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# The Research Patent

### Sean B. Seymore\*

The patent system gives courts the discretion to tailor patentability standards flexibly across technologies to provide optimal incentives for innovation. For chemical inventions, the courts deem them unpatentable if the chemical lacks a practical, non-research-based use at the time patent protection is sought. The fear is that an early-stage patent on a research input would confer too much control over yet-unknown uses for the chemical, thereby potentially hindering downstream innovation. Yet, denying patents on research inputs can frustrate patent law's broad goal of protecting and promoting scientific and technological advances.

This Article addresses this problem by proposing a new form of intellectual property—a "research patent." This regime would allow inventors to obtain patents on research inputs and extract their full value through licensing and enforcement. Research patents would impose minimal administrative costs on the patent system and ultimately promote the disclosure, development, and use of early-stage inventions. At a broader level, the proposed regime raises the theoretical question of how allowing patent protection on early-stage inventions like research inputs serves patent law's instrumental justification of promoting scientific progress. It also raises significant normative and policy questions about technology-specific patentability standards and their role in furthering the goals of the patent system.

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#### INTRODUCTION

Chemical inventions hold a special place in patent law. The first patent granted in the United States was for an improved method for making potash (potassium carbonate). A comprehensive study of the U.S. patent system shows that over two-thirds of the value of worldwide patents accrues to chemical and pharmaceutical firms. Indeed, a blockbuster drug patent can generate billions of dollars in annual revenue.

A fascinating aspect of chemical inventions is that their value often stems from unpredictability: it is often hard to predict what a chemical can do.<sup>4</sup> Researchers must engage in trial and error to figure out what works and what does not.<sup>5</sup> The inability to predict an outcome sets the stage for big paradigm shifts and radical innovations.<sup>6</sup> So it would seem that the patent system would encourage patenting

<sup>1.</sup> The Making of Potash and Pearl Ashes, U.S. Patent No. X1 (issued July 31, 1790).

<sup>2.</sup> James Bessen & Michael J. Meurer, Patent Failure 109 (2008).

<sup>3.</sup> Ronald J. Vogel, Pharmaceutical Economics and Public Policy 25 (2007).

<sup>4.</sup> See, e.g., In re Wright, 999 F.2d 1557, 1564 (Fed. Cir. 1993) (holding that a vaccine's success combating one strain of a virus is not necessarily indicative of its success combating other strains). Patent law considers inventions like electrical and mechanical devices "predictable" because they involve well-understood, predictable functions. In re Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991).

<sup>5.</sup> See Sean B. Seymore, Heightened Enablement in the Unpredictable Arts, 56 UCLA L. REV. 127, 137-39 (2008) (discussing the need for experimentation with chemical inventions); Cedarapids, Inc. v. Nordberg, Inc., No. 95-1529, 1997 WL 452801, at \*2 (Fed. Cir. Aug. 11, 1997) (explaining that in the chemical arts, "a slight variation . . . can yield an unpredictable result or may not work at all").

<sup>6.</sup> Jane Calvert, What's Special About Basic Research?, 31 SCI. TECH. & HUM. VALUES 199, 204 (2006).

chemical inventions. But interestingly enough, their unpredictable nature can *defeat* patentability.

A basic tenet of patent law is that inventions must be useful.<sup>7</sup> The utility requirement is codified in § 101 of the patent statute, which states in relevant part that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent." Commentators often describe utility as a "token" or "nonexistent" patentability requirement. A better description is that the utility threshold is technology-specific—de minimis for some inventions but more stringent for others. For example, mechanical and electrical inventions almost never face utility hurdles. But the opposite is true for chemical inventions, where the lack of a practical, non-research-based use renders them unpatentable. <sup>13</sup>

Why are chemical inventions treated differently? One reason is fear of the unknown. Consider a chemical compound, X. Predicting X's chemical reactivity or practical usefulness might be difficult—even if the behavior of similar compounds is well understood. <sup>14</sup> This scenario troubled the Supreme Court in the 1966 case Brenner v. Manson. <sup>15</sup> It hypothesized that upstream patents <sup>16</sup> on early-stage research inputs like X might create a "monopoly of knowledge" <sup>17</sup> that could "engross a

<sup>7.</sup> Brenner v. Manson, 383 U.S. 519, 534 (1966) (identifying utility as a part of the patent bargain); Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991) ("[Utility is] a fundamental requirement of American patent law, dating back some two-hundred years . . . ").

<sup>8. 35</sup> U.S.C. § 101 (emphasis added).

<sup>9.</sup> Kevin Emerson Collins, Patent Law's Authorship Screen, 84 U. CHI. L. REV. 1603, 1621 (2017).

<sup>10.</sup> Michael Risch, A Surprisingly Useful Requirement, 19 GEO. MASON L. REV. 57, 58 (2011).

<sup>11.</sup> Nathan Machin, Comment, Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act, 87 CALIF. L. REV. 421, 436 (1999) ("[T]he utility doctrine usually has been a low hurdle for patent applicants to clear.").

<sup>12.</sup> See Rebecca S. Eisenberg, Analyze This: A Law and Economics Agenda for the Patent System, 53 VAND. L. REV. 2081, 2085 (2000) ("[T]he utility requirement has played little role in evaluating the patentability of mechanical inventions . . . ."); JANICE M. MUELLER, PATENT LAW 492 (6th ed. 2020) ("Utility is rarely at issue for mechanical or electrical inventions.").

<sup>13.</sup> See infra Part I (discussing utility as a lever for patentability).

<sup>14.</sup> See, e.g., AstraZeneca Pharms. LP v. Teva Pharms. USA, Inc., 583 F.3d 766, 775 (Fed. Cir. 2009) ("[T]he properties of these structurally similar compounds [can] vary significantly with minor structural changes.").

<sup>15. 383</sup> U.S. 519 (1966).

<sup>16. &</sup>quot;Upstream" patents "claim technologies associated with basic and early stage research and development, as opposed to patents covering 'downstream' commercial products." Chris Holman, Clearing a Path Through the Patent Thicket, 125 CELL 629, 629 (2006).

<sup>17.</sup> Manson, 383 U.S. at 534.

vast, unknown, and perhaps unknowable area"<sup>18</sup> and potentially "block off whole areas of scientific development."<sup>19</sup>

But this fear of monopolization and hindered innovation has costs. For example, suppose the inventor of X is an academic researcher who wants to license it to a pharmaceutical firm interested in developing X and finding uses for it. Revenue from a patent license could pay for the research project—an important concern given the competition for funding in academic science and the decline in federal support for basic research. Without a patent, the firm or a subsequent researcher who learns about  $X^{21}$  could develop (and possibly patent) profitable uses for it based directly on the inventor's earlier work without having to provide any recognition of  $X^{22}$  or compensation.

Patenting a chemical invention is an all-or-nothing proposition—the inventor either gets a patent on the compound covering *all* uses (contemplated or not)<sup>24</sup> or gets nothing.<sup>25</sup> Utility is the patentability lever<sup>26</sup> that allows the Patent Office and the courts to

<sup>18.</sup> Id.

<sup>19.</sup> *Id.*; *cf.* O'Reilly v. Morse, 56 U.S. (15 How.) 62, 113 (1853) (fearing that early patents could "shut[] the door against inventions of other persons").

<sup>20.</sup> See infra note 260 (sources discussing academic research and the level of support from the federal government); Aaron S. Kesselheim & Jerry Avorn, University-Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property, 293 JAMA 850, 852–53 (2005) (noting that public funding has accounted for a diminishing percentage of total research funding). Basic research is "[e]xperimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view." NAT'L CTR. FOR SCI. & ENG'G STAT., NAT'L SCI. FOUND., SCIENCE & ENGINEERING INDICATORS 2018, at 4-105 (2018).

<sup>21.</sup> This could happen if the inventor discloses X in the peer-reviewed literature. See infra Part III (discussing the anticommons idea in patent law).

<sup>22.</sup> See Jordan P. Karp, Note, Experimental Use as Patent Infringement: The Impropriety of a Broad Exception, 100 YALE L.J. 2169, 2180 (1991) ("After all, but for the patentee's inventive efforts and... willingness to disclose the fruits of those efforts, competitors would not even be in a position to develop [their downstream innovations].").

<sup>23.</sup> Kesselheim & Avorn, supra note 20, at 852.

<sup>24.</sup> In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995); see also infra notes 149–150 and accompanying text (noting that even uses that are not known or disclosed are patented in this scenario).

<sup>25.</sup> Paul H. Eggert, Uses, New Uses and Chemical Patents—A Proposal, 51 J. PAT. OFF. SOC'Y 768, 775 (1969).

