Part demonstrates that certain cases invoking utility, written description, and patentable subject matter work together to create a de facto requirement of completeness. Part V explains why courts' implementation of this requirement is flawed. Part VI evaluates other scholars' proposals for improving the ways in which law deals with upstream inventions. Part VII sets forth the mechanics of the Research Patent and explains how it solves some of the problems with the current implementation of the completeness requirement. This Part also explains which inventions would qualify for no patent protection—even an RP—and considers objections to the proposal. Part VIII concludes.

II. WHAT ARE UPSTREAM INVENTIONS?

“Upstreamness,” for lack of a better word, has eluded a clear definition.³⁴ Several themes emerge from the cases and the literature, however. The three examples discussed in the Introduction represent three forms of upstream inventions—research tools, hypotheses, and laws of nature. Patent claims to all three types of inventions have engendered undue preemption concerns stemming from the fact that these inventions are, in some way, at an early developmental stage. 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, downstream

Materials, 98 IOWA L. REV. 1399 (2013) (proposing non-patent exclusivity for certain subject matter).

³³ See *infra* Subpart VI.B.

³⁴ 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 same computer chip might be an upstream invention relative to a device that uses the chip, such as cellular phone.”).

research.³⁵ Such inventions have been called “research tools”³⁶ and “research intermediates.”³⁷ One set of examples, discussed in the Introduction, includes chemical compounds not having a known end use and methods for making such compounds.³⁸ Another group of “research tool” patents 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.³⁹ Stem cells exemplify yet another set of research tools whose patenting has been subject of academic critiques.⁴⁰

The upshot of the critiques is that “whereas most patents cover the *outputs* of scientific investigation, patents on research tools cover the *inputs* of that investigation.”⁴¹ 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.”⁴² Research tools and intermediates are not limited to biological and chemical materials—the microscope⁴³ is perhaps the archetypal “invention the primary function of

³⁵ 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.”).

³⁶ 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 31, at 1302-03; Strandburg, *supra* note 35, 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.”).

³⁷ *In re Fisher*, 421 F.3d 1365, 1373 (Fed. Cir. 2005); see also *infra* notes 209-213 and accompanying text (exploring the difference between research intermediates and research tools).

³⁸ See *supra* note 1 and accompanying text.

³⁹ See Mueller, *supra* note 36, at 12-13 (describing patents on PCR methods).

⁴⁰ *Id.* at 13; see also Peter Yun-Hyong Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine To Constrain Patents on Biotechnology Research Tools*, 19 HARV. J.L. & TECH. 79, 106-08 (2005).

⁴¹ Lee, *supra* note 40, at 81 (emphasis is original); see Mueller, *supra* note 36, at 4 (“[T]he dispute stems from the broad rights conferred by the patents covering [PCR] tools.”).

⁴² *Id.*

⁴³ See *id.* at 1380 (Rader, J., dissenting).

which is to facilitate scientific and technological progress.”⁴⁴ Indeed, many types of scientific instruments are upstream in this sense.⁴⁵

A second category of upstream inventions has been variously characterized as a “wish,” “plan,” “hypothesis,” and so on.⁴⁶ Inventions in this category are similar to some research tool and research intermediate inventions in that they are viewed as only the beginning of a research project rather than a research result. Like tools and intermediates, “hypothesis” inventions often fail to describe an end product that a non-researcher end-user can benefit from.⁴⁷ One example, discussed in the Introduction, is a claim to a method of treatment based on the identification of a target of drug action—a so-called “receptor”—in the human body.⁴⁸ Inventions of this sort elicit completeness concerns because no drug has yet been found—the inventor provided only a search method for discovering the drug.⁴⁹

“Hypothesis”-type inventions are also not limited to the fields of chemistry and biochemistry because basic research must logically occur in some form in all areas of technology. Consider, for example, a patent claim to a method of flying by controlling motion along all three axes of rotation about the flying machine’s center of mass. The Wright brothers’ key insight that was that this so-called “three-axis” control was needed for controlled flight.⁵⁰ Yet if the inventors 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 the claim was to an invention that is too early in the development

⁴⁴ Strandburg, *supra* note 35, at 123; see Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 613-14 (2005) (describing specialized microscopes as “basic building blocks in nanotechnology”).

⁴⁵ See Burk, *supra* note 17, at 581.

⁴⁶ 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.”).

⁴⁷ 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).

⁴⁸ See *supra* notes 2-4 and accompanying text.

⁴⁹ 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-arounds. Although the knowledge of the drug target is extremely valuable, that invention is difficult to monetize until a drug is actually found. See Michael D. Plimier, *Genentech, Inc. v. Novo Nordisk & University of California v. Eli Lilly and Co.*, 13 BERKELEY TECH. L.J. 149, 161 (1998); see also *supra* notes 1-8 and accompanying text.

⁵⁰ See *What Did the Wright Brothers Invent*, WRIGHT BROTHERS AIRPLANE COMPANY, http://www.wright-brothers.org/Information_Desk/Help_with_Homework/Help_with_Homework_Intro/What%20did%20the%20Wright%20brothers%20invent.pdf, at *2 (“The Wrights never claimed to have invented the airplane, or even the first airplane to fly. In their own words, they made the first sustained, powered, *controlled* flights.” (emphasis in original)). Nevertheless, the Wright Brothers patent was titled “Flying Machine” and some of the claims are directed to “[a] flying machine.” U.S. Pat. No. 821,393 claims 14, 15 (filed Mar. 23, 1903) (issued May 22, 1906) (‘393 patent).

chain.⁵¹ A more modern version of what could be described a “hypothesis”-type invention is a functionally claimed software patent. The concern is similar: functional software claims identify the problem to be solved and list out generic steps for how one would go about solving it, but do not actually explain how to implement a solution.⁵²

Yet a third category of upstream inventions includes discoveries about the workings of the natural world. Commentators and courts have denominated them as “law[s]”⁵³ or “products”⁵⁴ of nature, “natural phenomena,”⁵⁵ “scientific truths,”⁵⁶ “concepts,”⁵⁷ “formulas,”⁵⁸ or by some other similar label.⁵⁹ An oft-repeated example of such a discovery is $E = mc^2$, Einstein’s famous formula for calculating energy from mass using the universal physical constant c , the speed of light.⁶⁰ This facet of upstreamness has a rich historical pedigree, harkening back to the distinction between patentable “industrial property” and unpatentable “scientific property” in the early international patent regimes.⁶¹ As we have seen, the Supreme Court

⁵¹ Assuming the 1903 Wright Flyer was the embodiment of the ’393 patent, there is evidence that the Wright Brothers patent—rather than describe a working flying machine—only provided a roadmap for how to build a flying machine. See MALCOLM J. ABZUG & E. EUGENE LARRABEE, AIRPLANE STABILITY AND CONTROL 3 (2d ed. 2005) (“Modern analysis . . . demonstrated that the 1903 Wright Flyer was so unstable as to be almost unmanageable by anyone but the Wrights . . .”). And even then, the famous December 1903 flight lasted only 12 seconds. Indeed, Mark Lemley suggested in a recent article that the Wright Brothers’ patent claims were overbroad, and perhaps this was due to incompleteness. See Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 726 (2012) (“The Wrights solved the stability problem by having a single cable warp the wing and turn the rudder at the same time. Their patent, however, was not so limited, and they successfully asserted it against subsequent inventors such as Glenn Curtiss. . . . A frustrated Curtiss reportedly said that the Wright Brothers believed their patent was so broad that anyone who jumped up and down and flapped their arms infringed it.”).

⁵² Lemley, *supra* note 17; see also *Comments of Michael Risch on Functional Claiming and Software Patents*, Docket No. PTO-P-2012-0052, http://www.uspto.gov/patents/law/comments/sw-f_risch_20130312.pdf. See generally Kevin Emerson Collins, *Patent Law’s Functionality Malfunction and The Problem of Overbroad, Functional Software Patents*, 90 WASH. U. L. REV. 1399 (2013).

⁵³ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013).

⁵⁴ *Id.* at 2111.

⁵⁵ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296 (2012).

⁵⁶ *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

⁵⁷ *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010).

⁵⁸ *Id.* at 3233.

⁵⁹ *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 31, at 1340-43; Yu, *supra* note 31, at 423-24.

⁶⁰ See, e.g., *Mayo*, 132 S. Ct. at 1293.

⁶¹ See Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, 13 J. SOC. PHIL. & POL’Y 145, 152-57 (1996); see also Thomas R. Ilosvay, *Scientific Property*, 2 AM. J. COMP. L. 178 (1953). See generally CHARLES J. HAMSON, PATENT RIGHTS FOR SCIENTIFIC DISCOVERIES (1930) (detailing

recently relied on the law-of-nature exclusion to invalidate 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.⁶² Assuming the Supreme Court’s analysis was correct, it is difficult to think of a stronger example of a claim “at the beginning of the development chain”⁶³ than a claim to a law of nature.

This list is not meant to be exhaustive, and the categories are not sharp. Perhaps, inventions in the second category really belong in the third category. For example, Robin Feldman argued that a patent adjudged by the Federal Circuit to be directed to a “hypothesis” invention in fact “ties up a natural phenomenon,”⁶⁴ 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. For example, although Peter Lee described stem cells as “research tools,” Allen Yu argued that they resemble natural phenomena in that isolated stem cells “faithfully preserve the pluripotent properties of stem cells as found in nature.”⁶⁵ Even if the categorization were robust, it is clear that patents on inventions described in this Part are problematic for more or less the same reasons. Although this common problem suggests that all of these inventions should be subject to the same patentability requirement, Part IV will explain that the reality is far from that simple. Before we get there, however, the next Part will sketch out arguments in favor of and against upstream patents in more detail.

III. ARGUMENTS FOR AND AGAINST UPSTREAM PATENTS

A. *Arguments for limiting patents on upstream inventions*

As suggested in the previous Part, patents on inventions at an early developmental stage are thought to be problematic because they impose intolerable costs on downstream research.⁶⁶ A pervasive concern is that upstream patents will interfere with the creation of new knowledge—in the words of the Supreme Court, “inhibit future innovation.”⁶⁷ For example, the fear behind allowing a patent on chemical compounds without an identified end use in the hands of the general public is that a subsequent researcher

European proposals for limited patents on “scientific property,” which eventually failed).

⁶² *Mayo*, 132 S. Ct. at 1298; *see supra* notes 5-7 and accompanying text.

⁶³ Lee, *supra* note 40, at 81.

⁶⁴ ROBIN C. FELDMAN, *RETHINKING PATENT LAW* 100 (2012); *see also id.* at 122.

⁶⁵ *See Yu, supra* note 31, at 433.

⁶⁶ *See supra* notes 40-42 and accompanying text; *see also, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1046-66 (1989); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 217-26 (1987); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 116-20 (1999); Richard L. Wang, *Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties*, 10 YALE J.L. & TECH. 251, 258-61 (2007-2008); Yu, *supra* note 31, at 428 (discussing the “cost side of patenting”).

⁶⁷ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1301 (2012).

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.⁶⁸ The patentee might threaten litigation to enjoin the downstream research, charge an unreasonable royalty, or tie up the downstream researcher in extensive, costly negotiations over the patent right.⁶⁹ Faced with this prospect, the downstream 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.⁷⁰ Similar arguments have been made about other “research tool” patents,⁷¹ “hypothesis” patents,⁷² and patents on fundamental principles.⁷³ To prevent such unduly preemptive patents, commentators have exhorted courts to apply completeness doctrines more stringently or praised them for already doing so.⁷⁴

⁶⁸ See generally ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 253-56 (4th ed. 2007). See also Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 789-92 (2000).

⁶⁹ For a general articulation of this argument (beyond “upstream patents”), see Robert P. Merges & Richard R. Nelson, *On Limiting or Encouraging Rivalry in Technical Progress: The Effect of Patent Scope Decisions*, 25 J. ECON. BEHAVIOR & ORG. 1 (1994); Merges & Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, in 1 INNOVATION POLICY AND THE ECONOMY 122-29 (Adam B. Jaffe et al. 2001).

⁷⁰ DAN L. BURK & MARK A. LEMLEY, *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.”).

⁷¹ See *supra* note 66 and accompanying text.

⁷² See, e.g., Margaret Sampson, Comment, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1273 (2000).

⁷³ Alan Devlin, *Patent Law’s Parsimony Principle*, 25 BERKELEY TECH. L.J. 1693, 1718-20 (2010); 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.”).

⁷⁴ Utility: Cynthia D. Lopez-Beverage, *Should Congress Do Something About Upstream Clogging Caused by the Deficient Utility of Expressed Sequence Tag Patents*, 10 J. TECH. L. & POL’Y 35 (2005); Teresa M. Summers, Note, *The Scope of Utility in the Twenty-First Century: New Guidelines for Gene-Related Patents*, 91 GEO. L.J. 475 (2003). Written description: Joseph Jakas, *supra* note 47, at 1325 (“The written description requirement encourages inventors to finalize their inventions and pursue and end product before seeking patent protection. . . . [The] requirement seems to be a positive step towards limiting problems associated with patents in the biotechnology industry.”); Sampson, *supra* note 72. Abstract ideas: Yu, *supra* note 31, at 417-27; Note, *Diagnostic Method Patents and Harms to Follow-on Innovation*, 126 HARV. L. REV. 1370 (2013). See generally Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 194-201 (2004).

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.⁷⁵ They contend that, if the patent on an invention early 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.⁷⁶ 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.”⁷⁷ 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.⁷⁸ Courts worry that claims to such inventions would dominate and preempt entire fields of research,⁷⁹ cover unpredictable, transformative applications,⁸⁰ and, as a result, over-reward their owners.⁸¹

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

⁷⁵ 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_of.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)).

⁷⁶ See *infra* note 259 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.

⁷⁷ Heller & Eisenberg, *supra* note 66, at 699; see also Strandburg, *supra* note 35, 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.”).

⁷⁸ Cf. Tun-Jen Chiang & Lawrence B. Solum, *The Interpretation-Construction Distinction in Patent Law*, 123 YALE L.J. 530, 607-12 (2013).

⁷⁹ 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.”).

⁸⁰ 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].”).

⁸¹ *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)).

exclude others from a scarce resource, and no one has an effective privilege of use.”⁸² 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.”⁸³ Heller and Eisenberg explain that granting patents on upstream inventions results in “too many fragments of concurrent intellectual property rights in potential future products.”⁸⁴ They conclude that such patents might impose significant transaction costs on downstream innovation and product development in the biomedical field.⁸⁵

Recent scholarship has made clear that many kinds of patents, not just those on inventions that are typically considered “upstream,” may lead to anticommons and related problems. Products such as cell phones, which incorporate numerous technologies, present particularly acute challenges for downstream manufacturers having to deal with multiple overlapping patent rights.⁸⁶ This so-called “royalty stacking” can exacerbate the threat of holdup and “give[] excessive reward to patent holders, especially in component industries.”⁸⁷ Nevertheless, commentators continue to single out upstream patents for particular scorn, contending that such patents would “reward patentees excessively and would fail to keep their property rights commensurate with their real contribution to society.”⁸⁸

B. *Arguments for allowing patents on upstream inventions*

Proponents of patents on upstream inventions counter that patent protection for the results of early-stage research provides the incentives for creation of, and a mechanism for disclosing, important, widely applicable inventions. These inventions often embody helpful research tools,⁸⁹ provide roadmaps for follow-on research,⁹⁰ and generally add to the storehouse of human knowledge.⁹¹ Further, as many critics of limiting upstream patents have argued, such inventions often require just as much, if not more, investment as inventions that are further downstream—investment that

⁸² Michael A. Heller, *Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 624 (1998).

⁸³ Heller & Eisenberg, *supra* note 66, at 699.

⁸⁴ *Id.*

⁸⁵ *Id.* at 700-01.

⁸⁶ See, e.g., Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1992, 2025-27 (2007); see also *supra* note 69 and accompanying text.

⁸⁷ *Id.* at 2035.

⁸⁸ Wang, *supra* note 66, at 267.

⁸⁹ See *In re Fisher*, 421 F.3d 1365, 1379-82 (Rader, J., dissenting).

⁹⁰ See David E. Adelman, *The Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 1026 (2005); Anne Y. Brody, *Rochester v. Searle: Complying with the Written Description and Enablement Requirements in Early-Stage Drug Discovery*, 22 BIOTECHNOLOGY L. REP. 472, 474 (2003).

⁹¹ See Devlin, *supra* note 73, 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.”); Mueller, *supra* note 31, at 617 (arguing that the Federal Circuit’s written description doctrine will “chill development in [a] critically important technological field and frustrate the . . . patent system’s policy goal of encouraging prompt disclosure of new inventions.”).

patent law would do well to encourage.⁹² These critics maintain that upstream inventions are highly susceptible to free-riding because of their broad applicability, and believe that there must be room in patent law to incentivize basic research that these inventions embody.⁹³ As put bluntly by Janice Mueller, 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.”⁹⁴

Another justification for patents on upstream inventions derives from prospect theory, which posits that broad patents on upstream inventions are socially beneficial because they promote commercialization.⁹⁵ Such patents can facilitate “coordination [that] could create benefits such as superior development of the patented invention, avoidance of duplicative investments from competing researchers, the arrangement of productive license transactions, and the facilitation of information sharing among researchers.”⁹⁶ Prospect theory has been subject to a great deal of criticism, but it continues to play an important role in patent theory.⁹⁷

John Duffy, one of the critics of prospect theory, nonetheless supports early patenting. He argues that patent law’s encouragement of early patenting is socially beneficial because it leads to faster dedication of inventions to the public domain after patent expiration.⁹⁸ Patent races and early patenting thus reduce social costs from the patent monopoly.⁹⁹ A related justification for upstream patents is that they “speed[] up disclosure with consequent facilitation of research.”¹⁰⁰ 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

⁹² See *infra* Subpart III.C.

⁹³ See *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 983 (Fed. Cir. 2002) (Rader, J., dissenting from the order denying rehearing en banc); Philip McGarrigle & Vern Norviel, *Laws of Nature and the Business of Biotechnology*, 24 SANTA CLARA COMPUTER & HIGH TECH L.J. 275, 305 (2008) (recounting policy reasons for protecting early-stage inventions).

⁹⁴ Mueller, *supra* note 31, at 651; see also Plimier, *supra* note 49, at 161 (“The written description requirement only allows very narrow patents, so narrow and easily dodged as to be almost worthless.”); cf. Rai, *supra* note 66, at 141 (“[F]or some research tools—laboratory machines, analytical and purification methods, certain types of genetically engineered mice—the costs of invention may be fairly high. Equally important, because these research tools will, in many circumstances, be licensed not for further improvement but for the comparatively straightforward purpose of direct use, the transaction and creativity costs associated with licensing will be relatively low. Where transaction and creativity costs are low relative to invention costs, patent protection is probably desirable.”).

⁹⁵ Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977). Kitch also argued that early-stage prospect rights help minimize inefficient patent “races,” though recent commentary suggests that the patent law’s tendency to encourage patent races by rewarding the first inventor is desirable because it speeds up the pace of innovation. See Lemley, *supra* note 51.

⁹⁶ Wang, *supra* note 66, at 267 (citing Kitch, *supra* note 95, at 276, 278-79). See generally Kieff, *supra* note 36.

⁹⁷ See Duffy, *supra* note 18, at 441-42.

⁹⁸ *Id.* at 444.

⁹⁹ *Id.* (“[T]he race to claim patent rights becomes a race to diminish the patentee’s rents by dedicating the invention to the public sooner.”).

¹⁰⁰ *In re Kirk*, 376 F.2d 936, 957 (C.C.P.A. 1967) (Rich, J., dissenting).

be vital to progress”¹⁰¹ and aid in “achieving and publicizing basic research.”¹⁰²

Scholars have also challenged anticommons arguments against upstream patents. For example, David Adelman argues that “biological complexity that makes discovery so challenging also mitigates the potential for patents to create broad monopoly power,” making “biomedical sciences relatively open-ended and less susceptible to patent anticommons.”¹⁰³ Adelman contends that “the open frontier of biomedical science” provides follow-on researchers for plentiful opportunities to design around patented research tools.¹⁰⁴ Although Adelman notes that patents on certain “common-method research tools” that can be difficult to avoid, he concludes that market mechanisms will generally solve problems of access.¹⁰⁵ Finally, Mark Lemley and Dan Burk note that anticommons problems can be solved via vertical integration of patent rights within a single firm.¹⁰⁶

C. *What sort of intellectual property protection, if any, makes sense for upstream inventions?*

¹⁰¹ *Brenner v. Manson*, 383 U.S. 519, 539 (1966) (Harlan, J., dissenting)

¹⁰² *Id.* Several scholars have argued that patents fail at their teaching function. *See, e.g.,* Holbrook, *supra* note 31, 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* Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1 (2012); *see also* Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 531 (2012).

¹⁰³ *Id.* at 1018.

¹⁰⁴ *Id.* at 1020-23. *But see* BURK & LEMLEY, *THE PATENT CRISIS*, *supra* note 70, at 152 (challenging Adelman’s thesis). Also, the need to reproduce experiments under the same conditions somewhat limits a follow-on user’s ability to switch from one research tool to another. *See* Strandburg, *supra* note 35, at 103 (“Published results are reproduced by those seeking to build on them not only, or necessarily even primarily, to verify them—but also to understand them—to see in detail how they were obtained and to explore their limitations and features not presented in the published description. . . . [T]he attempt to build on what has been established will almost unavoidably touch upon the previous results.”).

¹⁰⁵ Adelman, *supra* note 90, at 1023-24. Some empirical evidence supports the conclusion that research tool patents have not inhibited progress, at least at the level of academic research. *See* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in *PATENTS IN THE KNOWLEDGE-BASED ECONOMY* 285, 285 (Wesley M. Cohen & Stephen A. Merrill eds. 2003) (finding “little evidence that university research has been impeded by concerns about patents on research tools”). This may be due in part to underdetection of infringement and to litigation costs of enforcing such patents. *See* Alan Devlin, *supra* note 73, at 1735 (“The cost of litigation coupled with the immense difficulty of detecting unauthorized experimentation results in considerable underenforcement.”); *see also infra* note 134 and accompanying text.

¹⁰⁶ BURK & LEMLEY, *THE PATENT CRISIS*, *supra* note 70, at 86-88. Burk and Lemley go on to note however, that vertical integration does not necessarily make the anticommons problem go away completely. *Id.* at 88-89. *But cf.* Walter W. Powell, *Neither Market Nor Hierarchy: Network Forms of Organization*, 12 RES. IN ORG. BEHAVIOR 295 (1990) (explaining that the vertical integration model is being replaced by the network model).

I think that the concerns of the two sides in the upstream patent debate are in principle reconcilable. Even some critics of upstream patents concede that the incentive of a patent can promote the creation of socially beneficial basic discoveries and research tools.¹⁰⁷ But they argue that the costs outweigh the benefits—a patent claim on a broadly applicable upstream invention is just too powerful to belong to one owner.¹⁰⁸ More generally, if the argument against upstream patenting is that the amount of preemption obtained by the patent owner is undue, the right response seems to be to recalibrate the owner's rights so that he or she receives the *due* amount of preemption—perhaps, something less than a full patent.¹⁰⁹ Patent law permits 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 value from a path-breaking contribution.¹¹⁰ My proposed approach, which I describe in Part VII, is to allow the broader claims but circumscribe the remedies that the patentee can obtain. That approach recognizes the potential of claims to upstream inventions to be unduly preemptive, but also provides real incentives for creating such inventions.

Although trade secrecy in principle offers an alternative to patent protection,¹¹¹ there are reasons to believe that it would not be effective for upstream inventions. First, the trade secret may be eviscerated if the researcher needs to publish the subject matter of the upstream invention for reasons such pressures of tenure, grants, or prestige.¹¹² Second, at least some upstream inventions, such as chemical intermediates, are easily reverse-engineered once placed into the stream of commerce, eliminating both patent and trade secret protection.¹¹³ Third, although recent statutory changes have called this doctrine into doubt,¹¹⁴ it has long been the law that a commercial exploitation of a secret invention creates patent-defeating prior art against

¹⁰⁷ See, e.g., Strandburg, *supra* note 35.

¹⁰⁸ *Id.* at 121-30.

¹⁰⁹ The proposal given herein provides for scheduled damages and, in that sense, does not necessarily give the patentee the exact amount of compensation that is due. Nevertheless, I think it is clear that an owner of an upstream patent is due *something less than* a full patent right, and the proposal addresses this concern. See *infra* notes 354-359 and accompanying text.

¹¹⁰ See *supra* notes 1-8 and accompanying text. Cf. Benjamin N. Roin, *Solving the Problem of New Uses*, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2337821 (describing a particular type of patentable but effectively valueless claims); see also *supra* note 49 and accompanying text.

¹¹¹ See generally Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 397 (2002).

¹¹² But see Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, *supra* note 66, at 198 (explaining that key data may be withheld and protected as a trade secret even as a research paper is published).

¹¹³ See Limin Zheng, *Purdue Pharma L.P. v. Faulding Inc.*, 17 BERKELEY TECH. L.J. 95, 112-13 (2002); see also PHILIPPE G. DUCOR, *PATENTING THE RECOMBINANT PRODUCTS OF BIOTECHNOLOGY* 139-40 (1998).

¹¹⁴ See Mark A. Lemley, *Does "Public Use" Mean the Same Thing It Did Last Year?*, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2394153.

the inventor with the same effect as if the invention was published.¹¹⁵ This feature of the law often renders the choice to pursue trade secret rather than patent protection essentially irreversible.¹¹⁶ All this may discourage investments from venture capitalists, who generally prefer that their portfolio companies use patents rather than trade secrets to protect their inventions anyway.¹¹⁷ Finally, an invention kept as a trade secret by definition remains undisclosed, unless discovered and disclosed by someone else.

The absence of patent protection for upstream inventions may also generate significant challenges for researchers engaged in the development and commercialization of such inventions.¹¹⁸ The longer these researchers have to wait to patent an invention, the more they risk that the prior art will render claims to the downstream versions of their inventions invalid as anticipated or obvious¹¹⁹—often leaving them without adequate intellectual property protection.¹²⁰ This problem is particularly acute for inventors working for universities, who have to publish and present papers in order to advance in their careers.¹²¹ If these researchers cannot receive patents in parallel with publishing the subject matter in scientific journals, they risk being unable to obtain any useful downstream patents related to their inventions.¹²² This concern applies equally to “research plan” inventions—it may be obvious to come up with the drug once one knows the target and

¹¹⁵ See generally Dmitry Karshedt, *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 VILL. L. REV. 261 (2012).

¹¹⁶ Nevertheless, if the applicant receives an “Office Action” from the PTO rejecting the claims within 18 months of application, he or she can withdraw the application before it publishes.

¹¹⁷ Beckerman-Rodau, *supra* note 111, at 397 (“If a new basic technology is involved patent protection may be highly desirable.”); see also Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137, 143 (2000); Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 653 (2002) (“Among venture capitalists, both the quantity and quality of patents have long been factors that are taken into consideration when deciding whether to invest in a company, particularly in its early stages.”). But see Robin Feldman, *Patent Demands & Startup Companies: The View from the Venture Capital Community*, U.C. Hastings Research Paper No. 75, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2346338; Andrew A. Schwartz, *The Corporate Preference for Trade Secret*, 74 OHIO ST. L.J. 632 (2013).

¹¹⁸ See BURK & LEMLEY, *THE PATENT CRISIS*, *supra* note 70, at 265 (“[T]he effect of the [Federal Circuit’s] early decisions was to strengthen patents in the early biotechnology industry by making them easier to acquire and uphold. Doing so may have encouraged development of the industry in its infancy.”).

¹¹⁹ See Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 70 (2009); see also 35 U.S.C. §§ 102, 103 (2012).

¹²⁰ Beckerman-Rodau, *supra* note 111, at 401-02.

¹²¹ See Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, *supra* note 66, at 197-98 (“Delaying publication may handicap the competition, but the dilatory scientist thereby runs the risk that someone else will publish first and get all the credit.”). See generally Peter Lee, *Patents and the University*, 63 DUKE L.J. 1 (2013).

¹²² Cf. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, *supra* note 66, at 197-98 (explaining that the desire to obtain a patent may cause a delay of journal publications).

what properties to look for,¹²³ and “research tool” inventions—it may be obvious to make the downstream product once a key intermediate or an efficient process for making it has been discovered.¹²⁴ And it may also apply to “law of nature” inventions because courts have held that “routine” or “conventional” applications of such inventions may be unpatentable.¹²⁵

The result that university researchers may thus be barred from patenting their inventions is problematic. For example, it 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.¹²⁶ 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.¹²⁷ The Bayh-Dole regime has not, of course, escaped criticism,¹²⁸ but it is thought to make some sense for commercialization of upstream inventions in the biotechnology industry¹²⁹—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

¹²³ See Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 531-45 (2009).

¹²⁴ See, e.g., *In re Kubin*, 561 F.3d 151 (Fed. Cir. 2009).

¹²⁵ See, e.g., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

¹²⁶ 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 are themselves expressions of public policy. 358 F.3d 916, 929 (Fed. Cir. 2004). See *infra* notes 163-164 & 204 and accompanying text. See generally Holman, *supra* note 34.