<sup>26.</sup> The patentability requirements appear in Title 35 of the United States Code. Briefly, the claimed invention must be useful, novel, nonobvious, and directed to patentable subject matter. 35 U.S.C. §§ 101-103. In addition, the application must adequately describe, enable, and set forth the best mode contemplated for carrying out the invention, and conclude with claims that delineate the invention with particularity. *Id.* § 112(a)–(b).

choose "nothing,"<sup>27</sup> which is hard to swallow.<sup>28</sup> This reveals a reality of modern patent law: basic research in unpredictable fields, "no matter how important and valuable, does *not* merit protection and is therefore *not useful* in the patent sense."<sup>29</sup> For these inventions, patent law is unwilling "to grant exclusive rights for what is merely one step in a line of research. . . . [It] requires an inventor to know something about the trajectory of the future research and its ultimate practical application."<sup>30</sup> This reality has "drive[n] a wedge between academic science and the patent system."<sup>31</sup>

This paradigm raises two intriguing questions that deserve more attention from courts and scholars. First, why should an inventor's inability to articulate a practical application for X at the time patent protection is sought raise concerns about blocking future research or the commercialization of new uses discovered by others downstream?<sup>32</sup> As the law currently stands, disclosing a single practical application for X allows an inventor to get a broad patent that can dominate an entire technical field.<sup>33</sup> The point is that the inventor's disclosed use for X in the patent application—practical or research—does not portend blocking behavior.<sup>34</sup> Second, why should a practical, non-research-based use for X be a patentability requirement? There is a strong normative argument that affording patent protection for research on or with X serves the instrumental justification of patents—

<sup>27.</sup> See Eggert, supra note 25, at 775 (describing two cases where the courts chose "nothing"); DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 109 (2009) ("[T]he utility rule announced in *Brenner v. Manson* is applied only in biotechnology and chemical cases." (footnote omitted)).

<sup>28. &</sup>quot;[I]t is difficult to make the case that the right amount of intellectual property protection for such inventions is zero." Dmitry Karshtedt, *The Completeness Requirement in Patent Law*, 56 B.C. L. REV. 949, 1014 (2015).

<sup>29.</sup> Michael Risch, Reinventing Usefulness, 2010 BYU L. REV. 1195, 1220 (emphasis added); see also BURK & LEMLEY, supra note 27, at 111 ("[D]eveloping a new molecule without any particular use is not a completed innovation, but merely the opening stage of a long and complex research process."). But patents are permitted for basic research in predictable fields. See Stanley H. Cohen & Charles H. Schwartz, Editorial Note, Do Chemical Intermediates Have Patentable Utility?, 29 GEO. WASH. L. REV. 87, 90 (1960) ("Any non-frivolous, non-injurious use, even if only in a laboratory, will suffice.").

<sup>30.</sup> John F. Duffy, Embryonic Inventions and Embryonic Patents: Prospects, Prophecies, and Pedis Possessio, in Perspectives on Commercializing Innovation 234, 235 (F. Scott Kieff & Troy A. Paredes eds., 2012).

<sup>31.</sup> Peter Lee, Patents and the University, 63 DUKE L.J. 1, 23-24 (2013).

<sup>32.</sup> See infra Part II.A (discussing how altering the scope of claims can better avoid this blocking problem).

<sup>33.</sup> See infra notes 149–150 and accompanying text (noting that patents can block future uses which are not disclosed or known when the patent is granted).

<sup>34.</sup> See infra note 159 and accompanying text (acknowledging that courts are willing to tolerate upstream patents as long as the original inventor can articulate a practical use).

to promote scientific progress.<sup>35</sup> Throughout most of U.S. patent law's history, the courts and Patent Office agreed that research inputs like X were patentable despite the lack of a known practical application.<sup>36</sup>

This Article responds to these questions by introducing a new form of intellectual property—a research patent—which would allow an inventor to claim X "for use in research."<sup>37</sup> The nuts and bolts of acquiring a research patent would be the same as a traditional patent. And like a traditional patent, a research patent owner could extract its full value through licensing and enforcement. Remedies for infringement would include injunctive relief and damages based on the value of noninfringing products (like X) that emerge from the infringing research.<sup>38</sup>

A few additional points about the proposal bear mentioning here. First, it admittedly goes against the grain of most legal scholarship on patent reform, which seeks to *raise* patentability standards or otherwise make patents harder to obtain.<sup>39</sup> But the limited protection offered by research patents should allay concerns about overbreadth or quality. Second, implementing the proposal would not require a substantial investment of resources or a major reform of the current regime. Although the Patent Office would have to recognize a new form of patent protection, examining research patent applications would place little additional burden on the agency. Third, the ability to obtain a patent on early-stage basic research (which is *not* possible under the current regime)<sup>40</sup> would provide robust incentives for

<sup>35.</sup> The constitutional mandate of the patent system is "[t]o promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries." U.S. CONST. art. I, § 8, cl. 8. After Manson, the Supreme Court stated that "[t]he patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts." Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980). For commentary on patent law's instrumental justification, see Arti Kaur Rai, Regulating Scientific Research: Intellectual Property Rights and the Norms of Science, 94 Nw. U. L. Rev. 77, 116 n.215 (1999).

<sup>36.</sup> See infra note 49 and accompanying text (citing cases holding that value for educational and research purposes is sufficient to establish utility).

<sup>37.</sup> See infra Part II (introducing the research patent concept).

 $<sup>38.\</sup> See\ infra$  Part II (explaining the enforcement mechanisms of the proposed research patents).

<sup>39.</sup> See generally, e.g., Burk & Lemley, supra note 27 (discussing how the patent system can best adapt to the modern world); ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS (2004) (discussing how the current patent system is stifling innovation and progress); Michael J. Meurer, Patent Examination Priorities, 51 Wm. & Mary L. Rev. 675 (2009) (assessing how the Patent Office may more efficiently set its patent application examination priorities).

<sup>40.</sup> See supra notes 15-19 and accompanying text (laying out the current regime and its rationale).

inventors to opt for research patents.<sup>41</sup> Fourth, an inventor who gets a research patent on X could still obtain a traditional patent on the compound if the traditional patent application is timely filed.<sup>42</sup> Thus, the research patent could serve as a placeholder for a traditional patent, thereby creating an incentive for the inventor to (quickly) seek potential practical applications for X.<sup>43</sup> Fifth, implementing research patents would promote the disclosure, development, and use of X—which all align with the patent system's basic goal "to protect and promote advances in science and technology."

The remainder of the Article proceeds as follows. Part I explores how and why research inputs in unpredictable technologies receive harsh scrutiny in the patent system. Part II introduces research patents. It discusses how they would be acquired and enforced as well as what happens when a practical use for the research input is discovered. Finally, Part III explores the policy implications of research patents. It offers a theoretical justification for the proposal, addresses concerns about (too much) patent-owner control of downstream uses, and makes the normative case for giving research its due in patent law.

### I. ARE RESEARCH INPUTS (INHERENTLY) USEFUL?

### A. Utility as a Patentability Lever

The vagueness of the term "useful," combined with the absence of legislative guidance, makes utility the most malleable patentability requirement.<sup>45</sup> Malleability makes sense in patent law. As technology evolves, patent law must respond.<sup>46</sup> But malleability also allows the

<sup>41.</sup> For example, an early-stage patent allows its owner to play a role in coordinating the future development of the technology. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276-77 (1977) (articulating the prospect theory of patents).

<sup>42.</sup> See infra Part II (explaining what would happen to a research patent when a practical application is discovered).

<sup>43.</sup> Cf. Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI. L. REV. 1017, 1023 n.26 (1989) (discussing incentives for researchers "to keep an eye out for potential commercial applications").

<sup>44.</sup> Bilski v. Kappos, 561 U.S. 593, 617 (2010) (Stevens, J., concurring); see also supra note 35 and accompanying text (discussing the constitutional mandate of the patent system).

<sup>45.</sup> Machin, supra note 11, at 425 ("[D]ifferent observers see in it different things."); see also John F. Duffy, Rules and Standards on the Forefront of Patentability, 51 WM. & MARY L. REV. 609, 639 (2009) (noting that the utility requirement is governed by a "standard[] requiring judgments on a range of factors that admit of no precise lines"); Mark P. McKenna & Christopher Jon Sprigman, What's In, and What's Out: How IP's Boundary Rules Shape Innovation, 30 HARV. J.L. & TECH. 491, 508–16 (2017) (arguing that patent law lacks a coherent theory of utility).