¹²⁷ 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.”).

¹²⁸ See DAVID C. MOWERY ET AL., *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT* (2004).

¹²⁹ See Mark A. Lemley, *Are Universities Patent Trolls?*, 17 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611, 622-23 (2008) (“[V]alidity of commercialization theory depends a great deal on the industry in question and the particular technology. In the pharmaceutical and biotechnology industries, where coming up with an invention is only the first step down a very long road of regulatory process that can take hundreds of millions of dollars and several years, the commercialization argument makes some sense. . . . *We give the right to the university, but we do so expecting that they will transfer or exclusively license that right to a private company that will recoup the hundreds of millions of dollars they spend in clinical trials, product development, and marketing.* . . . In these industries, Bayh-Dole is probably a good thing.” (citations omitted) (emphasis added)).

transactions and otherwise disclose their inventions.¹³⁰ Indeed, besides the various doctrinal and career-related pressures, practical realities—such as demands of venture capital investors—also encourage early patenting.¹³¹

Perhaps, as critics of upstream patents contend, some inventions get patented at such an early stage that they inefficiently preempt transformative downstream applications. Disallowing patents on upstream inventions may thus “unclog” the path for downstream researchers. Nevertheless, given that certain upstream inventions are by hypothesis broadly applicable and have the potential to stimulate further research, it may be best for society to encourage inventors to disclose such inventions as soon as possible. Assuming the patent document or related disclosures are sufficiently informative,¹³² the improvers can use these discoveries as starting points for the discovery of downstream uses.¹³³ Even if additional development is required, an invention that enables or provides a roadmap for future research, or adds to the scientist’s toolkit, is can in principle be highly valuable to society.¹³⁴ The flipside, of course, is the ever-present threat of a

¹³⁰ See Rantanen, *supra* note 102, at 29 (“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.”).

¹³¹ See Beckerman-Rodau, *supra* note 111, at 402-06; Jorge Niosi & Susan E. Reid, *Biotechnology and Nanotechnology: Science-based Enabling Technologies as Windows of Opportunity for LDCs?*, 35 WORLD DEVELOPMENT 426, 435-36 (2007); see also *Edwards Lifesciences AG v. Corevalve, Inc.*, 699 F.3d 1305, 1309 (Fed. Cir. 2012) (“Continuing development is often contemplated and necessary, while early filing is often essential.”). But see generally Feldman, *supra* note 117.

¹³² See *supra* note 102 and accompanying text. Although there is a lot of room for debate over whether patents successfully fulfill their disclosure function, it appears beyond dispute that complete nondisclosure of inventions that can provide a foundation for substantial future research may result in significant social welfare costs.

¹³³ See Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, *supra* note 66, at 206 (“[B]y granting a property right that survives disclosure, patent law removes an obstacle to disclosure of inventions that would otherwise have to be kept secret in order to preserve their commercial value.”); see also Sven Bostyn & Nicolas Petit, *Patent = Monopoly: A Legal Fiction*, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2373471, at *13 (“Economic books are replete with stories documenting that the grant of a patent paves the way to the introduction of substitute technologies.”). Cf. Seymore, *supra* note 15, at 1078-79 (explaining how the utility requirement fosters secrecy and delayed disclosure); see also *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 149-51 (1989); *supra* notes 96-99 and accompanying text.

¹³⁴ See, e.g., *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371, 1377 (Fed. Cir. 2004) (“There can . . . arise situations wherein identification of the problem is itself the invention.”); see also Devlin, *supra* note 73, at 1718 (“[N]o one can credibly challenge the utility of such [fundamental] discoveries.”). Of course, this assumes development with the aid of the invention rather than independent development—and there is evidence that most accused patent infringers are in fact independent developers. See Christopher A. Cotropia & Mark A. Lemley, *Copying in Patent Law*, 87 N.C. L. REV. 1421 (2009). But this may be offset by the fact that a great deal of patent infringement is underdetected and underenforced. See *supra* note 105 and accompanying text; see also THOMAS F. COTTER, *COMPARATIVE PATENT REMEDIES: A LEGAL AND ECONOMIC ANALYSIS* 145-46 (2013) (discussing underdeterrence in patent law); *Comments of Colleen V. Chien and Michael J. Guo*

devastating patent infringement lawsuit that is thought to discourage the improvers.¹³⁵

If, based on the foregoing, some form of patent protection is needed for upstream inventions, designing the appropriate legal regime presents two serious challenges. The first, which I have begun to address in the previous Part, is identifying such inventions. The second challenge is providing an appropriate remedy their enforcement. Those issues are addressed in Part VII. The three Parts that follow describe and critique extant judicial and scholarly approaches to patenting and enforcement of upstream inventions.

IV. CONTOURS OF PATENT LAW'S COMPLETENESS REQUIREMENT

Patent law's completeness requirement is reflected in three distinct doctrines. That, in itself, is a part of the problem.¹³⁶ Although policy reasons behind the requirement are sound, its implementation is not entirely so. The fact that cases draw upon three distinct statutory sources to invalidate upstream patents gives an ad hoc and disorganized character to the completeness requirement. This Part analyzes the three completeness doctrines, which roughly track the distinction between research tool, hypothesis, and law of nature inventions.¹³⁷

A. Completeness doctrines

1. Utility

As discussed in the Introduction, one way that the law polices completeness is via the utility requirement.¹³⁸ The modern utility doctrine took shape in the case of *Brenner v. Manson*.¹³⁹ At issue was a patent application directed to a process of making chemical compounds falling within a larger class of molecules called steroids.¹⁴⁰ Expecting the Supreme Court's hostility to an older doctrine that chemical compounds had "inherent" utility,¹⁴¹ the patent applicant asserted that the chemicals made by

on a Patent Small Claims Proceeding in the United States, http://www.uspto.gov/ip/global/patents/comments/small_claims_court_proposal_for_submission.pdf, Docket No. PTO-P-2012-0050 (discussing underenforcement).

¹³⁵ See J. Jonas Anderson, *Secret Inventions*, 26 BERKELEY TECH. L.J. 917, 952 (2011) (patent litigation "costs upwards of \$15 billion per year to patentees and accused infringers").

¹³⁶ Cf. 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").

¹³⁷ See *supra* Part II.

¹³⁸ 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 & 10 and accompanying text.

¹³⁹ 383 U.S. 519 (1966).

¹⁴⁰ *Id.* at 520-22.

¹⁴¹ 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

the claimed process were of interest as drug candidates because they were structurally similar to other compounds that were used to fight cancer.¹⁴² The Supreme 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.”¹⁴³

The Court justified its holding in terms of undue preemption: Because the claimed process was not “refined and developed to . . . where specific benefit exists in currently available form”—because the inventor has not done enough—“there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”¹⁴⁴ The applicant could not patent an invention that might itself serve as a genesis for another research project because that could “block off whole areas of scientific development, without compensating benefit to the public.”¹⁴⁵ 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 good enough for the Court.¹⁴⁶ 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.”¹⁴⁷

Although it has been argued that the utility requirement became “minimal” under the Federal Circuit’s interpretation of *Brenner*,¹⁴⁸ recent 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.¹⁴⁹ The court held that ESTs lacked utility because they are “no more than research intermediates”¹⁵⁰ lacking “an immediate, well-defined, real world benefit to the public meriting the grant of a patent.”¹⁵¹ As in *Brenner*, research utility

frivolous.”). *But see* *Petrocarbon Ltd. v. Watson*, 247 F.2d 800, 801 (D.C. Cir. 1957).

¹⁴² *Id.* at 530-31.

¹⁴³ *Id.* at 532 (emphasis added).

¹⁴⁴ *Brenner*, 383 U.S. at 534-35.

¹⁴⁵ *Id.* at 534.

¹⁴⁶ *Id.* at 529, 535.

¹⁴⁷ Brent N. Rushforth, *The Patentability of Chemical Intermediates*, 56 CALIF. L. REV. 497, 513 (1968); *see also* Lawrence R. Velvel, *A Critique of Brenner v. Manson*, 49 J. PAT. OFF. SOC’Y 5, 9-10 (1967).

¹⁴⁸ Lopez-Beverage, *supra* note 74, at 64 (“[I]t has been the [Federal Circuit’s] position that minimal utility is all that is required to obtain a patent.”); *see In re Brana*, 51 F.3d 1560, 1562 n.3, 1566-67 (Fed. Cir. 1995) (holding that experiments establishing a biological effect of the claimed chemicals on an animal model can be sufficient to establish utility); *Cross v. Iizuka*, 753 F.2d 1040, 1050-51 (Fed. Cir. 1985) (holding that testing *in vitro*, i.e., in a test tube, can establish utility).

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

¹⁵⁰ *Id.* at 1373.

¹⁵¹ *Id.* at 1376.

did not render the inventions complete enough to be patentable.¹⁵² Thus, courts continue to rely on utility as a “policy lever”¹⁵³ to prohibit “premature [patent] filing[s]”¹⁵⁴ 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.¹⁵⁵ Modern developments in the law of written description have fashioned this requirement into the 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 the structures.¹⁵⁶

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.¹⁵⁷ The patentee disclosed experiments for finding non-steroidal chemical compounds that would perform the claimed inhibiting function, but did not actually provide any examples of compounds that could do the job.¹⁵⁸ 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.¹⁵⁹ For the invention to be complete, the court required a chemical structure, not merely a “search method.”¹⁶⁰ One could argue that identifying a drug target and providing a roadmap for finding drugs that treat a condition by acting on the target counts as an invention of a method of treatment.¹⁶¹ But the court did not see the facts this way. After citing *Brenner*—a utility case—the court

¹⁵² 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))).

¹⁵³ See generally Burk & Lemley, *supra* note 17.

¹⁵⁴ 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).

¹⁵⁵ 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.”

¹⁵⁶ In some cases, broad patent claims containing functional language can fail the written description requirement even when some examples of chemical structures are disclosed. See, e.g., *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1364-67 (Fed. Cir. 2011).

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

¹⁵⁸ *Id.* at 918, 927.

¹⁵⁹ *Id.* at 927, 929.

¹⁶⁰ *Id.* at 930 n.10.

¹⁶¹ 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 291 and accompanying text.

went on to make the odd suggestion that the patentees did not invent the claimed methods at all.¹⁶²

In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, the Federal Circuit sitting en banc further explained why “research hypotheses do not qualify for patent protection.”¹⁶³ It asserted that the written description requirement gives “incentive to *actual invention* and not attempts to preempt the future before it has arrived.”¹⁶⁴ Again, the implication of this statement is that a claim the court labels as a “hypothesis” is not “an actual invention.” But this label is inaccurate—there is an important, fundamental invention disclosed in the patent, but it may not be sufficiently developed to warrant a claim that captures the invention’s valuable downstream applications.¹⁶⁵ The familiar policy concern behind this result is that “claims to research plans . . . impose costs on downstream research, discouraging later invention.”¹⁶⁶

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 do more work and 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” under utility and lack of 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, section 101 of the Patent Act has been read to impose “an important implicit exception”¹⁶⁷ that places certain claims outside the category of patentable subject matter. This exception bars patents to natural phenomena, laws of nature, and abstract ideas.¹⁶⁸ 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.”¹⁶⁹ 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.”¹⁷⁰ 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

¹⁶² *Rochester*, 358 F.3d at 930 n.10 (quoting *Brenner v. Manson*, 383 U.S. 519, 536 (1966)).

¹⁶³ 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc).

¹⁶⁴ *Id.* (alterations and internal quotation marks omitted) (emphasis added).

¹⁶⁵ See *supra* notes 2-4 and accompanying text.

¹⁶⁶ *Ariad*, 598 F.3d at 1353.

¹⁶⁷ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012).

¹⁶⁸ *Id.*

¹⁶⁹ 409 U.S. 63, 67 (1972). The term “phenomena of nature” may refer to laws of nature and products of nature. Cf. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013).

¹⁷⁰ *Benson*, 63 U.S. at 71.

and in practical effect would be a patent on the algorithm itself.”¹⁷¹ Thus, as with utility and written description, the failure to limit the patent to some type of a downstream use of the basic discovery was the reason for holding the claim unpatentable. Again, preemption of downstream uses is an important policy driver behind this result.¹⁷²

A recent patentable subject matter case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,¹⁷³ further demonstrates how the doctrine functions to bar patents on inventions that courts consider incomplete. In *Mayo*, the Supreme Court 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 Introduction¹⁷⁴—and effectiveness of a drug used to treat gastrointestinal disorders.¹⁷⁵ 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.’”¹⁷⁶ In other words, the patent failed because the inventors did not, according to the Court, sufficiently develop a downstream use of the fundamental discovery, as reflected by the patent’s broad claims. 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.¹⁷⁷

The *Mayo* Court thus believed that the patentee impermissibly received a reward out of proportion its owner’s contribution. Of course, any patent claim by definition “preempts” the embodiments that fall within its scope. In the completeness cases, however, courts appear to believe that the amount of preemption the patentee is getting is undue.¹⁷⁸

¹⁷¹ *Id.* at 71-72.

¹⁷² *But see* Strandburg, *supra* note 31, 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); *see also infra* note 229 and accompanying text.

¹⁷³ 132 S. Ct. 1289 (2012).

¹⁷⁴ *See supra* notes 5-8 and accompanying text.

¹⁷⁵ *Id.* at 1295.

¹⁷⁶ *Id.* at 1294.

¹⁷⁷ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1301-02 (2012); *see supra* notes 79-81 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.”).

¹⁷⁸ The term “undue preemption” in the context of patentable subject matter appears to have been first used by Richard Stern. 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’

In another recent pronouncement on patentable subject matter, *Association for Molecular Pathology v. Myriad Genetics, Inc.*,¹⁷⁹ the Supreme Court explained how incompleteness analysis functions in a “product of nature” case. Some of the patentee’s claims to isolated genetic materials failed because they were effectively drawn to the upstream discovery of “the precise location and genetic sequence of [particular] genes”¹⁸⁰ rather than “*new applications* of knowledge about”¹⁸¹ these genes. In other words, these claims were rejected for failure to develop and claim a downstream use of a product of nature.¹⁸² 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.”¹⁸³

B. A single, integrated requirement

The similarities across utility, written description, and Section 101 exclusion doctrines are striking. Surely, the inventors in all of these cases have discovered something that was previously unknown—a new chemical compound (made unpatentable by the utility doctrine), a method of treatment involving drug action on a previously unrecognized biological target (made unpatentable by the written description requirement), or a natural product or novel correlation (made unpatentable by section 101 exclusions). We have already seen strong arguments for intellectual property protection for such inventions, though perhaps not with the full extent of possible remedies that the Patent Act now provides.¹⁸⁴ Nevertheless, the courts in all of these cases held that inventors must do something more beyond these contributions (find an end use for the compound, disclose a chemical that would act on the biological target, invent a non-trivial downstream application of the correlation or natural product) in order to obtain a patent.¹⁸⁵ This is the completeness requirement at work.

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 . . .”). Of course, the idea of undue preemption is much older. *See, e.g., O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-13 (1853).

¹⁷⁹ 133 S. Ct. 2107 (2013).

¹⁸⁰ *Id.* at 2116.

¹⁸¹ *Id.* at 2120 (emphasis in original).

¹⁸² Colloquy from the oral argument further illustrates the similarities between this case and other completeness cases. *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.”).

¹⁸³ *Myriad*, 133 S. Ct. at 2116.

¹⁸⁴ *See supra* Subpart III.B.

¹⁸⁵ The doctrines, however, function in different ways in practice. To satisfy the utility requirement, the downstream use merely needs to be disclosed in the patent application. But to satisfy the written description and patentable subject matter requirements, the downstream use needs to be both disclosed *and claimed*.

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.”¹⁸⁶ 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 specification¹⁸⁷ to describe a mere “wish” or “plan,” for that would be “an attempt to preempt the future before it has arrived.”¹⁸⁸ And in *Mayo* (a patentable subject matter case), the Supreme Court invalidated claims that “tie[d] up too much future use of laws of nature”¹⁸⁹ by allowing its owner to appropriate “basic tools of scientific and technological work.”¹⁹⁰

The completeness requirement has real force, and it was behind many significant patent cases of recent years. Courts do not like patents on upstream inventions, and they have used three distinct statutory sources to invalidate claims that are drawn to them.¹⁹¹ While there is no statutory completeness requirement, courts act as if it existed, putting a great deal of pressure on existing doctrines.¹⁹² I believe the lack of explicit recognition of the completeness requirement is problematic. To function effectively, the requirement must be acknowledged as such and unified within a single statutory source, openly reflecting the fact that the problem with certain patents is incompleteness. The next Part discusses the problems that the court’s implementation of the completeness requirement has created.

V. PROBLEMS WITH THE COMPLETENESS REQUIREMENT

A. Inconsistent coverage

1. Utility and written description

Completeness cases have created a doctrinal mess. As an example, consider utility cases like *Brenner*, which purport to apply the requirement of section 101 that inventions be “useful.”¹⁹³ The invention at issue in *Brenner* was a method for making chemical compounds.¹⁹⁴ To say that such

¹⁸⁶ *Brenner v. Manson*, 383 U.S. 519, 536 (1966).

¹⁸⁷ “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.

¹⁸⁸ 894 F.2d 1164, 1171 (Fed. Cir. 1993).

¹⁸⁹ 132 S. Ct. 1289, 1301 (2012).

¹⁹⁰ *Id.* at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

¹⁹¹ *Cf.* Kresh, *supra* note 15, at 540.

¹⁹² *Cf.* Oren Bar-Gill & Gideon Parchomovsky, *A Marketplace for Ideas?*, 84 TEX. L. REV. 395, 412 (2005) (arguing that “[t]he binary choice between patent and no protection has led Congress, courts, and patent examiners to grant patent protection too leniently”); Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 UC IRVINE L. REV. 265, 277 (2011). *See generally* Richard S. Gruner, *Intangible Inventions: Patentable Subject Matter for an Information Age*, 35 LOY. L.A. L. REV. 355 (2002). In this, the unmodified completeness requirement resembles the judicially recognized nonobviousness requirement before its codification in 1952 under 35 U.S.C. § 103. *See, e.g.*, *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850). I thank Rochelle Dreyfuss for calling this parallel to my attention.

¹⁹³ 35 U.S.C. § 101 (2012).

¹⁹⁴ *Brenner v. Manson*, 383 U.S. 517, 521 (1966).

an invention is not “useful” in the ordinary sense of that word defies common sense, as numerous commentators have observed.¹⁹⁵ Also worth noting is that, before and since *Brenner*, the PTO has been granting patents on silly, ridiculous, and plain useless inventions without issuing section 101 utility rejections.¹⁹⁶ In contrast, courts and the PTO have applied the utility requirement quite rigorously in the serious and generally useful fields of chemistry of biotechnology.¹⁹⁷ Sean Seymore has argued that the utility requirement is highly subjective, contending that courts’ application of the requirement “led to a bias against granting patentability for certain types of inventions.”¹⁹⁸

The application of the written description requirement to bar “functional” claims has also been criticized by numerous commentators as anomalous.¹⁹⁹ Echoing the complaints about the utility requirement, the written description line of cases exemplified by *Rochester* has been thought to impose heightened disclosure requirements on biotechnology inventions.²⁰⁰ Unlike the utility requirement, which has only been applied

¹⁹⁵ Timothy J. Balts, Note, *Substantial Utility, Technology Transfer, and Research Utility: It’s Time for a Change*, 52 SYRACUSE L. REV. 105, 108 (2002) (“[B]y excluding research discoveries from being ‘useful,’ the substantial utility requirement . . . discourages disclosure and research, and thus, does not promote the progress of the useful arts.”); Phanesh Koneru, *To Promote the Progress of Useful Art[icle]s?: An Analysis of the Current Utility Standards of Pharmaceutical Products and Biotechnological Research Tools*, 38 IDEA 625, 658 (1997) (“[T]he law [on utility] produces results that defies common experiences of those in the art.”); Eric P. Mirabel, “*Practical Utility*” Is a Useless Concept, 36 AM. U. L. REV. 811 (1986) (“In common parlance, a thing ‘having utility’ is, by definition, ‘useful.’ When dealing with chemical compounds, the judiciary has not equated these expressions.”).

¹⁹⁶ BURK & LEMLEY, THE PATENT CRISIS, *supra* note 70, at 111 (“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 31, 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 Duffy, *supra* note 18, at 453 (“[P]atent law has no aversion to awarding commercially worthless property rights.”); see also *id.* 453 n.53.

¹⁹⁷ See BURK & LEMLEY, THE PATENT CRISIS, *supra* note 70, at 111 (“The only exceptions to the effective elimination of the utility requirement in patent law are in the fields of biology and chemistry.”).

¹⁹⁸ Seymore, *supra* note 15, at 1050.

¹⁹⁹ See references on written description *supra* note 31; see also JANICE M. MUELLER, PATENT LAW 153 (4th ed. 2013) (calling the written description requirement as applied to biotechnology inventions as anomalous); Allen K. Yu, *The En Banc Federal Circuit’s Written Description Requirement: Time for the Supreme Court To Reverse Again?*, 33 CARDOZO L. REV. 895, 895, 898 (2012) (calling the written description requirement an “unsatisfactory patchwork of band-aid, ad hoc solutions” for striking down claims that courts deem unacceptable).

²⁰⁰ 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.*, 323 F.3d 956, 976 (Rader, J., dissenting from the order denying rehearing en banc); BURK & LEMLEY, THE PATENT CRISIS, *supra* note 70, at 118 (“[W]ritten description evolved as a highly technology-specific

against chemical and biochemical patents, the written description requirement has appeared in other areas of technology.²⁰¹ But, outside of the biotechnology area, patents are only rarely invalidated on the basis that the invention is a wish, plan, or hypothesis.²⁰²

Indeed, some commentators believe that the enforcement of utility and written description requirements in the biotechnology arena is so vigorous relative to other areas of technology that courts have effectively built in industry-specific “policy levers” to prohibit certain biotechnology patents that may have very broad applicability.²⁰³ Robin Feldman echoes their conclusion, noting that the written description requirement is not about possession in some abstract sense, but about policy. She explains that “[a] court . . . cannot determine what an inventor possessed at a given time without making assumptions about how far a particular invention can reach.”²⁰⁴ Although I do not reject wholesale the thesis that courts should be more proactive in developing “policy levers” based on the existing legal

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); Christopher M. Holman, *Is Lilly Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and Its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1, 4 (2007) (describing the written description requirement as “a ‘super-enablement’ requirement specifically targeting biotechnology and substantially restricting the patentability of biotechnology-related inventions”); Hodges, *supra* note 161, 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.”). For some defenses of the written description requirement, see Ajeet P. Pai, Note, *The Low Written Description Bar for Software Inventions*, 94 VA. L. REV. 457, 486-93 (2008) (defending the Federal Circuit’s technology-specific applications of the written description requirement based on the “unpredictable arts” doctrine); Michael Risch, *A Brief Defense of the Written Description Requirement*, 119 YALE L.J. ONLINE 127 (2010); *see also* references on written description *supra* note 74.

²⁰¹ *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).

²⁰² *See Comments of Michael Risch, supra* note 52. 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.

²⁰³ This thesis, advanced by Dan Burk and Mark Lemley, is provocative because nothing in the Patent Act suggest *sui generis* treatment of certain technologies. *See generally* Burk & Lemley, *supra* note 17. In contrast, Jeffrey Lefstin argues that the written description requirement is necessary as a means of defining what the invention is. Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1131, 1204-07 (2008). But Lefstin notes that the written description doctrine has moved away from this function, *id.* at 1207-10, and appears to suggest that patent law’s requirement of definiteness, *see* 35 U.S.C. § 112(b), may more naturally play this role, *id.* at 1220-22.

²⁰⁴ FELDMAN, *RETHINKING PATENT LAW, supra* note 64, at 196.

framework,²⁰⁵ I argue that it may be time, based on courts' questionable track record in implementing the completeness requirement, for Congress to adjust and redirect those levers.²⁰⁶ Thus, my proposal details a statutory policy lever—one that is not-industry specific, but rather general to incomplete inventions.²⁰⁷

To be sure, academic critiques of utility and written description doctrines are not unanimous.²⁰⁸ For example, John Duffy defends the distinctions made by the current utility regime.²⁰⁹ He contends that it makes sense to allow patents on research *tools* such as microscopes but reject patents on chemical and biochemical research *intermediates* such as ESTs and molecules having unknown end use.²¹⁰ 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.²¹¹ Thus, Duffy finds it problematic that—because of overlapping patent rights—a downstream researcher could practice his or her patented inventions created 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

²⁰⁵ See *supra* note 203 and accompanying text.

²⁰⁶ Burk and Lemley themselves recognize that “in some ways the Federal Circuit cases have it exactly backwards” in terms of how they use the policy levers. Dan L. Burk & Mark A. Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 692 (2004); see also R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341 (2004) (criticizing the Burk-Lemley thesis); Wagner, *Exactly Backwards: Exceptionalism and the Federal Circuit*, 54 CASE W. RES. L. REV. 749 (2004) (same). Although Burk and Lemley primarily advocate for change in patent law via courts, they also recognize that “Congress, too, can and should facilitate judicial use of policy levers by giving courts the flexibility to take industry specific differences into account.” BURK & LEMLEY, *THE PATENT CRISIS*, *supra* note 70, at 141. Cf. Rebecca S. Eisenberg, *Biotech Patents: Looking Backward While Moving Forward*, 24 NAT. BIOTECH. 317, 317 (2006) (“US courts are bound to apply the rules laid down by US Congress and are therefore severely restricted in their ability to fine-tune the law as new technologies arise.”); S. Jay Plager, *The Federal Circuit As an Institution: On Uncertainty and Policy Levers*, 43 LOY. L.A. L. REV. 749, 768 (2010) (“[M]ost cases that come to us are cabined by the elaborate statutory framework Congress provides . . . , including, of course, the entirety of Title 35 of the U.S. Code dealing with patents.”).

²⁰⁷ See *supra* notes 21-23 and accompanying text; *infra* Part VII. To be sure, unlike the utility and written description requirement, the patentable subject matter requirement does have a great deal of bite with regard to limiting software inventions. But a large number of software inventions that many consider to be unduly preemptive escape patentable subject matter scrutiny. See *supra* note 52 and accompanying text.

²⁰⁸ See *supra* notes 74 & 199 and accompanying text.

²⁰⁹ See John F. Duffy, *Embryonic Inventions and Embryonic Patents*, in PERSPECTIVES ON COMMERCIALIZING INNOVATION 234, 245-48 (F. Scott Kieff & Troy A. Paredes eds. 2011). Duffy does join in the criticism of the written description requirement. *Id.* at 256-57.

²¹⁰ *Id.* at 246-47.

²¹¹ *Id.*

invention.”²¹² As Duffy notes, “research facilitated by a microscope is not a step in refining a microscope.”²¹³

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.²¹⁴ 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.²¹⁵ 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.”²¹⁶ 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 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.²¹⁷ Given these policy considerations, it is difficult to explain why the completeness cases pick out ESTs over microscopes.²¹⁸ The distinction that matters is one between claims to basic, widely applicable inventions and narrower claims to directed to fruits of applied research. Patent claims on microscope inventions, just like on chemical inventions, can be complete or incomplete depending on the stage of the respective inventions’ development and the number and extent of their downstream applications.²¹⁹

2. Patentable subject matter

Section 101 patentable subject matter exclusions have not fared much better. As with the utility and written description doctrines,

²¹² *Id.*

²¹³ *Id.* Nevertheless, 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).

²¹⁴ *See* Kevin Emerson Collins, *The Reach of Literal Claim Scope into After-Arising Technology: On Thing Construction and the Meaning of Meaning*, 41 CONN. L. REV. 493, 497 (2008).

²¹⁵ *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”).

²¹⁶ *In re Thuau*, 135 F.2d 344, 347 (C.C.P.A. 1943).

²¹⁷ *See infra* note 231 and accompanying text.

²¹⁸ *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) (explaining criticisms of 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 74, at 47-48, 73-75.

²¹⁹ 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 209, at 246. But the result of *Brenner* is directly contrary to this observation because that case involved with a *process* patent for making molecules, and invalidated it. *Brenner v. Manson*, 383 U.S. 519, 520-22 (1966).

commentators have vigorously criticized section 101 opinions because they lack consistency and appear to overstep courts' institutional role.²²⁰ In an article on the abstract idea exclusion, Kevin Collins chastised the Supreme Court's *Bilski v. Kappos* opinion 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*.²²¹ 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."²²²

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.²²³ 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.²²⁴ Following *Mayo*, Max Oppenheimer argued that the Court saddled patent law with "the ambiguity and uncertainty which results from judicial intervention in a policy decision."²²⁵ Oppenheimer explained that the Court's invocation of the Constitution's mandate to "promote the progress of useful arts" to justify section 101 exclusions is unhelpful because "the Constitution charges Congress with promoting progress, not finding a hypothetical optimal point of promotion."²²⁶

²²⁰ For an early criticism presaging Supreme Court patentable subject matter cases to come, see Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591 (2008).