<sup>46.</sup> This makes sense because "any law[s] purporting to provide a regulatory foundation for innovation must be able to account for both the broad range of technologies and the rapid pace of [technological] change." R. Polk Wagner, Of Patents and Path Dependency: A Comment on Burk and Lemley, 18 BERKELEY TECH. L.J. 1341, 1344 (2003).

courts to create technology-specific patentability standards to achieve certain outcomes.<sup>47</sup> To wit, the courts have imposed a clear but harsh utility standard for chemical inventions. If the only known use of a chemical compound at the time of filing is for research, it lacks utility within the meaning of the Patent Act.<sup>48</sup>

Until the mid-twentieth century, a de minimis utility standard applied to *all* inventions.<sup>49</sup> *Some* beneficial use was sufficient<sup>50</sup> unless the invention was inoperable<sup>51</sup> or detrimental to the public interest.<sup>52</sup> As noted in one treatise:

Want of utility is a bar seldom raised against an application by the Patent Office and seldom successfully employed as a defense in [litigation] . . . . [U]tility in its broadest sense approaches a presumption more nearly than any other point recited in the statute and is seldom questioned by the courts or the Patent Office . . .  $^{53}$ 

Putting aside inventions that were once deemed immoral,<sup>54</sup> utility was rarely questioned during this era:

- 47. Cf. Risch, supra note 29, at 1222 ("Recognition of a normative bias against basic science is important; it frees... the courts to either embrace or oppose basic science by varying utility requirements in a particular technological field.... [T]o the extent the field is favored, ... utility could be made easier to prove.").
  - 48. Brenner v. Manson, 383 U.S. 519, 535 (1966).
- 49. See, e.g., Potter v. Tone, 36 App. D.C. 181, 184-85 (D.C. Cir. 1911) (rejecting the contention that a compound must have a commercial use and holding that its disclosure in the patent document had value for educational and research purposes sufficient to establish utility); Ex parte Watt, 63 U.S.P.Q. 163, 165 (Pat. Off. Bd. App. 1942) (determining that a chemical compound whose sole use was that of a chemical intermediate met the utility requirement).
  - 50. Bedford v. Hunt, 3 F. Cas. 37, 37 (Story, Circuit Justice, C.C.D. Mass. 1817) (No. 1,217).
- 51. The issue is whether the invention could achieve its intended result. See infra notes 82–84 and accompanying text (discussing the three prongs of the utility test).
- 52. Bedford, 3 F. Cas. at 37. Justice Story believed that the market should be the best judge of an invention's utility. Lowell v. Lewis, 15 F. Cas. 1018, 1019 (Story, Circuit Justice, C.C.D. Mass. 1817) (No. 8,568) ("[Whether the invention] be more or less useful [than existing products] is a circumstance very material to the interests of the patentee, but of no importance to the public. If it be not extensively useful, it will silently sink into contempt and disregard.").
- 53. 1 WALTER F. ROGERS, THE LAW OF PATENTS AS ILLUSTRATED BY LEADING CASES 9 (1914), quoted in part in In re Nelson, 280 F.2d 172, 180 (C.C.P.A. 1960). The U.S. Court of Customs and Patent Appeals ("C.C.P.A.") was a five-judge Article III appellate court on the same level as the U.S. Courts of Appeals. The Federal Courts Improvement Act of 1982 abolished the C.C.P.A. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.). Soon after its creation, the Federal Circuit adopted C.C.P.A. decisional law as binding precedent. See S. Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (en banc) ("That body of law represented by the holdings of the Court of Claims and the Court of Customs and Patent Appeals . . . is herewith adopted by this court sitting in banc.").
- 54. Most noteworthy here were patents for gambling devices. See Nat'l Automatic Device Co. v. Lloyd, 40 F. 89, 90 (C.C.N.D. Ill. 1889) ("[T]he only use to which the invention has been put being for gambling purposes, I must hold that it is not a useful device, within the meaning of the patent law, as its use so far has been only pernicious and hurtful."); Brewer v. Lichtenstein, 278 F. 512, 513 (7th Cir. 1922) (holding that a patent with "[n]o other utility than as a lottery device . . . has no useful function"). But this is no longer the law. See Ex parte Murphy, 200 U.S.P.Q. 801, 803 (Pat. Off. Bd. App. 1977) (reversing an examiner's lack-of-utility rejection for a

[I]n all the years we have had a [P]atent [O]ffice . . . , there has never been the slightest obedience to the requirement that inventions must be found useful. . . . Not only is it the fact that the Patent Office pays no heed to the requirement of utility, but it is also true that when one attempts to distinguish an invention from a prior patent by showing that the invention is operative and useful while the prior patent . . . is wholly inoperative and consequently not useful, he fails to make the slightest impression upon the Patent Office . . . . <sup>55</sup>

The standard was truly de minimis.<sup>56</sup>

Throughout most of U.S. patent law's history, the courts and Patent Office agreed that chemical compounds had utility despite the lack of a practical use.<sup>57</sup> As Justice Harlan explained in his *Manson* dissent, "usefulness was typically regarded as *inherent* during a long and prolific period of chemical research and development in this country."<sup>58</sup> But in the 1950s, the Patent Office abandoned its liberal utility standard for chemical inventions.<sup>59</sup> This triggered a clash between the Patent Office and the U.S. Court of Customs and Patent Appeals ("C.C.P.A.")<sup>60</sup> over the inherent utility of chemical compounds.

A key opinion addressing this issue is the 1960 case *In re Nelson.*<sup>61</sup> The applicant sought to patent several compounds known as intermediates—chemicals whose purpose is to serve as a research input

claim to a slot machine), cited with approval in Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367 (Fed. Cir. 1999) (explaining that there is no basis in 35 U.S.C. § 101 to deem an invention unpatentable for a lack of utility because it has capacity to deceive).

- 55. Wm. Macomber, Judicial Discretion in Patent Causes, 24 YALE L.J. 99, 105 (1914).
- 56. "As to the term 'useful,' the courts have construed the condition expressed by it so liberally that it almost never serves to defeat a patent." HENRY CHILDS MERWIN, THE PATENTABILITY OF INVENTIONS 75 (Boston, Little, Brown & Co. 1883), quoted in Nelson, 280 F.2d at 179.
- 57. See supra note 49 and accompanying text (citing cases holding that certain chemical patents met the utility requirement).
- 58. Brenner v. Manson, 383 U.S. 519, 540 (1966) (Harlan, J., concurring in part and dissenting in part) (emphasis added).
- 59. In 1956, the Commissioner of Patents squarely rejected the Patent Office's pre-war liberal view of utility in chemical cases:

[I]n the past very little attention was paid to the requirement for a disclosure of utility in chemical cases. Some chemical patents were issued with specifications reciting the barest suggestions of uses for the new compounds claimed, or even without uses being stated at all. It was generally the position of the Patent Office that a chemical compound could be regarded as an intermediate substance useful in the preparation of other compounds, since it was regarded as obvious that any organic compound could be so used.

In re Kirk, 376 F.2d 936, 952–53 (C.C.P.A. 1967) (Rich, J., dissenting) (quoting Robert C. Watson, Comm'r of Pats., U.S. Pat. Off., Remarks to the Division of Medicinal Chemistry of the American Chemical Society (Sept. 19, 1956)). There was a C.C.P.A. decision in the 1950s that aligned with the Commissioner's view. See In re Bremner, 182 F.2d 216, 217 (C.C.P.A. 1950) (affirming the rejection of a claim to a chemical because there was neither an assertion of utility nor "anything indicating what use of the product may be made"). The C.C.P.A., however, eventually reverted back to a liberal utility standard. See In re Szwarc, 319 F.2d 277, 285 (C.C.P.A. 1963) (rejecting Bremner), cited in Manson, 383 U.S. at 530.

- 60. See supra note 53 (discussing the C.C.P.A.).
- 61. 280 F.2d at 180, overruled by Kirk, 376 F.2d at 946.

for other compounds.<sup>62</sup> The issue was whether an intermediate has its own utility or whether the applicant had to disclose a use for the final product in order to patent the intermediate.<sup>63</sup> Writing for the majority,<sup>64</sup> Judge Giles Rich (the codrafter of the 1952 Patent Act and regarded by many as "the founding father of modern patent law")<sup>65</sup> explained that requiring the latter would frustrate fundamental goals of the patent system:

We have never received a clear answer to the question "Useful to whom and for what?" Surely a new group of steroid intermediates is useful to chemists doing research on steroids.... They are often actually placed on the market before much, if anything, is known as to what they are "good" for, other than experimentation and the making of other compounds in the important field of research. Refusal to protect them at this stage would inhibit their wide dissemination, together with the knowledge of them which a patent disclosure conveys, which disclosure the potential protection encourages. This would tend to retard rather than promote progress. <sup>66</sup>

The Supreme Court settled the conflict concerning the intrinsic utility of chemical compounds in *Brenner v. Manson*.<sup>67</sup> The case was about Manson's attempt to provoke an interference—a fight between two inventors over who is entitled to a patent.<sup>68</sup> The invention was a new process for making a steroid ("S"). By the time Manson filed his patent application, the Patent Office had already issued a patent on the process to a competitor.<sup>69</sup> Although Manson could prove that he was the

<sup>62.</sup> *Id.* For example, a chemist reacts A + B to make I (the intermediate). Then, the chemist can react I with C, D, or something else to make other compounds.