²²¹ Kevin Emerson Collins, *Bilski and the Ambiguity of "An Unpatentable Abstract Idea,"* 15 LEWIS & CLARK L. REV. 37, 39 (2011) (quoting *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010)).

²²² *Id.*; see also John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1100-11 (2011) (describing the "tangled state of existing judge-made doctrine").

²²³ Kresh, *supra* note 15, 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)).

²²⁴ Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J. ONLINE 341 (2013) (criticizing *Mayo* for lack of clarity); Samantak Ghosh, *Prometheus and the Natural Phenomenon Doctrine: Let's Not Lose Sight of the Forest for the Trees*, 94 J. PAT. & TRADEMARK OFF. SOC'Y 330, 322, 349-50 (2012) (calling the *Mayo* doctrine "unadministrable"); Kresh, *supra* note 15, at 539 ("[T]he Court chose to return to the inventive step and did so without clarifying how much must be added to a natural law to make a claim eligible."); Jacob S. Sherkow, *Mayo v. Prometheus and the Method of Invention*, 122 YALE L.J. ONLINE 351 (2013) (criticizing the *Mayo* Court's "well-understood, routine, conventional activity" approach). For an argument justifying the approach in *Mayo*, see Joshua D. Sarnoff, *Patent-Eligible Inventions After Bilski: History and Theory*, 63 HASTINGS L. J. 53 (2011).

²²⁵ Max Stul Oppenheimer, *Patents 101: Patentable Subject Matter and Separation of Powers*, 15 VAND. J. ENT. & TECH. L. 1, 46 (2012).

²²⁶ *Id.* at 44; 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 218, at 360 (arguing that the patentable subject matter requirement is coherent

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.²²⁷ One group of commentators proposed that courts forget trying to define "abstract" and focus exclusively on claim scope in order to prohibit preemptive claims to upstream inventions: "We don't exclude inventions from patentability because the invention is too abstract. We refuse to patent certain claims when those claims reach too broadly and thereby threaten downstream innovation."²²⁸ Other commentators contend that preemption concerns should be disentangled from the notion that certain subject matter should be excluded from patentability per se.²²⁹ These commentators argue that, before we begin asking if a patent claim is unduly preemptive, we should focus our attention on what it is the claim is trying to preempt. Under this approach, the first step is to determine whether the claim contains subject matter falling into an unpatentable category of "product of nature," "natural phenomenon," or "abstract idea," and the second is to determine if the claim's additional elements limit it in such a way that the claim as a whole is no longer directed to one of these taboo categories.²³⁰ The bottom line, however, is that there is little satisfaction with the decisional law on patentable subject matter.

and rooted in historical case law); Sarnoff, *supra* note 224 (similar); *see also* Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity To Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1295-96 (2011). For a judicial explication of this view, *see In re Bilski*, 545 F.3d 943, 966 (Fed. Cir. 2008) (en banc) (Dyk, J., concurring).

²²⁷ *See, e.g.*, Chao, *supra* note 31; Collins, *supra* note 221; Lemley at al., *Life After Bilski*, *supra* note 27; Strandburg, *supra* note 31; *see also* Menell, *supra* note 226 (proposing a "technological arts" approach to patentable subject matter derived from common law).

²²⁸ Lemley at al., *Life After Bilski*, *supra* note 27, at 1346. Unlike Oppenheimer, these scholars endorse the courts' use of the abstract idea exclusion as a policy lever. *See also* Devlin, *supra* note 73, at 1735 ("[T]he Court views abstract discoveries with consternation because of their broad field of use, unencumbered by limitations to specific applications, threatens to hinder all subsequent applications of those basic scientific discoveries."); Rochelle C. Dreyfuss & James P. Evans, *From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1351, 1353-57 (2011) (noting that the Court in *Bilski* refused to "comment[] on the patentability of any particular invention" and explaining that the case's focus was on preemption); *supra* notes 177-178 and accompanying text.

²²⁹ *See, e.g.*, Strandburg, *supra* note 31. Categorical subject matter exclusions of invention types whose creation might be incentivized by patents seem to be in tension with the utilitarian foundations of patent law. *But cf.* Sarnoff, *supra* note 224, at 106-124; *see also infra* Subpart VII.A.

²³⁰ The Supreme Court adopted this two-step approach, but the Court also explained that it was driven by preemption concerns. *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354, 2355-59 (2014); *cf.* Tun-Jen Chiang, *The Rules and Standards of Patentable Subject Matter*, 2010 WIS. L. REV. 1353, 1353, 1375 (arguing that the patentable subject matter doctrines involve *both* "rule like categorical exclusions form patentability," i.e., products of nature and "standard-like limits on patent scope," i.e., abstract ideas and natural laws); John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609, 639 (2009) ("[M]ost patentable subject matter decisions are accounted for by two legal doctrines: (i) the prohibition against natural principles and natural phenomena, and (ii) the doctrine forbidding patents on abstract ideas. Both of these operate much

3. Summary

Even agreeing, as I do, that the overarching policy justifications for limiting patents on upstream inventions are sound, the doctrinal implementation of the completeness requirement is unsatisfying. While some inventions cannot be the subject of a patent at all under completeness doctrines, others inventions that engender similar concerns are allowed. As suggested above, stem cells, certain scientific instruments, methods for amplifying nucleic acids, functionally claimed software inventions, and so on, are early in the development chain and are amenable, at the time of patent filing, to variety of transformative downstream applications.²³¹ Even the Wright Brothers' patent may have had completeness problems.²³² Courts are concerned about undue preemption by incomplete inventions, but allow plenty of patents on such inventions. The doctrine is inconsistent, and, in the case of patentable subject matter exclusions, problematically opaque.

B. All-or-nothing and disproportionate

As already suggested, the remedy of complete patent invalidation is a harsh one, and it strikes one as disproportionate. Even if additional development is required, an invention that blazes a path forward for future research or adds to a scientist's toolkit is often extremely valuable to society and would seem to require the incentive of some patent protection.²³³ Nevertheless, patent law cannot provide intermediate rights for inventions when regular patent protection might not be efficient. Faced with a "borderline-upstream" invention, courts or the PTO have only two choices. They can allow a full patent right, or entirely invalidate or reject the patent—no in-between solution is possible.²³⁴

Invalidation is a blunt tool, and the costs getting it wrong can be high. Deleterious effects of improvidently granted patents on upstream inventions having uncertain, potentially very broad scope on future innovation are likely to be significant.²³⁵ The same may be true of completely denying any patent protection to meritorious early-stage inventions. Thus, the uniformity cost of the patent system—the cost of having all-or-nothing patent rights—includes the cost of misapplying the completeness requirement.²³⁶ The all-or-nothing approach puts tremendous

more like standards than rules, and their very malleability has led to their longevity.”).

²³¹ See, e.g., Lee, *supra* note 40, at 106-08 (discussing concerns over the broad reach of stem cell patents); Lemley, *supra* note 17 (software patents); Lemley, *supra* note 44, at 618 (microscopy patents); Mueller, *supra* note 36, at 12-13 (PCR patents); see also *supra* notes 39-40 and accompanying text.

²³² See *supra* notes 50-51 and accompanying text.

²³³ See *supra* notes 133-134 and accompanying text.

²³⁴ Cf. Mark A. Lemley, *The Economic Irrationality of the Patent Misuse Doctrine*, 78 CALIF. L. REV. 1599 (1990) (discussing circumstances where the remedy of patent unenforceability is out of proportion to the economic harm caused by the patentee's actions); see also Bar-Gill & Parchomovsky, *supra* note 192, at 402.

²³⁵ This problem can be exacerbated by a broad reading of “pioneering” patent claims. See Brian J. Love, *Interring the Pioneer Invention Doctrine*, 90 N.C. L. REV. 379 (2012); Joshua D. Sarnoff, *The Historic and Modern Doctrines of Equivalents and Claiming the Future: Part II (1870-1952)*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 441 (2005).

²³⁶ See *supra* notes 22-23 and accompanying text.

pressure on the completeness doctrines. Unsurprisingly, this pressure leads to controversial decisions.

The fact that courts cannot currently provide tailored, “continuized” patent rights for inventions for which a regular patent protection might not be desirable is a problem.²³⁷ A solution is suggested by John Duffy: “embryonic inventions should be covered by embryonic property rights.”²³⁸ Duffy’s vision of an embryonic right is “doctrinal uncertainty” in the validity of the upstream patent,²³⁹ but uncertainty—especially at the enforcement stage—might discourage investments and contractual transfers.²⁴⁰ Another approach is to grant a right that is certain, but weaker than the presently available patent right in terms of the available remedies. I explore this approach in Part VII, but the Part that immediately follows discusses other scholarly proposals for improving the ways in which law handles patents on upstream inventions.

VI. OTHER PROPOSALS FOR HANDLING UPSTREAM INVENTIONS, AND THEIR DRAWBACKS

An extensive literature addresses patent rights in inventions that are unquestionably valid under the current law, yet troubling for reasons of incompleteness.²⁴¹ The scholars’ focus on undue preemption resonates with the policy reasons that courts have used to justify denials of patents to chemical intermediates, “research plan” inventions, and inventions thought to claim monopolies over natural laws and abstract ideas.²⁴² As discussed above, patented subject matter that commentators have found to be problematically preemptive includes (besides ESTs) stem cells, methods of manipulating genetic material, and other “bottleneck” inventions.²⁴³ While some commentators have proposed denying patents for certain upstream

²³⁷ See LEO KATZ, WHY IS THE LAW SO PERVERSE? 145-51 (2012) (contrasting all-or-nothing results in law with intermediate or “continuized” results). As discussed above, claims of narrower scope are often unhelpful because they do not provide any valuable coverage. See *supra* notes 49 & 110-111 and accompanying text.

²³⁸ Duffy, *supra* note 209, at 236; see also *id.* at 267. Bar-Gill and Parchomovsky appear to equate “embryonic inventions” with “naked ideas,” or at least argue that they two should be treated the same way. Bar-Gill & Parchomovsky, *supra* note 192, at 396-402, 429-30. I attempt, however, to distinguish “naked ideas” from “embryonic inventions” and argue that the two should be treated differently. See *infra* Subpart VII.A.

²³⁹ *Id.* at 235 (“[T]he law has enormous ambiguity, and enormous opportunity for judges to invalidate or to sustain patents on embryonic or prophetic inventions.”).

²⁴⁰ See *supra* notes 108-111 and accompanying text; see also 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.”).

²⁴¹ Some of the work I discuss in this Part predates *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005), the case that made ESTs unpatentable for lack of utility, and it includes generalized proposals for curtailing patents on ESTs and other research tools. See, e.g., Mireles, *supra* note 74; Strandburg, *supra* note 35.

²⁴² See references at *supra* notes 34-37 & 66 and accompanying text; see also Lee, *supra* note 40.

²⁴³ See *supra* notes 44-40 and accompanying text.

inventions generally,²⁴⁴ most have argued for less radical solutions. These solutions generally have one feature in common: they entail *ex post* defenses to patent infringement rather than *ex ante* substantive limitations on the patent right tied to specific patentability requirements.²⁴⁵ Still other proposals provide for *sui generis* treatment of specific subject matter.

A. Exemptions and other infringement defenses

One type of a solution preserves the validity of upstream patents but provides for a personal “experimental use” exemption to patent infringement.²⁴⁶ 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. Some have contended that the experimental use exemption should be available only to noncommercial entities, like universities,²⁴⁷ while others have argued that, based on the character of the use, they should be available to all.²⁴⁸

Katherine Strandburg’s work provides an interesting example of this approach. Strandburg identifies a distinction between “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.²⁴⁹ She 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.²⁵⁰ While this latter solution appears to provide for an *ex ante* limitation on the remedy associated with the patent right, Strandburg’s proposal does not seek to distinguish, *ex ante*, a “research tool” or “upstream” patent from another type of a patent. Indeed, Strandburg’s scheme “affects only infringement liability and not any patentability requirements.”²⁵¹ Her focus is on the type

²⁴⁴ See, e.g., Lee, *supra* note 40. See generally Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813 (2001).

²⁴⁵ For a recent article comparing *ex ante* and *ex post* approaches to limiting overbroad patents, see Stephen M. Maurer, *Ideas into Practice: How Well Does U.S. Patent Law Implement Modern Innovation Theory?*, 12 J. MARSHALL REV. INTELL. PROP. L. 644, 686-690 (2013).

²⁴⁶ The experimental use exemption is practically defunct. See *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (“[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.”). But see 35 U.S.C. § 271(e)(1) (2012) (providing a form of experimental use defense under narrow circumstances).

²⁴⁷ See Mueller, *supra* note 36, at 36-37 (explaining and criticizing this view); Strandburg, *supra* note 35, at 96-100 (same).

²⁴⁸ See, e.g., Strandburg, *supra* note 35, at 119-38.

²⁴⁹ *Id.* Strandburg argues that the former type of activity should be subject to the experimental use exemption, *id.* at 100-21, while the latter should be subject to compulsory licensing after an exclusivity period, *id.* at 121-42.

²⁵⁰ Strandburg, *supra* note 35, at 138-42.

²⁵¹ *Id.* at 145.

of *accused use*, not on the type of patented invention.²⁵² This approach would create a great deal of uncertainty in the value of the right.²⁵³

Another set of proposals entails reviving the so-called reverse doctrine of equivalents.²⁵⁴ That rarely-used doctrine protects “radical improvements” of the patented technology—occurring when “a product precisely described in a patent claim is in fact so far changed in principle that it performs in a substantially different way and is not therefore an appropriation.”²⁵⁵ This doctrine may not apply when the infringer actually uses a research tool, as it was intended, to arrive at a transformative invention. But it may apply in a following scenario: ignoring the utility requirement for a moment, suppose a patented chemical compound whose intended use was only as an intermediate turns out to be an effective cancer drug.²⁵⁶ One could argue that the chemical is now used in a “substantially different way” from that conceived in the original patent, which argues in favor of protecting the discoverer of the cancer-curing property from infringement under the reverse doctrine of equivalents.²⁵⁷

Still a third doctrine that can be deployed against upstream inventions is patent misuse. That doctrine renders patents unenforceable when the patent owner does something to improperly extend the scope of the patent right, such as using the patent to facilitate an antitrust violation.²⁵⁸ Robin Feldman argues that reach-through licensing arrangements, which give licensors who own upstream patents a “cut” of the revenues on downstream products made with the aid of their upstream inventions, should trigger the doctrine of misuse under some circumstances.²⁵⁹ Feldman’s

²⁵² See also Katherine J. Strandburg, *What If There Were a Business Method User Exemption to Patent Infringement?* 2008 MICH. ST. L. REV. 245, 248-50 (2008).