<sup>63.</sup> *Id.* at 175. Interestingly, Nobel Laureate and legendary organic chemist Robert B. Woodward obtained a patent on a chemical intermediate in 1957. Production of Steroid Intermediate, U.S. Patent No. 2,802,873 (filed Apr. 13, 1951) (issued Aug. 13, 1957). The intermediate's asserted usefulness "in the production of steroids, particularly the adrenal cortical hormones such as cortisone" cleared the 35 U.S.C. § 101 hurdle since cortisone had a well-established utility. *See id.* col. 2, ll. 1–2 (explaining the utility of the patent).

<sup>64.</sup> For dissenting views, see *Nelson*, 280 F.2d at 190 (Worley, J., dissenting) ("[G]ranting a patent here will...give appellants an unearned monopoly on a substantial area in the field of chemistry..."); *id.* at 190–92 (Kirkpatrick, J., dissenting) (accusing the majority of reading "useful" out of the patent statute).

<sup>65.</sup> F. Scott Kieff, Pauline Newman, Herbert F. Schwartz & Henry E. Smith, Principles of Patent Law 24 (5th ed. 2011). Judge Rich joined the C.C.P.A. in 1956 and later served on the Federal Circuit until his death in 1999 at age ninety-five. *Id*.

<sup>66.</sup> Nelson, 280 F.2d at 180-81 (emphasis added).

<sup>67. 383</sup> U.S. 519 (1966).

<sup>68.</sup> Under the first-to-invent system, patent rights are awarded to the first inventor. 35 U.S.C. § 102(g) (repealed by the America Invents Act of 2011 ("AIA")). When two parties claim the same invention, the Patent Office institutes an "interference" proceeding to determine priority (i.e., which party is entitled to a patent). *Id.* The first party to reduce the invention to practice usually wins; however, a party that was "first to conceive the invention but last to reduce it to practice" (either actively or constructively) will win if that party "demonstrates reasonable diligence [toward] reduction to practice." Cooper v. Goldfarb, 240 F.3d 1378, 1382 (Fed. Cir. 2001).

<sup>69.</sup> See Process for the Production of 2-Methyl-Dihydrotestosterones, U.S. Patent No. 2,908,693 (filed Dec. 17, 1956) (issued Oct. 13, 1959).

first to invent the process, the examiner would not declare an interference because Manson failed to disclose a utility for  $S^{.70}$ 

Manson argued that *S*'s utility could be presumed because similar steroids were known to inhibit tumors in mice.<sup>71</sup> The Patent Office disagreed because, in its view, the unpredictable nature of steroid chemistry made it impossible to presume that *S* would have the same tumor-inhibiting properties.<sup>72</sup> A divided C.C.P.A. reversed, holding that "a process which operates as disclosed to produce a known product is [itself] 'useful' within the meaning of section 101."<sup>73</sup>

The Supreme Court reversed the C.C.P.A. and resolved the question about the intrinsic utility of chemical inventions. It held that an inventor seeking to patent a new process for making a compound could only do so if the inventor establishes utility for the compound.<sup>74</sup> Unless and until a chemical invention can provide a *specific* benefit in its currently available form, "there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."<sup>75</sup> A patent could become a "hunting license,"<sup>76</sup> conferring the power to "block off whole areas of scientific development, without compensating benefit to the public."<sup>77</sup> Dmitry Karshtedt provides a hypothetical that illustrates the fear:

[T]he concern behind allowing a patent on a chemical compound without an identified consumer utility is that subsequent researchers who discover such a use—for example, biological activity against cancer cells—will be beholden to the owner of the patent on the compounds. The patentee might threaten litigation to enjoin downstream research, charge an unreasonable royalty, or tie up the follow-on researcher in extensive, costly negotiations over the patent right. Faced with this prospect, the follow-on researcher

<sup>70.</sup> When a person believes that he or she is the inventor of the subject matter claimed by another in a patent application or issued patent, the remedy is to file a patent application claiming that subject matter to "provoke" an interference with the other application or issued patent. See 35 U.S.C. § 135 (pre-AIA) (describing the structure of interference proceedings).

<sup>71.</sup> Manson, 383 U.S. at 521-22.

<sup>72.</sup> As stated by the Board, "It is our view that the statutory requirement of usefulness of a product cannot be presumed merely because it happens to be closely related to another compound which is known to be useful." *Id.* at 522. This is true because "minor changes in the structure of a steroid may produce profound changes in its biological activity." *Id.* at 532 n.19 (quoting Transcript of Record at 52, *Manson*, 383 U.S. 519 (No. 58)).

<sup>73.</sup> In re Manson, 333 F.2d 234, 236 (C.C.P.A. 1964). The court's rationale was that a process is a separate category of invention specifically recognized in the statute. See also 35 U.S.C. § 100(b) ("The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."); id. § 101 ("Whoever invents or discovers any new and useful process . . . .").

<sup>74.</sup> Manson, 383 U.S. at 531, 534-35.

<sup>75.</sup> Id. at 534-35.

<sup>76.</sup> Id. at 536.

<sup>77.</sup> Id. at 534 (footnote omitted).

might forgo investigating a certain chemical structure during the life of the patent, and society would then lose out  $\dots$ .<sup>78</sup>

So the fear is that an early-stage patent on a research input could become a "bottleneck" that stifles downstream research and innovation.<sup>79</sup>

## B. The Current Paradigm

Inventions emerging from unpredictable fields receive special scrutiny in patent law. For example, as described by one judge, inventors in the field of chemistry are "improperly set apart from all inventors as a class" and are burdened with special requirements, including the need for "more of a disclosure of utility... than what [the Patent Office and the courts] require from inventors in the other technical areas." 81

The current utility test has three prongs. The first prong, operability, requires that the invention be capable of achieving its intended result.<sup>82</sup> The question is whether a person having ordinary skill in the art ("PHOSITA")<sup>83</sup> would consider the inventor's assertions credible.<sup>84</sup>

<sup>78.</sup> Karshtedt, supra note 28, at 966 (footnotes omitted); see also Katherine J. Strandburg, What Does the Public Get? Experimental Use and the Patent Bargain, 2004 Wis. L. Rev. 81, 123 (2004) ("The concern with patented research tools arises from the fear that a research tool may give the tool inventor the ability to block technological progress by controlling the research that may be performed using the tool . . . . "); Peter Yun-hyoung Lee, Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on Biotechnology Research Tools, 19 HARV. J.L. & TECH. 79, 81 (2005) ("Allowing [patents] 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.").

<sup>79.</sup> Karshtedt, supra note 28, at 967.

<sup>80.</sup> In re Joly, 376 F.2d 906, 929 (C.C.P.A. 1967) (Smith J., dissenting).

<sup>81.</sup> Id.; cf. David A. Anderson & Edward E. Dyson, Editorial Note, Some Special Problems with the Utility Requirement in Chemical Patents, 35 GEO. WASH. L. REV. 809, 817 (1967) (explaining that Manson and its progeny "will work a hardship on chemical researchers, who have now been excluded from the class of people for whom compounds are 'useful'"); Brent Nelson Rushforth, Comment, The Patentability of Chemical Intermediates, 56 CALIF. L. REV. 497, 513 (1968) (same).

<sup>82.</sup> Mitchell v. Tilghman, 86 U.S. (19 Wall.) 287, 396 (1873).

<sup>83.</sup> The PHOSITA is a hypothetical construct of patent law akin to the reasonably prudent person in torts. See Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987). Factors relevant to constructing the PHOSITA in a particular technical field include the sophistication of the technology, the educational level of the inventor, the educational level of active workers in the field, the types of problems encountered in the art, the prior art solutions to those problems, and the rapidity with which innovations are made. Env't Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 696 (Fed. Cir. 1983).

<sup>84.</sup> The Patent Office can establish reasonable doubt if the applicant's disclosure "suggests an inherently unbelievable undertaking or involves implausible scientific principles." *In re* Cortright, 165 F.3d 1353, 1357 (Fed. Cir. 1999) (quoting *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995)).

The two other prongs, "specific" and "substantial" utility, were identified but not fully defined in *Manson*. 85 The U.S. Court of Appeals for the Federal Circuit did define these terms in *In re Fisher* 86 when it adopted the Patent Office's guidelines for assessing utility. 87 For *substantial utility*, a PHOSITA must be able to use the invention to provide a "significant" and "immediate" benefit to the public. 88 The patent application "must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research." 89 So basic research, chemical intermediates, and methods of making a chemical compound where the compound itself has no identifiable utility all fail this prong. 90 Thus, this prong is rooted both in ripeness concerns (avoiding problems that might arise from granting patent protection too early) 91 and the

<sup>85.</sup> See Brenner v. Manson, 383 U.S. 519, 534-35 (1966) (briefly mentioning specific and substantial utility).

<sup>86. 421</sup> F.3d 1365, 1371-72 (Fed. Cir. 2005).

<sup>87.</sup> Id. at 1372 ("The [Patent Office's] standards for assessing whether a claimed invention has a specific and substantial utility comport with this court's interpretation . . . .") (citing U.S. Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 1,092 (Jan. 5, 2001) [hereinafter Utility Examination Guidelines]). The guidelines have been incorporated into the Manual of Patent Examining Procedure. See U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure. See U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure. \$2107 (2018), https://www.uspto.gov/web/offices/pac/mpep/old/e9r08-2017/mpep-2100.pdf [https://perma.cc/LBM7-VQN9] [hereinafter MPEP] (detailing guidelines for examination of applications for compliance with the utility requirement).

<sup>88.</sup> Fisher, 421 F.3d at 1371 (citing Nelson v. Bowler, 626 F.2d 853, 856 (C.C.P.A. 1980)).

<sup>89.</sup> Id. The Patent Office's view is that "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient...." MPEP, supra note 87, § 2107.01(I)(B). Ultimately, examiners "must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm." Id. § 2107.01(I)(C).

<sup>90.</sup> See MPEP, supra note 87, § 2107.01(I)(B) (identifying each of these as unpatentable); 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 Manson, 383 U.S. at 534)). But this is only true in unpredictable technologies. See Cohen & Schwartz, supra note 29, at 90 (noting that outside the chemical context courts are more liberal about finding utility); Note, The Utility Requirement in the Patent Law, 53 GEO. L.J. 154, 157 (1964) (explaining that in the mechanical arts, "if the function of the end product satisfies the statutory requirement of utility, that satisfaction is imputed to the intermediate contributing invention."). Dmitry Karshtedt suggests that there might be an unwritten "completeness" requirement of patentability which "is concerned with whether . . . the invention is too foundational to qualify for a patent." Karshtedt, supra note 28, at 952 (footnote omitted). Such inventions include "artifacts of basic research." Id. at 952 n.16.

<sup>91.</sup> See Manson, 383 U.S. at 534-35 (articulating concerns surrounding granting a patent too early); Dan L. Burk & Mark A. Lemley, Policy Levers in Patent Law, 89 VA. L. REV. 1575, 1646 (2003) (explaining that the rule emerging from Manson is that "[b]y giving patent protection too early—before the actual use of the product has been identified—patent law might deter research by others on the use of the product.").

substantive view that research inputs in unpredictable fields (like chemical intermediates)<sup>92</sup> lack a legally acceptable utility.<sup>93</sup>

Finally, *specific utility* requires that an invention "provide a well-defined and particular benefit to the public." This prong denies patents for inventions where the asserted use is "so vague as to be meaningless." For example, usefulness for "biological activity" or "pharmaceutical purposes" fail the requirement.96

A lack-of-utility rejection triggers a burden-shifting process.<sup>97</sup> Once the examiner has established a prima facie case of a lack of utility, the burden shifts to the applicant to either attack or rebut it.<sup>98</sup> An applicant can successfully attack the prima facie case if the examiner produces no (or insufficient) evidence to support a finding of a lack of utility.<sup>99</sup> Alternatively, an applicant can concede the prima facie case and rebut it. So, for example, if specific utility is at issue, the applicant must come forward with persuasive arguments or proof that the invention provides an immediate benefit to the public.<sup>100</sup> A preponderance of the evidence is the standard of proof.<sup>101</sup> Whether an invention complies with the utility requirement of § 101 is a question of fact.<sup>102</sup>

<sup>92.</sup> See supra note 62 and accompanying text (discussing a case involving chemical intermediates).

<sup>93.</sup> Sean B. Seymore, Foresight Bias in Patent Law, 90 NOTRE DAME L. REV. 1105, 1118–20 (2015) (discussing patent law's aversion to building block inventions like chemical intermediates).

<sup>94.</sup> Fisher, 421 F.3d at 1371.

<sup>95.</sup> Id.

<sup>96.</sup> See, e.g., Ex parte Aggarwal, 23 U.S.P.Q.2d 1334, 1339 (B.P.A.I. 1992) ("There is no question that appellants have made an important discovery with regard to chemical compounds (proteins) which are the subject of serious scientific investigation but [it is nevertheless unpatentable because of its] unverified and speculative utility.").

<sup>97.</sup> In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (describing the framework).

<sup>98.</sup> See id. ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

<sup>99.</sup> MPEP, supra note 87, § 2107(II)(C); see also In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (explaining that the examiner bears the initial burden of presenting a prima facie case of unpatentability); Fregeau v. Mossinghoff, 776 F.2d 1034, 1038 (Fed. Cir. 1985) (applying the prima facie case to 35 U.S.C. § 101).

<sup>100.</sup> See supra note 88 and accompanying text (discussing one prong of the utility requirement).

<sup>101.</sup> Oetiker, 977 F.2d at 1445; see also In re Langer, 503 F.2d 1380, 1395 (C.C.P.A. 1974) (affirming the Patent Office's rejection of the applicant's claims because the prima facie case for lack of utility remained un-rebutted).

<sup>102.</sup> Raytheon Co. v. Roper Corp., 724 F.2d 951, 956 (Fed. Cir. 1983).

#### C. The "Double Standard"

The harsh treatment of research inputs implicates a quintessential paradox in patent law. This paradox involves novelty—the statutory requirement that an invention be new. 103 If the invention is already known, society loses free access to knowledge already in the public domain 104 and thus receives no benefit from a patent's issuance. 105

Assessing novelty requires a comparison of the claimed invention with the prior art—preexisting knowledge and technology already in the public domain. 106 Documents (like issued patents and printed publications), devices, and activities are sources of prior art. 107 A specific document, device, or activity asserted against the claimed invention is called a prior art reference. 108

The America Invents Act of 2011 ("AIA") converted the U.S. patent system from a first-to-invent regime to a first-inventor-to-file regime.<sup>109</sup> To qualify as novelty-defeating prior art under the AIA,<sup>110</sup> a reference must satisfy three criteria. First, it must predate the

<sup>103. 35</sup> U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent . . . ." (emphasis added)).

<sup>104.</sup> Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989); Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

<sup>105.</sup> George Ticknor Curtis, A Treatise on the Law of Patents for Useful Inventions § 292, at 394 (Boston, Little, Brown & Co. 2d ed. 1854). The essence of the U.S. patent system is a quid pro quo between the patentee and the public. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 63 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time."). If the invention is already in the public domain, a patent should not issue because the inventor cannot give the public anything that it does not already possess. Pennock v. Dialogue, 27 U.S. (2 Pet.) 1, 23 (1829); see also Robert P. Merges, Uncertainty and the Standard of Patentability, 7 High Tech. L.J. 1, 12–13 (1992) (explaining that the logic behind the novelty requirement "is fairly straightforward . . . [because if] information is already in the public domain when the 'inventor' seeks to patent it[,] society has no need to grant a patent to get this information").

<sup>106.</sup> Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984) (citing Graham, 383 U.S. at 6).

<sup>107.</sup> See 35 U.S.C. § 102(a) (outlining what may be considered prior art). For a comprehensive discussion of prior art categories, see Timothy R. Holbrook, *Prior Art and Possession*, 60 WM. & MARY L. REV. 123, 148–83 (2018).

<sup>108.</sup> HERBERT F. SCHWARTZ, PATENT LAW AND PRACTICE 18 (3d ed. 2001).

<sup>109.</sup> See Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285-87 (2011) (amending § 102(a) and repealing § 102(g)).