²⁵³ See *supra* notes 239-240 and accompanying text.

²⁵⁴ See Koneru, *supra* note 195, at 663-65; Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 991, 1011-13 (1997) (“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 69, at 860-68. 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 209-213, the application of the doctrine is not limited to those circumstances.

²⁵⁵ *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1123 (Fed. Cir. 1985) (en banc) (internal quotation marks and emphasis omitted).

²⁵⁶ Before the Federal Circuit held that ESTs are unpatentable for lack of utility, one author proposed that the reverse doctrine of equivalents should protect accused infringers using ESTs in recombinant protein production. Michael S. Greenfield, Note, *Recombinant DNA Technology: A Science Struggling with the Patent Law*, 44 STAN. L. REV. 1051, 1090-91 (1992).

²⁵⁷ Cf. Peter Lee, *The Accession Insight and Patent Infringement Remedies*, 110 MICH. L. REV. 175 (2011) (analyzing this concept through the lens of the property law principle of accession and discussing its impact on patent remedies).

²⁵⁸ See generally Lemley, *supra* note 234.

²⁵⁹ 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

proposal reflects the concern that the value of some upstream patents is highly uncertain.²⁶⁰ The misuse doctrine would thus help prevent the patentee from receiving a windfall if the downstream products turn out to be particularly successful for reasons having little to do with the patented invention.²⁶¹

Generalizing from these proposals, Strandburg sets forth a “fair use” right to protect users of patented inventions.²⁶² Strandburg’s proposal would help deal with many of the problems with upstream patents, including holdup, anticommons issues, and preemption of substantial or even transformative improvements of the patented technology.²⁶³ Strandburg argues that contextual infringement determinations based on a flexible, multifactor test inspired by the statutory fair use factors in copyright law²⁶⁴ can account for implications of technological unpredictability—such as uncertain value and applicability of upstream inventions.²⁶⁵ The concern remains, however, that “[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.”²⁶⁶ While all of these proposals entail very useful contributions, they sidestep the general problem of identifying upstream inventions ex ante.

Strandburg identifies still another “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.²⁶⁷ But there are flaws with this as with any other ex post approach. Besides the problems with the uncertainty in the value of the right, the major worry is that the costs associated with figuring out ex post whether the

now be of uncertain value or utility.”); see *Bayer AG v. Housey Pharm., Inc.*, 228 F. Supp. 2d 467 (D. Del. 2002).

²⁶⁰ See *supra* note 75 and accompanying text.

²⁶¹ See Feldman, *supra* note 259, at 439-49. Cf. Neal Seegert, *Compulsory Licensing By Judicial Action: A Remedy for Misuse of Patents*, 47 MICH. L. REV. 613, 618-19, 637-38 (1949).

²⁶² Strandburg, *supra* note 192. See generally Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

²⁶³ Cf. *supra* Subpart III.A and accompanying text.

²⁶⁴ See *infra* note 301 and accompanying text.

²⁶⁵ Strandburg, *supra* note 192, at 274-79.

²⁶⁶ Devlin, *supra* note 240, at 635; 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 66, 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.”).

²⁶⁷ Strandburg, *supra* note 192, 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).

accused infringer is liable and how much it should pay are very high.²⁶⁸ Indeed, expenses associated with patent litigation, which is the dominant way of adjudicating whether a user is liable for infringing a valid patent and what the infringement remedies should be, are thought to distort patent value.²⁶⁹ Although the parties can of course settle or choose arbitration,²⁷⁰ 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.²⁷¹

B. *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 patent term for certain upstream inventions,²⁷² while others advocated compulsory licensing for their use²⁷³ and proposed other limits on remedies for successful enforcement of such patents.²⁷⁴ Implicitly or

²⁶⁸ For a sampling of works, see James E. Bessen & Michael J. Meurer, *The Direct Costs from NPE Disputes*, 99 CORNELL L. REV. 387 (2014); Colleen V. Chien & Michael J. Guo, *Does the US Patent System Need a Patent Small Claims Proceeding?*, available at <http://ssrn.com/abstract=2249896>; see also *supra* note 135 and accompanying text. For my own work on an approach to limiting litigation costs in certain circumstances, see Dmitry Karshedt, *Contracting for a Return to the USPTO: Inter Partes Reexaminations as the Exclusive Outlet for Licensee Challenges to Patent Validity*, 51 IDEA 309, 331-32 (2011).

²⁶⁹ See Judge J.T. Ellis, III, *Distortion of Patent Economics by Litigation Costs*, CASRIP pub. Ser. No. 5, available at <https://www.law.washington.edu/CASRIP/Symposium/Number5/pub5atcl3.pdf>. The validity of the patent can also be adjudicated via post-grant inter partes review in the PTO, but this forum is not available for determining infringement liability and remedies.

²⁷⁰ See 35 U.S.C. § 294.

²⁷¹ See, e.g., FED. TRADE COMM'N, *The Evolving IP Marketplace, Aligning Patent Notice and Remedies with Competition* 161-62 (March 2011), available at www.ftc.gov/os/2011/03/110307patentreport.pdf. But see Michael J. Mazzeo et al., *Excessive or Unpredictable? An Empirical Analysis of Patent Infringement Awards*, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1765891.

²⁷² Julian D. Forman, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications*, 12 ALB. L.J. SCI. & TECH. 647, 681-82 (2002) (proposing this solution for ESTs); Holman & Munzer, *supra* note 68, at 810-20 (discussing a shortened patent term for ESTs and proposing a registration system). Cf. Clarisa Long, *Information Costs in Patent and Copyright*, 90 VA. L. REV. 465, 546 n.194 (2004) (listing proposals for sui generis forms of intellectual property protection of software).

²⁷³ Lopez-Beverage, *supra* note 74, at 90-91 (proposing this solution for ESTs).

²⁷⁴ 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 74, 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. Uhler ed. 2011); Michael J. Stimson, *Damages for Infringement of Research Tool Patents*:

explicitly, these proposals stem from the fact that the completeness requirement in its current form is not entirely effective at balancing the considerations in the upstream invention debate. These proposals are important, but they tend to be technology-specific and limited in scope. In contrast, the proposal described below seeks to provide a general, comprehensive solution to the problem of upstream patents.

VII. THE RESEARCH PATENT AS THE RESOLUTION

If the unwritten completeness requirement fails and the ex post solutions are not adequate, what should be done? As I already suggested, there is a need for a comprehensive statutory “completeness of invention” requirement, which would limit but not eliminate patent rights in upstream inventions, to supersede the current judicial patchwork. Thus, I propose abrogating several controversial patent law doctrines for limiting upstream patents and providing a firm statutory grounding to the notion of completeness. The completeness requirement would also address long-standing concerns with patents on certain software, “research tools,” and other inventions, currently unaffected by judicial forays into completeness, that commentators have characterized as worryingly upstream.²⁷⁵ Finally, the requirement would aid in the conceptual separation of the concepts of completeness and patent claim breadth. For some broad claims, complete patent rights are fully justified, while other broad claims should fail but for reasons different from incompleteness—for example, due to the claims’ failure to meet section 112’s enablement requirement.²⁷⁶ Incomplete patents, however, are often overbroad and thus unduly preemptive because they are directed to inventions that are early in the developmental chain.

A firm grounding of the completeness requirement will address policy concerns with undue preemption by upstream inventions and allow for better tailoring between these concerns and patent rights and remedies than under the current regime. The proposed new patent right—the Research Patent—will create a limited patent incentive for upstream inventions and avoid the harsh and disproportionate result of complete invalidation. Furthermore, the completeness requirement would operate to limit patents as against the world and independently of the nature of the potential infringer’s activity, thus fostering greater certainty than proposed ex post “experimental use” approaches and other solutions (such as compulsory licenses) that limit remedies for enforcement of extant patents.²⁷⁷ An ex ante limitation on the upstream patent right and the removal of the cause of action for infringement

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).

²⁷⁵ See *supra* notes 39-40 and accompanying text.

²⁷⁶ See 35 U.S.C. § 112(a) (2012) (“The specification shall [describe] the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same”). See generally Dmitry Karshedt, *Limits on Hard-To-Reproduce Inventions: Process Elements and Biotechnology’s Compliance with the Enablement Requirement*, 3 HASTINGS SCI. & TECH. L.J. 109 (2011).

²⁷⁷ See *supra* Part VI.A and accompanying text.

of an upstream patent from a district court might also help avoid distortions created by litigation costs.²⁷⁸

A. Abrogation—and what remains completely unpatentable

The first step in the proposed scheme is the abrogation by statute of the holdings of *Brenner v. Manson*,²⁷⁹ the use of the written description requirement to invalidate claims directed to an end result, and the holding of the *Mayo v. Prometheus* case.²⁸⁰ The proposed statutory language reads:

A patent claim should not be denied if the claimed invention has only research utility. Unless drafted in means-plus-function format,²⁸¹ a patent claim should not be denied solely on the basis that the specification does not provide an example of a chemical or physical structure for carrying out the claimed result. A patent claim should be denied as directed to a law of nature, natural phenomenon, or an abstract idea only if it is manifestly directed to one of these categories. This section shall apply to all areas of technology. Nothing in this section excuses compliance with other requirements of patentability, including enablement, novelty, and nonobviousness.

The first sentence eliminates the *Brenner* utility doctrine. The second eliminates the *Rochester* doctrine. The third puts an end to the troubling and hard-to-implement doctrine requiring decision-makers to “look through” the claim to figure out what the “invention” actually is²⁸² by dissecting away claim elements corresponding to “well-understood, routine, conventional activity previously engaged in by researchers in the field.”²⁸³ The last sentence ensures that the statute is not applied in a technology-specific manner—one of the most problematic aspects of the completeness requirement as currently implemented.

That does not mean, however, that there will be no limits on the patentability of upstream inventions. 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,”²⁸⁴ and I do not propose to change this regime. Indeed, some of the attempted claims to “relatively ‘pure’ abstract ideas, natural laws, and natural phenomena”²⁸⁵—claims that simply state a fundamental discovery and do not purport to apply it outside the realm of pure science—will fall outside

²⁷⁸ See *supra* notes 268-271 and accompanying text.

²⁷⁹ 383 U.S. 517, 521 (1966).

²⁸⁰ 132 S. Ct. 1289 (2012).

²⁸¹ 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 in the specification. I do not propose to change this aspect of patent law.

²⁸² See *supra* notes 224-225 and accompanying text.

²⁸³ *Mayo*, 132 S. Ct. at 1294, 1297-98.

²⁸⁴ 35 U.S.C. § 101.

²⁸⁵ Sichelman, *supra* note 226, at 370.

the statutory categories.²⁸⁶ Thus, discoveries such as facts, information, and formulae without any limits on their downstream uses will remain unpatentable even within the proposed framework.²⁸⁷

In addition, even if a claim is nominally drawn to a statutory category, long-standing precedent prohibits patent claims that are manifestly directed to 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.”²⁸⁸ Indeed, exclusion of such discoveries from patentability has a long history, and is relatively uncontroversial.²⁸⁹ In contrast, I think that it is fairly clear that the inventions discussed throughout this Article are not in this category. Discoveries of processes for making chemical intermediates, of targets of drug action, and of methods of screening amounts of a probe molecule to determine a response to a drug may be validly viewed as upstream in the research process. Nevertheless, all three types of inventions involve more than an idea or a statement of a scientific principle.

Admittedly, the line between pure ideas and incomplete or “embryonic” inventions is difficult to draw, and some commentators have suggested that they should be treated the same way.²⁹⁰ Nevertheless, I think 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 representative 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 treatment of a patient. Applications of this sort should be sufficient to allow the invention to pass the initial hurdle of patent-eligibility.

Pure hypotheses (i.e., those without any roadmap for implementation) and conjectures without a credible scientific basis will continue to be ineligible for intellectual property protection in spite of my

²⁸⁶ Lemley et al., *Life After Bilski*, *supra* note 27, at 1325-26; *see also In re Bergy*, 596 F.2d 952, 965 (C.C.P.A. 1979), *aff’d sub nom. Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

²⁸⁷ Cf. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2114-15 (2013). *See generally* Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783 (2000); Symposium, *Molecules vs. Information: Should Patents Protect Both?*, 8 B.U. J. SC. & TECH. L. 190 (2002).

²⁸⁸ *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).

²⁸⁹ *See supra* note 61 and accompanying text.

²⁹⁰ *See Bar-Gill & Parchomovsky*, *supra* note 192, at 402. As I do here, these authors argue against full property-right protection in embryonic inventions (and ideas). *Id.* at 403-12. Others have argued that different limiting principles, perhaps a prohibition on patents on “organizing human activity,” should distinguish patentable from non-patentable subject matter. *See Collins*, *supra* note 221, at 68 (describing this approach); cf. *Bar-Gill & Parchomovsky*, *supra* note 192, at 426 (arguing that the “make love not war” idea is not entitled to any intellectual property protection).

proposed scheme.²⁹¹ Under the current regime, such claims can be rejected for lack of credible or operable utility under section 101,²⁹² or under the enablement prong of section 112 as failing to teach a person of ordinary skill in the art how to practice the invention without undue experimentation.²⁹³ I do not purport to propose any changes to this area of patent law—inventions that are inoperative or are non-enabled in ways other than for lack of consumer utility should not qualify even for limited patent protection.²⁹⁴

Nor do I propose to change the novelty and nonobviousness requirements, which might serve to eliminate certain patents that have forced courts to resort to completeness doctrines. It has been suggested that concerns about the patentability of ESTs may have been avoided if the Federal Circuit properly applied the nonobviousness doctrine.²⁹⁵ And some of the debates over the patentability of products of nature and natural phenomena may be mooted by a proper application of novelty doctrines—particularly, express or inherent anticipation.²⁹⁶

The requirements of operability, enablement, novelty, and nonobviousness are not merely completeness doctrines repackaged in a different form. Instead, they are independent requirements of patentability with distinct bodies of case law around them.²⁹⁷ While not without

²⁹¹ 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.

²⁹² See, e.g., *In re Swartz*, 232 F.3d 862 (Fed. Cir. 2000). See generally Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1492 (2011).

²⁹³ See, e.g., *Rasmusson v. Smithkline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005); see also Seymore, *supra* note 15 (proposing doing away with the utility requirement and using enablement to police some of the problematic claims that currently fail utility).

²⁹⁴ To be sure, the enablement requirement sometimes appears to function as a completeness requirement. I focus on the other three doctrines, however, because they tend to concentrate more squarely on the developmental stage of the invention rather than on an ordinary artisan's ability to practice the invention's full scope.