<sup>110.</sup> Prior art is also used to gauge nonobviousness—the statutory requirement that bars a patent if the claimed invention is a trivial extension of what is already known. See 35 U.S.C. § 103 (requiring that the claim is not obvious to a PHOSITA).

applicant's filing date.<sup>111</sup> Second, the applicant's claimed invention<sup>112</sup> must be identically disclosed or described within the four corners of the reference.<sup>113</sup> Third, the reference must be *enabling*—meaning that it must disclose the invention in sufficient detail to teach a PHOSITA how to make it without undue experimentation.<sup>114</sup> A reference satisfying all three criteria "anticipates" the applicant's claim<sup>115</sup> and renders it unpatentable.<sup>116</sup> Anticipation is a question of fact.<sup>117</sup>

The enablement criterion is particularly relevant here. Enablement questions typically arise in two contexts in patent law. Section 112(a) compels a patent applicant to submit a written description of the invention<sup>118</sup> that is sufficient to enable a PHOSITA to make and use it without undue experimentation.<sup>119</sup> This statutory or

<sup>111.</sup> Id. § 102(a)(1) (denying patentability if "the claimed invention was patented... before the effective filing date of the claimed invention"); id. § 102(a)(2) (denying patentability if "the claimed invention was described in a patent... [which] names another inventor and was effectively filed before the effective filing date of the claimed invention").

<sup>112.</sup> A patent claim must define "the subject matter which the [applicant]  $\dots$  regards as the invention." Id. § 112(b).

<sup>113.</sup> For example, if an applicant seeks to claim a paper clip made with titanium and nickel, the reference must also disclose a paper clip made with titanium and nickel. Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 923 (2011). In this hypothetical, titanium and nickel are claim elements.

<sup>114.</sup> In re Morsa, 713 F.3d 104, 110 (Fed. Cir. 2013). Determining whether a disclosure in an asserted reference is enabling for novelty-defeating purposes is a legal conclusion that rests on underlying factual inquiries. Sitrick v. Dreamworks, LLC, 516 F.3d 993, 999 (Fed. Cir. 2008). The Federal Circuit has set forth several factors relevant to the enablement analysis in In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). They are: (1) the amount of direction or guidance presented in the disclosure, (2) the existence of working examples, (3) the nature of the invention, (4) the predictability or unpredictability of the art, (5) the PHOSITA's level of skill, (6) the state of the prior art, (7) the breadth of the claims, and (8) the quantity of experimentation necessary to practice the claimed invention. Impax Lab'ys., Inc. v. Aventis Pharms. Inc., 545 F.3d 1312, 1314–15 (Fed. Cir. 2008) (applying the Wands factors in the anticipatory enablement context).

<sup>115.</sup> See In re Skvorecz, 580 F.3d 1262, 1266 (Fed. Cir. 2009) ("A rejection for 'anticipation' means that the invention is not new.").

<sup>116.</sup> See In re Morsa, 803 F.3d 1374, 1377 (Fed. Cir. 2015) (finding that a reference was disclosed and enabling, preventing a patent); Impax Lab'ys., 545 F.3d at 1314 (finding that a reference was not enabling, and thus did not anticipate the claims). Thus, "anticipation is the converse of novelty: if an invention lacks novelty, it is anticipated." Timothy R. Holbrook, Patent Anticipation and Obviousness as Possession, 65 EMORY L.J. 987, 993 (2016).

<sup>117.</sup> In re Hyatt, 211 F.3d 1367, 1371 (Fed. Cir. 2000) (citing Bischoff v. Wethered, 76 U.S. (9 Wall.) 812, 814–15 (1869)).

<sup>118.</sup> The written description is the part of the patent document that completely describes the invention. 35 U.S.C. § 112(a). It includes background information, a summary of the invention, and a detailed description of it. MUELLER, *supra* note 12, at 1167. Although I will not discuss it in this Article, the terms "written description" and "specification" are often used interchangeably (and mistakenly) in patent law. KIEFF ET AL., *supra* note 65, at 155 n.4.

<sup>119.</sup> See 35 U.S.C. § 112(a) ("The specification shall contain a written description of the invention... as to enable [a PHOSITA]... to make and use the same...."). Although "undue experimentation" does not appear in the statute, "it is well established that enablement requires that the [written description] teach those in the art to make and use the invention without undue experimentation." Wands, 858 F.2d at 737.

patent-supporting form of enablement places an outer limit on the scope of the claims. The nonstatutory, patent-defeating form applied for anticipation purposes asks whether a PHOSITA in possession of the prior art reference could *make* the invention without undue experimentation. Thus, the enablement standard for patentability differs from the enablement standard for anticipation: *a prior disclosure of the invention that does not teach a PHOSITA how to use it can still serve as prior art.* 

This "double standard"<sup>125</sup> has created one of patent law's major paradoxes: making or describing how to make a research input can serve as anticipatory prior art and thus be patent-defeating, yet the research input itself is unpatentable if it lacks a practical utility. <sup>126</sup> While this standard makes sense, <sup>127</sup> it frustrates patent policy by encouraging inventors to delay disclosure and maintain secrecy unless and until a practical application is discovered. <sup>128</sup>

To illustrate, consider a university researcher who invents X and discloses its method of preparation in a peer-reviewed scientific journal. Suppose the researcher subsequently discovers a practical use for X.

<sup>120.</sup> The scope of the claims must "be less than or equal to the scope of the enablement." Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999). The scope of enablement "is that which is disclosed in the [written description] plus the scope of what would be known to [a PHOSITA] without undue experimentation." Id.

<sup>121.</sup> Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1355 (Fed. Cir. 2005). "Enablement" does not appear within the text of § 102. Anticipatory enablement is a "judicially imposed limitation" on § 102 that the description of the subject matter in the reference must be an enabling description. *In re* LeGrice, 301 F.2d 929, 939 (C.C.P.A. 1962).

<sup>122.</sup> Novo Nordisk, 424 F.3d at 1355 (citing Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1325 (Fed. Cir. 2005)); see also In re Hafner, 410 F.2d 1403, 1405 (C.C.P.A. 1969) (affirming a patent rejection for failure to disclose how to use the invention).

<sup>123.</sup> Verizon Servs. Corp. v. Cox Fibernet Va., Inc., 602 F.3d 1325, 1337 (Fed. Cir. 2010) ("The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102...differs from the enablement standard under section 112." (quoting Rasmusson, 413 F.3d at 1325)).

<sup>124.</sup> In re Gleave, 560 F.3d 1331, 1335 (Fed. Cir. 2009) (citing Rasmusson, 413 F.3d at 1326). Judge Rich provided a statutory basis for the distinction, noting that § 112 provides that the written description "must enable [the PHOSITA] to 'use' the invention whereas § 102 makes no such requirement as to an anticipatory disclosure." Hafner, 410 F.2d at 1405.

<sup>125.</sup> Hafner, 410 F.2d at 1405 (explaining that the "double standard" is "implicitly[,] if not explicitly, required by law").

<sup>126.</sup> This was the factual scenario in Hafner. Id. at 1403-05.

<sup>127.</sup> For example, if a description of how to make a chemical compound is in the public domain, it would seem unjust to allow an inventor who discovers a new use to obtain a patent on the compound. In other words, a patent cannot deny free access to knowledge already available to the public. See sources cited supra note 104 (providing two examples of courts protecting knowledge in the public domain).

<sup>126.</sup> See Brenner v. Manson, 383 U.S. 519, 538–39 (1966) (Harlan, J., concurring in part and dissenting in part) (noting that in the chemical research field, the "abstractly logical choice . . . [is] to maintain secrecy until a product use can be discovered"); infra notes 237–248 and accompanying text (discussing how current doctrine incentivizes secrecy).

Unfortunately, the inventor's own prior disclosure in the scientific journal could defeat a subsequent attempt to patent X (by the inventor or a third party) because the journal publication described how to make X before the patent application's filing date, thereby constituting anticipatory prior art.<sup>129</sup> Keep in mind that X was unpatentable when first made because it lacked a practical use.<sup>130</sup> So, from a patentability standpoint, the inventor would have been better off keeping quiet and forgoing (or delaying) publication in the scientific journal.

# D. Utility and Useful Disclosures

Statutory enablement compels the applicant to provide a disclosure that teaches a PHOSITA how to make and use the invention. The how-to-use requirement of § 112(a), however, differs from the utility requirement of § 101. The purpose of the § 112(a) how-to-use requirement is simply to provide a PHOSITA with a meaningful disclosure. So the how-to-use prong of § 112(a) is satisfied if the disclosure teaches a PHOSITA how to use the invention as broadly as it is claimed without undue experimentation.

There is a link between the how-to-use requirement of § 112(a) and the utility requirement of § 101. Case law dictates that an invention lacking utility under § 101 fails to satisfy the how-to-use prong of the enablement requirement of § 112(a) as a matter of law. This makes sense when the § 101 problem is inoperability, because if the invention cannot operate to achieve the intended result, then it is

<sup>129.</sup> Hafner, 410 F.2d at 1405; see also 35 U.S.C. § 102(a)(1) (denying patentability if "the claimed invention was... described in a printed publication... before the effective filing date of the claimed invention"). But the AIA provides a grace period for certain prior disclosures that came directly or indirectly from the inventor. See id. § 102(b) (discussed infra Part II (providing the one year grace period)).