²⁹⁵ See *In re Fisher*, 421 F.3d 1365, 1382 (Fed. Cir. 2005) (Rader, J., dissenting). Arguably, ESTs would not have been adjudged obvious under the reasoning of *In re Kubin*, 561 F.3d 151 (Fed. Cir. 2009). See Mark D. Janis, *Tuning the Obviousness Inquiry After KSR*, 7 WASH. J.L. TECH. & ARTS 335, 337-40 (2012); Anna Bartow Laakmann, *Restoring the Genetic Commons: A "Common Sense Approach to Biotechnology Patents in the Wake of KSR v. Teleflex*, 14 MICH. TELECOMM. & TECH. L. REV. 43 (2007) (explaining how the obviousness requirement could be used to limit other upstream patents in the biotechnology field).

²⁹⁶ See Dan L. Burk, *Anticipating Patentable Subject Matter*, 65 STAN. L. REV. ONLINE 109 (2013); Risch, *supra* note 220, at 653-55; see *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343 (Fed. Cir. 2002). Indeed, concern expressed in some patent-eligibility cases that well-established, fundamental concepts should not be patent eligible appears to relate to novelty rather than concepts like abstractness. See, e.g., *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010) ("Hedging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.") (citation omitted).

²⁹⁷ See generally Risch, *supra* note 220.

controversy,²⁹⁸ court decisions applying these requirements have not been as susceptible to criticism as the completeness doctrines.²⁹⁹

B. *The substance of the Research Patent framework*

1. The legal test and Research Patent prosecution

This Subpart defines the contours of the completeness requirement. Two helpful examples of tests for analyzing whether patent claims overreach are the *Wands* factors used to evaluate whether practicing the claimed invention requires undue experimentation (i.e., to determine whether the claims are enabled, per section 112(a)),³⁰⁰ and the factors proposed by Mark Lemley, Michael Risch, Ted Sichelman, and Polk Wagner to determine whether claims are unpatentable under section 101 as abstract ideas.³⁰¹ Statutory fair use factors from copyright law provide an example of the multifactor approach that has been codified.³⁰² This Article adopts a statutory test based on two factors to determine completeness. The factors are (1) whether, according to a person of ordinary skill in the art, the claims would cover many significant downstream applications, many of which are yet to be discovered, at the time of the patent filing,³⁰³ and (2) whether a person of ordinary skill in the art would recognize that the claimed invention has the features of a hypothesis or a conjecture.³⁰⁴

The two factors reflect some of the considerations in the completeness cases, but are aimed at systematizing them and eliciting factual inquiries to help ensure that the requirement is not applied in an ad hoc or technology-specific manner.³⁰⁵ This approach addresses the central problem

²⁹⁸ See, e.g., Tun-Jen Chiang, *The Levels of Abstraction Problem in Patent Law*, 105 NW. U. L. REV. 1097 (2011) (criticizing the enablement requirement); Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1083, 1085-89 (2009) (calling the Federal Circuit's enablement jurisprudence "a doctrinal chaos"); Peter D. Smith, *Anticipating too Much: Why the Court Should Avoid Expanding the Doctrine of Inherent Anticipation*, 61 N.Y.U. ANN. SURV. AM. L. 832 (2006) (criticizing the inherent anticipation requirement); Seymore, *supra* note 292 (criticizing the PTO's approach to the operable utility requirement).

²⁹⁹ See generally *supra* Part V.

³⁰⁰ See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (factors in determining whether experimentation would be undue are "1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims").

³⁰¹ See Lemley et al., *Life After Bilski*, *supra* note 27, at 1341 ("Is the claimed invention potentially generative of many kinds of new inventions? Does the industry rely heavily on cumulative invention? Is the technological field fast-moving? Has the patentee disclosed a small number of embodiments but claimed a broad inventive principle? Has the patentee made an important contribution relative to the prior art?").

³⁰² See 17 U.S.C. § 107 (2012).

³⁰³ See *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972); *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966).

³⁰⁴ *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353-54 (Fed. Cir. 2010) (en banc).

³⁰⁵ 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*,

with the current law of completeness—the courts’ invocation of disparate doctrines to police completeness. This implementation has led to a supervening requirement for patentability that has been difficult to define apart from the facts of the specific cases in which it is applied.³⁰⁶ The two factors constitute a legal definition of the completeness requirement that aims to bring the doctrine into line with its core policy aims without the “baggage” stemming from the fact that the requirement, as now enforced, has multiple doctrinal homes.³⁰⁷

The test would foster a fact-intensive inquiry of the sort that courts and the PTO undertake in their enablement and obviousness analyses, where the ultimate questions of law are resolved based on subsidiary facts.³⁰⁸ Based on these factors, the PTO would decide whether the invention qualifies for a regular patent, assuming that other requirements of patentability have been met. A weighing of both factors will not always be required—an invention could be adjudged incomplete if it fails either one of them. If the factors do not favor full patent rights, the claims would be deemed to qualify only for a Research Patent (unless completely unpatentable), with a limited bundle of rights.³⁰⁹

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.³¹⁰ This, however, is a systemic issue in the prosecution process and affects all the patentability requirements—for example, to overcome an obviousness rejection, an applicant might submit self-serving “evidence” of unexpected results,³¹¹ and a PTO examiner might err by viewing that evidence as persuasive. One possible cure for the problem is invalidation of the regular patent, if improvidently granted in spite of incompleteness, during post-grant review,³¹² inter partes review,³¹³ or in

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.”); *see also supra* note 28 and accompanying text (describing the person of ordinary skill in the art). And others have contended that the application of patentable subject matter and utility requirements also seems to improperly hinge on subjective views of judges. *See, e.g., supra* note 15 and accompanying text.

³⁰⁶ *See supra* notes 136-137 and accompanying text.

³⁰⁷ This is one of the reasons I believe that it is undesirable to look for a “home” for the completeness requirement in the existing statutes. *Cf.* Sean Seymore, *Foresight Bias in Patent Law*, 90 NOTRE DAME L. REV. (forthcoming 2015) (proposing addressing some problems with utility via the enablement requirement).

³⁰⁸ *See KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007); *Cephalon, Inc. v. Watson Pharm., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013).

³⁰⁹ *See infra* Subpart VII.C. Unless, of course, the invention is adjudged to be completely unpatentable. *See supra* Subpart VII.A.

³¹⁰ It is possible, however, that some inventors might prefer RPs because they might signal to investors that they own transformative, “platform” technology.

³¹¹ *Cf. In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012) (discussing evidentiary value of unexpected results for proving nonobviousness).

³¹² 35 U.S.C. § 321 (2012).

³¹³ *Id.* § 311.

district court litigation.³¹⁴ In the serious cases, a charge of inequitable conduct—which would render the regular patent unenforceable if successful—might be a possibility.³¹⁵ These prospects might deter some of the self-serving behavior during prosecution and induce the applicants to opt for the “bird in the hand” of the Research Patent rather than the “two in the bush” of a regular patent, which would be more easily susceptible to invalidation.³¹⁶ Another 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.³¹⁷

Another general objection to the proposed scheme concerns errors due to the failure to predict broad downstream applicability of the claimed technology.³¹⁸ It is true that history provides examples of inability to foresee that an invention would be transformative.³¹⁹ But, at least with regard of some of the upstream inventions discussed in this Article—Donald Young and co-workers’ discovery of selective Cox-1 inhibition,³²⁰ Kary Mullis’ development of the PCR technique,³²¹ James Thomson’s derivation of human embryonic stem cells,³²² and the invention of the atomic force microscope by Binnig, Quate, and Berger³²³—the potential for numerous downstream applications 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

³¹⁴ *Id.* § 282.

³¹⁵ *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

³¹⁶ *See also infra* notes 329-330 and accompanying text. Of course, the incentive of having a regular rather than only RP patent could serve as the “carrot” for “completing” the invention—i.e., a reward for doing enough to meet the completeness requirement.

³¹⁷ *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323-36 (Fed. Cir. 2003).

³¹⁸ *Cf. Lemley, supra* note 254, at 1050 (“Economic history provides some striking examples of inventors who grossly understated the market value of their own inventions.”) (citing Kathleen O’Toole, *The Future Was “Obviously Not Obvious,”* STAN. OBSERVER, May-June 1994, available at <http://news.stanford.edu/pr/94/940601Arc4231.html>).

³¹⁹ *See, e.g., Duffy, supra* note 209, 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.*

³²⁰ *See University Awarded Historic Drug Patent*, 62 ROCHESTER REV., Spring-Summer 2000, <http://www.rochester.edu/pr/Review/V62N3/inrev06.html>. The attribution of who discovered this process is not without controversy. *See TOM NESI, POISON PILLS: THE UNTOLD STORY OF THE VIOXX DRUG SCANDAL* 77-39. *Cf. Lemley, supra* note 51.

³²¹ *See DENNIS W. ROSS, INTRODUCTION TO MOLECULAR MEDICINE* 39-41 (2008).

³²² James A Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145 (1998).

³²³ Ben Ohler, *Perspectives on Over Twenty Years of Life Science Research with Atomic Force Microscopy and a Look Toward the Future*, 16 MICROSCOPY & MICROANALYSIS 1034 (2010) (noting that the atomic force microscope was “immediately recognized as a valuable new technique”).

rush” to patent newly discovered ESTs began, their potential was clear as well.³²⁴ 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 RP rather than regular protection is appropriate.³²⁵ And if the PTO improvidently grants a regular patent on an incomplete invention, the costs of error might sometimes be mitigated by the lack of downstream researchers’ desire to develop the invention’s applications during the life of the patent.³²⁶

Finally, 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 invention’s broad-reaching nature was actually unpredictable.³²⁷ And in cases where an invention truly, surprisingly becomes transformative quickly contrary to everyone’s expectations, letting the inventor reap the “windfall” seems fairer 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.³²⁸

In litigation of regular patents, a validity challenge for lack of completeness would function just as any other validity challenge.³²⁹ If the PTO granted a regular patent but a court found that the invention did not satisfy the completeness requirement, the patent becomes invalid. To hedge against this result, the patent applicant might seek both an RP and a regular patent for the same invention at the PTO. This practice, however, is undesirable because the applicant would be able to get two bites at the apple with an RP and a regular patent. A better solution is to permit applicants to choose to pursue either regular or RP protection for a given invention.³³⁰

³²⁴ See Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, ANN. REV. GENOMICS HUM. GENET. 382, 399-400 (2010).

³²⁵ See *supra* note 53 and accompanying text.

³²⁶ Cf. O’Toole, *supra* note 318 (listing examples).

³²⁷ Cf. Dmitry Karshedt, *Formalism and Pragmatism in the Analysis in the Analysis of Damages for Indirect Patent Infringement*, 91 WASH. U. L. REV. 911 (2014) (discussing the “book of wisdom” concept in the context of patent damages).

³²⁸ See *supra* notes 238-242 & 265-268 and accompanying text.

³²⁹ See *supra* note 314 and accompanying text.

³³⁰ This practice would be consistent with the “petty patent” (also called “utility model”) regimes in foreign jurisdictions, including Germany and China. These patents have shorter terms and relaxed patentability requirements relative to regular utility patents. See *Protecting Innovation By Utility Models*, http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm. See Mauri Sankus, *From the Experts: 5 Ways to Maximize Patent Strategy in BRIC Countries*, CORP. COUNSEL (Sept. 4, 2012), available at <http://www.gtlaw.com/News-Events/Publications/Published-Articles/164775/From-the-Experts-5-Ways-to-Maximize-Patent-Strategy-in-BRIC-Countries>, at *1 (“[B]ecause of double patenting rules, the same invention cannot be protected by both a traditional patent and by a utility model.”). The crucial difference between RPs and petty patents, however, is that the former are not protected by full property rights. Cf. Mark D. Janis, *Second Tier Patent Protection*, 40 HARVARD INT’L L.J. 151, 218 (1999) (“[C]urrent property rights regimes are not the answer for protecting subpatentable innovation.”).

This rule would channel inventors who are risk-averse toward RP protection.³³¹

2. Applying the two factors

The two completeness factors should help ensure that upstream inventions, many of which fail utility, written description, and section 101 patentable subject matter exclusions under the current regime, would generally qualify only for an RP. But the framework I propose might lead to a more textured analysis than what has come out of the messy case law. For example, a chemical compound whose only utility is that as an “object of research” might be relegated to RP status based on the first factor because that compound could be a cancer drug, a lubricant, a fuel, and who knows what else.³³² In contrast, a method for forming a new chemical bond in a specific structural setting might be entitled to a regular patent. A patent on a catalyst for coupling carbon and nitrogen atoms using a very limited set of nitrogen-containing compounds might not be incomplete because there is nothing “hypothetical” about the method and because it does not cover transformative and unpredictable downstream applications—but only uses in connection with a particular, known class of drugs.³³³ Furthermore, some types of inventions that currently invariably receive full patent rights (as long as they meet the extant requirements for patentability) might qualify only for an RP under the proposed scheme. Thus, certain methods of manipulating genetic material, like PCR, would have been protected only by an RP because it is likely that an ordinary artisan would have recognized the broad applicability of this sort of an invention at the time of filing.³³⁴

Scientific instrument inventions provide another illustration of how the two factors can be applied. Some machines, like scintillation counters, would be expected to have many downstream applications and would thus qualify only for an RP, while others, perhaps gold metal detectors, would qualify for a regular patent. Chemical compounds isolated from natural sources, such as DNA molecules at issue in the case of *Association for*

³³¹ See *supra* note 316 and accompanying text.

³³² This observation suggests 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 214, an invention’s broad applicability must, under my proposed scheme, be identified with particularity to support the conclusion of incompleteness. I thank Professor Joshua Sarnoff for bringing this issue to my attention.

³³³ My own graduate research might be an example of such a method. See Dmitry Karshtedt et al., *Platinum-Based Catalysts for the Hydroamination of Olefins with Sulfonamides and Weakly Basic Anilines*, 127 J. AM. CHEM. SOC’Y 12640 (2005).

³³⁴ See *supra* notes 231-232 & 321-323 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. See *supra* note 40 and accompanying text. Since we are concerned with preemption of downstream applications, the latter set of uses would be taken into account in the incompleteness analysis.

Molecular Pathology v. Myriad Genetics, Inc., provide yet another illustration.³³⁵ Oddly, 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.³³⁶ Under the proposed framework, however, both types of molecules would likely receive the protection of an RP 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. Rather, it focuses on the material’s applicability and, more generally, on the invention’s developmental stage.