<sup>130.</sup> See supra Part I (discussing utility requirements).

<sup>131.</sup> See supra note 120 and accompanying text (discussing enablement requirements).

<sup>132.</sup> See supra note 119 and accompanying text (discussing the disclosure requirements in the text of  $\S$  112(a)).

<sup>133.</sup> John W. Klooster, Historical Developments of Contemporary Scope, Impact of Section 112 upon Patent Practice, 6 APLA Q.J. 171, 172 (1978); see also In re Nelson, 280 F.2d 172, 181 (C.C.P.A. 1960) (explaining that the purpose of statutory enablement is "the addition [the disclosure] makes to technical literature immediately upon issuance of the patent").

<sup>134.</sup> In re Cortright, 165 F.3d 1353, 1356 (Fed. Cir. 1999) (citing In re Vaeck, 947 F.2d 488, 495–96 (Fed. Cir. 1991)).

<sup>135.</sup> In re Ziegler, 992 F.2d 1197, 1200–01 (Fed. Cir. 1993). But the converse is not true: it is possible to invent something with utility yet still "fail[] so to describe it as to teach the [PHOSITA] how to practice it." Mowry v. Whitney, 81 U.S. (14 Wall.) 620, 644 (1871); see also Paul M. Janicke, Patent Disclosure - Some Problems and Current Developments: Part II, 52 J. PAT. OFF. SOC'Y 757, 768 (1970) (providing examples).

impossible to enable a PHOSITA to use it.<sup>136</sup> But a disclosure can certainly enable a PHOSITA to use an invention yet fall short of the harsh utility threshold currently applied to chemical inventions. The best example is the factual scenario presented in *Brenner v. Manson*.<sup>137</sup> Manson provided an enabling disclosure that taught a PHOSITA how to both make the steroid at issue and how to use it to make other compounds.<sup>138</sup>

This last point reveals the paradoxical nature of the utility requirement as it relates to disclosure. An applicant can disclose X in sufficient detail to enable a PHOSITA to make and use it for  $\S$  112 purposes but nevertheless fail to satisfy the  $\S$  101 utility threshold because X is merely a research input. 139

# II. PATENTING INVENTIONS "FOR USE IN RESEARCH"

This Part proposes a new form of intellectual property—a research patent—which grants patent rights for research inputs that lack a practical application at the time patent protection is sought.

### A. Claiming Research Uses

# 1. The Primacy of the Patent Claim

Judge Giles Rich once stated that in patent law, "the name of the game is the claim."<sup>140</sup> Claims are the numbered sentences at the end of the patent document that define the "technological territory" that the inventor seeks to control<sup>141</sup> and "provide[] the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention."<sup>142</sup>

<sup>136.</sup> In re Swartz, 232 F.3d 862, 863 (Fed. Cir. 2000); Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1358 (Fed. Cir. 1999).

<sup>137.</sup> See supra Part I (discussing the facts, legal proceedings, and outcome of the case).

<sup>138.</sup> See In re Manson, 333 F.2d 234, 238–39 (C.C.P.A. 1964) (discussing the utility requirement and how Manson's disclosure met those requirements). In evaluating Manson's application, the Patent Office never asserted lack of enablement as grounds for unpatentability.

<sup>139.</sup> See In re '318 Pat. Infringement Litig.,  $583 ext{ F.3d } 1317$ , 1324 (Fed. Cir. 2009) (describing how the utility requirement prevents patenting research ideas and objects of research).

<sup>140.</sup> Giles S. Rich, Extent of Protection and Interpretation of Claims – American Perspectives, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990).

<sup>141.</sup> Robert P. Merges & Richard R. Nelson, On the Complex Economics of Patent Scope, 90 COLUM. L. REV. 839, 844 (1990).

<sup>142.</sup> Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989). At the application stage, the inventor dickers with the Patent Office for an expansive exclusory right; in litigation, the parties try to convince the court to construe the claims in their favor. Seymore, *supra* note 5, at 128–29.

For research inputs like chemical compounds, an inventor typically pursues several types of claims.  $^{143}$  For example, if the invention is compound Y, which is useful for treating arthritis, the claim matrix will likely include a "composition" claim to Y, the compound itself,  $^{144}$  and one or more "method" claims directed to making Y or using Y to treat the disease.  $^{145}$  Method claims provide a fallback position if the composition claim is unavailable, rejected by the Patent Office, or invalidated in litigation.  $^{146}$ 

Claims differ in their scope and potential value. Patentees want the broadest claim scope possible. A composition claim affords the most protection. Harold Wegner has explained that

[composition claims] have always been the premium form of patent protection in the chemical industry.... A claim to the compound, per se, dominates every method of making that compound and every single use of that compound, every single mixture of different components that includes that compound, and every end use composition inclusive of the compound.<sup>149</sup>

<sup>143.</sup> See JEFFREY G. SHELDON, HOW TO WRITE A PATENT APPLICATION § 6.5.4 (2009) (providing examples of when and why it is useful to include different statutory classes of claims in a patent application).

<sup>144.</sup> MUELLER, supra note 12, at 520-22.

<sup>145.</sup> See SHELDON, supra note 143, § 6.5.1 (considering different types of claims to file). A typical method claim in this hypothetical scenario might recite "[a] method of treating arthritis comprising administering to a patient a therapeutically effective amount of Y." Sean B. Seymore, Patenting Around Failure, UNIV. PA. L. REV. 1139, 1174 (2018).

<sup>146.</sup> KIRK TESKA, PATENT SAVVY FOR MANAGERS 121 (2007). A composition claim might be unavailable because the compound might be covered by an existing patent or in the public domain. Sean B. Seymore, *Patenting New Uses for Old Inventions*, 73 VAND. L. REV. 479, 498 (2020).

<sup>147.</sup> Merges & Nelson, *supra* note 141, at 839 ("The economic significance of a patent depends on its scope: the broader the scope, the larger the number of competing products and processes that will infringe the patent.").

 $<sup>148.\</sup> In\ re$  Papesch, 315 F.2d 381, 391 (C.C.P.A. 1963) (discussing the "well-recognized advantages" of composition claims).

<sup>149.</sup> HAROLD C. WEGNER, PATENT LAW IN BIOTECHNOLOGY, CHEMICALS & PHARMACEUTICALS § 260 (1992). An inventor of a product need only disclose a single use to satisfy patent law's utility requirement. See In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (accepting a disclosure of chemotherapeutic agents that did not disclose the specific disease against which the agents are used as meeting the utility requirement). But the resulting patent covers the full scope of the product, including all uses. In re Thuau, 135 F.2d 344, 347 (C.C.P.A. 1943); accord Utility Examination Guidelines, supra note 87, at 1095 ("A patent on a composition gives exclusive rights . . . for a limited time, even if the inventor disclosed only a single use for the composition. Thus, a patent granted on an isolated and purified DNA composition confers the right to exclude others from any method of us[e] . . . ." (emphasis omitted)). As Robin Feldman has explained, "Once the inventor identifies a single use for the product, the inventor may exclude others from the full spectrum of the product, including any use of the product and other embodiments of the product. Thus, one embodiment provides an inventor with a broad range of rights." Robin Feldman, Rethinking Rights in Biospace, 79 S. CAL. L. REV. 1, 9 (2005) (footnote omitted).

Every use includes those not discovered or contemplated at the time of filing. The broad scope afforded by a composition claim has considerable practical importance. The research and development required to make X can be a capital-intensive endeavor that would provide firms with little incentive to invent without adequate exclusivity. 151

### 2. Modulating Claim Scope

At present, recall that *no* patent protection is available for research inputs like X that lack a specific and substantial use at the time of filing. <sup>152</sup> The concern is scope: granting the original inventor a claim on X would be too big a reward <sup>153</sup> or provide too much control over downstream activities. <sup>154</sup> The upstream patent holder could possibly block research or the commercialization of new uses discovered by others downstream. <sup>155</sup> Michael Risch explains that

[a] blocking patent stops future improvers from [working on or commercializing] an invention because the underlying technology is patented by someone else. Thus, a patent

150. Thuau, 135 F.2d at 347. For example:

[S]uppose an inventor patents a chemical that is useful for treating an enlarged prostate. . . . Subsequently, a different inventor discovers that the chemical helps to generate hair growth and thus can be used to treat baldness. Even though the first inventor had no idea that the chemical could be used to treat baldness, her patent on the chemical itself means any subsequent use of the chemical to treat baldness would infringe her patent.

Timothy R. Holbrook, Method Patent Exceptionalism, 102 IOWA L. REV. 1001, 1011 (2017).