The inventions at issue in the written description cases might fail to qualify for a regular patent right because of the second factor, which reflects the cases’ concerns with patenting a “hypothesis” or a “research plan”—for example, patenting a method of treatment without a showing of how to implement it with specific drugs.³³⁷ But the factors may apply beyond biotechnology inventions and impact patent applications in, for example, the software field, where the written description requirement has been underenforced.³³⁸ Indeed, Mark Lemley has recently argued that many of the software and business method patents seem to be directed to a “problem” rather than to the “solution,” and the second factor squarely addresses this problem with software patents.³³⁹ If, for example, a PTO examiner determines that a functionally drafted software claim is drawn to a broadly-stated “wish” for solving a problem, only an RP would issue.³⁴⁰ In this application to software claims, the two factors also indirectly reflect the courts’ concerns in the computer-related patentable subject matter cases, such as the prohibition on patenting algorithms and abstract ideas generally.³⁴¹

Note, however, that the factors do not include the Supreme Court’s unhelpful and unwieldy doctrine prohibiting “conventional” applications of abstract ideas, laws of nature, and natural phenomena.³⁴² The focus of the two factors is squarely on the invention’s developmental stage and potential for undue preemption.³⁴³ Consider the claims at issue in *Mayo*, which 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

³³⁵ 133 S. Ct. 2107 (2013).

³³⁶ *Id.* at 2118.

³³⁷ See *supra* Subpart IV.B.

³³⁸ See *supra* notes 199-202 and accompanying text.

³³⁹ See Lemley, *supra* note 17; see also *Comments of Michael Risch*, *supra* note 52.

³⁴⁰ Such claims could be also viewed as “incomplete” on the basis of the first factor—because there are numerous ways to solve the problem “defined” by the claims, the claim covers many significant downstream applications.

³⁴¹ See *Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972).

³⁴² See *supra* notes 222-224 and accompanying text. Jacob Sherkow criticizes the Supreme Court’s requirement that the PTO determine whether the claimed invention involves “well understood, routine, conventional activity, previously engaged in by researchers in the field” because “[t]he PTO is poorly equipped to handle that inquiry.” Sherkow, *supra* note 224, at 356 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012)).

³⁴³ See *supra* notes 280-283 and accompanying text.

administration, whether to increase or decrease the dosage of the drug.³⁴⁴ 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.³⁴⁵ 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. Furthermore, one would be hard-pressed to argue that the invention at issue in *Mayo* has the features of a hypothesis—instead, the claims reflect a completed study of the correlation's significance. The *Mayo* claims would likely receive a regular patent.

C. *The limited bundle of rights*

In terms of enforcement, the key difference between a regular patent and the proposed RP framework is the absence of district court jurisdiction over lawsuits involving RPs. There would be no injunctions. Instead, the owner of the RP and the user of the technology would have to privately determine nonexclusive license terms (and, if applicable, past damages).³⁴⁶ If that fails, the patent owner would pursue its claim in a specialized tribunal, such as a small claims court or the Patent Trial and Appeal Board (PTAB).³⁴⁷ As discussed above, the most significant drawbacks of having to determine whether an infringer is entitled to some type of a “safe harbor” ex post—and if not, what the remedies should be—are the costs of litigation and the costs of uncertainty.³⁴⁸ Indeed, litigation costs and the resulting potential for nuisance-value settlements have spurred proposed changes to the Patent Act in the past year, including a suggestion for a loser-pays

³⁴⁴ *Mayo*, 132 S. Ct. at 1295-97.

³⁴⁵ See Dreyfuss & Evans, *supra* note 229, at 1360-61 (“[T]here are arguably other ways to achieve the goals of the [*Mayo*] patent.”). This is the virtue of relying on factual inquiries rather than deciding issues of patentable subject matter as pure questions of law.

³⁴⁶ The additional requirement of a nonexclusive, rather than exclusive, license will ensure that the technology covered by the RP could be used widely.

³⁴⁷ Currently, the PTAB is responsible for reviewing the validity of patents after they are granted and for handling patent applicants' appeals from examiners' rejections of claims, 35 U.S.C. § 6 (2012), so this additional power would need to be granted by statute. Although performing patent infringement analysis would require further expertise on the part of the PTAB, that analysis is conceptually similar to the analysis PTAB must already perform in assessing a patent claim's novelty. See, e.g., *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F. 2d 744, 747-48 (Fed. Cir. 1987). 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) (proposing forced arbitration before a specialized board to determine royalties for use of inventions covered by research tool patents); see also Chien & Guo, *supra* note 268 (discussing proposals for a patent small claims court).

³⁴⁸ See *supra* Part V.

system, heightened pleading requirements, the “customer suit” exception to protect smaller defendants—and a small claims court.³⁴⁹

Furthermore, liability-rule protection of upstream patents makes sense because full rights are granted in such patents appear to be associated with a high rate of market failure.³⁵⁰ Because of their uncertain valuation, negotiations over upstream patents are thought to impose high transaction costs—a classic justification for a liability-rule regime.³⁵¹ 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 need for a government-mandated liability-rule solution.³⁵²

In order to account for the concerns that drive the impending patent reform and mitigate the problems of market failure, “windfall” reach-through royalties,³⁵³ and holdup in the face of high litigation costs and uncertain jury verdicts,³⁵⁴ RP infringement claims must be amenable to a low-cost, efficient resolution in a specialized tribunal if a private solution is unworkable. Accordingly, 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.³⁵⁵ Damages caps are a familiar feature of tort reform efforts—for example, several states put caps on compensation for medical malpractice.³⁵⁶ If damages can be capped for physical injury, damage caps or scheduled damages for patent infringement also appear to be reasonable.³⁵⁷ Accordingly, my proposal provisionally

³⁴⁹ See, e.g., Tony Dutra, *Goodlatte and Leahy Begin Patent Reform Round Two With Legislation Discussion Draft*, BLOOMBERG BNA (May 28, 2013), <http://www.bna.com/goodlatte-leahy-begin-n17179874240>.

³⁵⁰ See FELDMAN, *RETHINKING PATENT LAW*, *supra* note 64, 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). See generally Ben Depoorter, *Property Rules, Liability Rules, and Patent Market Failure*, 1 *ERASMUS L. REV.* 59 (2008).

³⁵¹ See Daniel R. Crane, *Intellectual Liability*, 88 *TEX. L. REV.* 253, 270 (2009); see also Mark A. Lemley & Philip J. Weiser, *Should Property or Liability Rules Govern Information*, 85 *TEX. L. REV.* 783, 793-97 (2007).

³⁵² See *infra* note 363 and accompanying text. In contrast, “patent pools” and related private arrangements, such as standard-setting organizations, have been formed for “standard-essential” patents in telecommunications field. See generally Mark A. Lemley & Carl Shapiro, *A Simple Approach to Setting Reasonable Royalties for Standard-Essential Patents*, 28 *BERKELEY TECH. L.J.* 1135 (2013).

³⁵³ See *supra* notes 75-79 & 259-261 and accompanying text.

³⁵⁴ See generally Lemley & Shapiro, *supra* note 86.

³⁵⁵ 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.

³⁵⁶ See, e.g., Cal. Civ. Code § 3333.2 (2013); Colo. Rev. Stat. § 13-64-302 (2005); Fla. Stat. Ann. § 766.118 (2013). For a summary of malpractice cap statutes and their analysis, see Catherine M. Sharkey, *Unintended Consequences of Medical Malpractice Damages Caps*, 80 *N.Y. L. REV.* 391, 476 (2005).

³⁵⁷ 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

limits recovery to any claim under an RP to \$100,000 for a “large entity” infringer, \$50,000 for a “small entity,” and \$25,000 for a “micro entity.”³⁵⁸ 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 the following schedule: \$100,000-\$50,000-\$25,000 for large, \$50,000-\$25,000-\$10,000 for small, and \$25,000-\$15,000-\$5,000 for micro entities.³⁵⁹

Although these amounts seem 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, and perhaps to enter into private agreements and thus bypass the designated tribunal.³⁶⁰ This approach promotes fairer results than the current system by encouraging the spreading of liability rather than focusing on a few “deep pockets” infringers in an effort to obtain large damages or an injunction.³⁶¹

perceive to be due to jury biases regarding the entity involved in litigation, variations between venue, and other factors that open the system to manipulation)

³⁵⁸ Provisionally, these definitions are adopted from the Patent Act. *See* 35 U.S.C. § 123 (defining micro entity); 37 C.F.R. § 1.27 (defining small entity). In addition, 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 of patents that are familially related or are directed to closely similar technology).

³⁵⁹ The numbers are merely suggestions—Congress may wish to set different numbers or set different tiers based on the evidence provided by the stakeholders. The overall approach resembles the determination of copyright royalties for song covers, but with more rigid “scheduling” awards. *Cf.* Schmieder, *supra* note 347, at 226-27 (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 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 350-352 and accompanying text; *see also supra* Parts III.A & VI.

³⁶⁰ Indeed, “[if you create enough certainty in the commercial and regulatory landscape, a private market will fill in the spaces unless impeded by some other barrier.” Cahoy, *supra* note 359, at 506; *see* Dreyfuss, *supra* note 350, 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).

³⁶¹ 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-pocket” target.

Indeed, by hypothesis, the RP covers a wide variety of downstream applications. Although the lack of a full patent right, as reflected in a cap on damages, means that the value of an RP would be lower than that of a regular patent, RP owners may still recoup their research and development costs if the subject matter of the RP is broadly applicable. Although 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. Finally, while proposed small claims adjudications of regular patent rights raise Seventh Amendment concerns due to lack of a jury trial, no such problems arise in the proposed RP scheme because the RP does not come with the right to sue in a district court.

Although scheduled damages are certainly inaccurate as estimates of patent value for a number of reasons³⁶²—for example, because of the differences in the value of patents from one technology to another—this approach sidesteps the notoriously difficult problem of valuation of patents by courts.³⁶³ Indeed, courts have often questioned their own competence to measure patent damages,³⁶⁴ and proposals to put the measurement into the hands of administrative agencies are open to the same critiques. 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.³⁶⁵

In keeping with the low costs of the proposed approach, the tribunal would only be able to evaluate ordinary infringement and invalidity based on

³⁶² Another approach might be to require patent owners to purchase “infringement insurance” and rely on the coverage amounts as self-assessed damages. See Saul Levmore, *Self-Assessed Valuation Systems for Tort and Other Law*, 68 VA. L. REV. 771 (1982); see also Abraham Bell & Gideon Parchomovsky, *Reinventing Copyright and Patent*, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2399998.

³⁶³ See *supra* note 75 and accompanying text; see also 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). Indeed, the valuation problem is one of the common objections to compulsory licensing of upstream patents. See Epstein, *supra* note 266. One alternative proposal is a patent pool, which is a mechanism often used for the aggregation of standard essential patents. See Schmieder, *supra* note 347; USPTO White Paper, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (Dec. 5, 2000), available at <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>. For criticisms of the USPTO proposal, see Scott Iyama, Comment, *The USPTO's Proposal of a Biological Research Tool Patent Doesn't Hold Water*, 57 STAN. L. REV. 1223 (2005); Levang, *supra*. Indeed, patent pools generally form spontaneously, through private bargaining, and this has not happened for many of the patents discussed in this Article. See *supra* note 352 and accompanying text.

³⁶⁴ 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”).

³⁶⁵ Consistent with this approach, sublicensing of the right to use the RP subject matter by the “infringer” to another party would not be allowed.

patents and written publications.³⁶⁶ This approach avoids costly, discovery-intensive subjects like inequitable conduct and willfulness,³⁶⁷ as well as non-prior art invalidity.³⁶⁸ Reflecting the limited nature of the RP right, no claims for infringement under the doctrine of equivalents would be allowed.³⁶⁹ The tribunal's additional task would be to determine the size of the accused entity and the extent of infringement according to the maximum-medium-small schedule. These sorts of determinations would be developed on a case-by-case basis, or perhaps through statutory guidelines that would be further developed in regulations.³⁷⁰ Article III judicial review of the RP infringement determinations would be very limited—under the same deferential standard as review of arbitration decisions.³⁷¹

VIII. CONCLUSION

Courts have had trouble developing coherent law for curbing unduly preemptive patents on upstream inventions. Concerns over upstream patenting have produced many controversial cases and generated worries that patent law does not provide an adequate incentive for creating early-stage inventions. Furthermore, completeness cases are considered by many to be unjustifiably technology-specific, failing to address patents on many types of upstream inventions considered to be unduly preemptive.³⁷² Nevertheless, the cases that enforce this unspoken incompleteness requirement of patent law reflect important policy concerns—particularly, the worry that downstream research will be inhibited.

The statutory solution provided in this Article addresses the concerns on both sides of the upstream patenting debate and provides a balanced approach in the form of limited patent rights in early-stage, incomplete inventions. The proposed scheme will eliminate several controversial doctrines in patent law, give a firm statutory grounding to the notion of completeness, and address long-standing concerns with patents on software and “research tools” and other upstream inventions that currently receive full patent rights. By providing a framework for highly fact-intensive inquiries, the statutory completeness regime will help ensure that patents are

³⁶⁶ Because my proposal allows for some types of validity challenges, the PTAB may be a particularly appropriate tribunal for the resolution of RP claims. While a challenge to a patent's validity at the PTAB may be costly, it is nowhere near as expensive as district court litigation. Whatever the tribunal, in order to encourage the limited validity challenges, claim amendments will not be allowed.

³⁶⁷ See *Comments of Michael Risch in Response to PTO Request for Comments on Patent Small Claims*, Docket No. PTO-P-2012-0050, http://www.uspto.gov/ip/global/patents/comments/comments_to_us_pto_re_patent_small_claims.pdf; see also Karshtedt, *supra* note 268.

³⁶⁸ 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).

³⁶⁹ See *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997).

³⁷⁰ See also *supra* note 358 and accompanying text.

³⁷¹ See 35 U.S.C. § 294 (2012). Perhaps, in the course of Article III review, courts could entertain a claim that the applicant has committed fraud on the PTO and the RP should therefore be unenforceable (e.g., a form of an inequitable conduct charge made in litigation)—though the requirements to plead such a claim would be very stringent.

³⁷² See *supra* Part V.A.

not refused in inconsistent manner, promoting doctrinal coherence and greater predictability. Further, the tailored legislative solution should lead to reduced uniformity costs in the patent system. The limited-remedy feature of the RP has similarities to the long-ago proposed “scientific property” regime, but its interplay with the modern concerns of undue preemption makes it a good fit for the twenty-first century.³⁷³

³⁷³ See *supra* note 61 and accompanying text; see also Stephen B. Ladas, *The Efforts for International Protection of Scientific Property*, 23 AM. J. INT’L L. 552, 553 (1929) (describing a proposal setting forth that “every new discovery or invention of whatever nature, confers upon its author the right to demand a royalty from all those who draw an industrial profit therefrom” and abrogating a provision that all patents concerning “principles, methods, systems, discoveries and theoretical or purely scientific conceptions of which no industrial applications are indicated”).