151. Peter Lee, Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law, 58 EMORY L.J. 889, 906 (2009); cf. Dan L. Burk, Biotechnology in the Federal Circuit: A Clockwork Lemon, 46 ARIZ. L. REV. 441, 451 (2004) ("[I]f there are . . . very expensive development costs and high innovation costs, we would want to make it easier to get a patent and easier to get a big patent, as to offer a big reward and big incentive to invest in innovation.").

152. See supra Part I (discussing the utility requirement).

153. Eggert, *supra* note 25, at 781 ("The first inventor is rewarded for much more than he has given. He discloses one use, yet is 'paid' for all.").

154. See id. at 781–82 ("[T]he necessity of seeking the first inventor's cooperation can hardly be an inducement to experimentation or investment by others."); supra notes 78–79 and accompanying text (discussing the dangers of allowing patents on research inputs); Strandburg, supra note 78, at 125 ("Patents on research tools... 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... is performed."); BURK & LEMLEY, supra note 27, at 111 ("Permitting broad upstream patenting of such chemicals might discourage the downstream research necessary to find a market for those chemicals.").

155. Ted Sichelman, Commercializing Patents, 62 STAN. L. REV. 341, 344 (2010). A downstream researcher who discovers a new use for X can possibly obtain a patent covering that use. See infra notes 208–209 and accompanying text (distinguishing between composition claims and method claims). If X is still covered by the original inventor's patent, the earlier patent will "dominate" the new-use patent until the original inventor's patent expires. Merges & Nelson, supra note 141, at 861–62. Note that granting the new-use patent does not give the patent holder

on Chemical X will stop anyone who later discovers a use for Chemical X from [working on or commercializing] it. This, of course, reduces the incentive for future researchers to discover a use for Chemical X, leaving the task solely to the original inventor, which may be economically inefficient.  $^{156}$ 

The utility requirement prevents this by denying patents on research inputs because they *could* mature into blocking patents. <sup>157</sup> And while all upstream composition patents can block downstream inventors to some extent, <sup>158</sup> the courts will tolerate blocking and permit upstream patents if the original inventor can articulate a practical use for X. <sup>159</sup> But it is unclear why X should raise greater blocking concerns than inventions that pass the current utility test. <sup>160</sup> Dmitry Karshtedt argues that the critical policy concern is not blocking, <sup>161</sup> but rather the possibility of upstream patents preempting downstream research. <sup>162</sup>

One way to allay fears about control over downstream uses is to modulate claim scope by using the statutory patentability requirements as "levers." 163 Utility is ill-suited for this task because it is harshly

the positive right to practice the invention. See 35 U.S.C. § 154(a)(1) (noting that a patent gives the patentee a negative right to exclude others from using their invention, not a positive right to practice it themselves); 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.02[1] (2009) ("A patent basically grants to the patentee . . . the right to exclude others from making, using, and selling the invention. It does not grant the affirmative right to make, use or sell." (footnote omitted)).

- 156. Risch, supra note 29, at 1224 (footnotes omitted) (citing Merges & Nelson, supra note 141, at 860, 870–71).
  - 157. Machin, supra note 11, at 438.
  - 158. Id. at 438-39.
  - 159. Risch, supra note 29, at 1225.
- 160. For example, consider an inventor who seeks to patent compound X. The inventor can disclose a trivial use—that X is useful as an air freshener since it has a pleasant odor—to satisfy § 101. After the patent issues, it is discovered that X is a precursor to Z—the first compound known to effectively treat a rare type of cancer. The owner of the patent on X can control what happens with Z. See supra note 149 and accompanying text (discussing the broad rights that accompany composition claims). Nevertheless, the decision of how, whether, or when to license X for cancer research has nothing to do with the (trivial) utility disclosed (X's fragrant properties) to get the patent. Put differently, if X had a nontrivial, legally acceptable utility at the time of filing, that would have no bearing on a subsequent decision to license it for cancer research.
- 161. "Indeed, the Patent Act expressly contemplates patents for new uses of known things, even when the known thing is itself patented." Karshtedt, supra note 28, at 984 (citing 35 U.S.C. § 100(b)). In discussing Fisher, Karshtedt argues that "[p]atent claims on microscope inventions, just like claims on chemical inventions, can be complete or incomplete depending on the stage of the invention's development and that invention's potential to facilitate (and, if patented, to block) further research and development activity." Id. at 985.
- 162. *Id.* at 984. Karshtedt convincingly argues that "[c]ourts do not like patents on upstream inventions, and, in the absence of a statutory prohibition against the patenting of objects of basic research, they . . . [find ways] to invalidate claims that are drawn to them." *Id.* at 981 (footnote omitted); *cf.* Dan L. Burk, Essay, *The Problem of Process in Biotechnology*, 43 Hous. L. Rev. 561, 580 (2006) (explaining that "the utility rationale in *Fisher*" could simply be "a façade for a policy judgment about the desirability of 'upstream' patents early in the research process").
- 163. A policy "lever" is a flexible doctrine that courts use to modulate a uniform patent statute to achieve certain needs and ends. Dan L. Burk, *The Curious Incident of the Supreme Court in* Myriad Genetics, 90 NOTRE DAME L. REV. 505, 535 (2014); Burk & Lemley, *supra* note 91, at 1675.

applied (as evinced by the explicit bias against certain inventions). <sup>164</sup> Another possibility is the aforementioned enablement requirement of § 112(a). <sup>165</sup> Recall that enablement ensures that a patent "is of an appropriate scope, in light of the contribution her research makes to the relevant field." <sup>166</sup> If the original inventor provides a disclosure that doesn't enable a PHOSITA to make and use a downstream invention, then the downstream invention would lie outside the scope of the upstream patent. <sup>167</sup>

Enablement is a standard that affords the decisionmaker a fair amount of discretion. 168 Thus, the decisionmaker can set the threshold for enablement sufficiently high to render any claim covering uses not explicitly disclosed in the patent invalid. 169 To illustrate, consider an inventor who makes the aforementioned chemical compound Y. Suppose at the time of filing the only known use for Y is treating arthritis, which is disclosed in the patent. Now suppose a decade later a subsequent researcher discovers that Y is useful for treating baldness. The baldness use was neither contemplated by the inventor, disclosed in the patent application, nor within the PHOSITA's competence at the time of filing. Although the inventor's composition claim to Y covers all uses for infringement purposes, 170 an accused infringer could raise nonenablement as a defense, arguing that the baldness use was not enabled as of the patent's filing date. The issue here is what enablement standard should apply to an "after-arising" technology, which is a technology that "come[s] into existence after the filing date of a[]

<sup>164.</sup> Sean B. Seymore, *Patently Impossible*, 64 VAND. L. REV. 1491, 1493 (2011); see also Karshtedt, supra note 28, at 982 ("[I]t seems counterintuitive that, although the PTO has been granting patents on silly, ridiculous, and useless inventions without issuing utility rejections, the utility requirement has been enforced relatively vigorously in the serious and generally useful fields of chemistry and biotechnology." (footnote omitted)).

<sup>165.</sup> See supra notes 118–119 and accompanying text (discussing the written description and enablement requirements).

<sup>166.</sup> Merges, *supra* note 105, at 18. Enablement is a legal conclusion based on underlying factual inquiries. *See supra* note 114 (listing the *Wands* factors for enablement analysis).

<sup>167.</sup> The scope of the claims can be no broader than the scope of enablement provided in the patent document. In re Goodman, 11 F.3d 1046, 1050 (Fed. Cir. 1993); see also supra note 120 (discussing the scope of claims as related to the scope of enablement). Note that enablement of X is satisfied if the patent document discloses a single mode of using it; meaning that the original inventor need not enable all uses to obtain a composition claim for X. Invitrogen Corp. v. Clontech Lab'ys, Inc., 429 F.3d 1052, 1071 (Fed. Cir. 2005).

<sup>168.</sup> See discussion supra Part I (noting that while a research input itself is unpatentable, it can serve as prior art).

<sup>169.</sup> This is because gauging enablement involves a multifactor analysis. See supra note 114 (setting forth the Wands factors).

<sup>170.</sup> See supra Part II.A (explaining the importance of patent claims).

[patent] application."<sup>171</sup> Until recently, the applicable standard depended on the technology. The "single embodiment" doctrine applied to inventions in predictable technologies,<sup>172</sup> meaning that a claim was enabled as long as the patent's written description taught how to make and use at least one embodiment.<sup>173</sup> This essentially "place[d] no limit whatsoever on [claim] scope."<sup>174</sup> In unpredictable fields a "full scope" enablement requirement applied, meaning that "[c]laims are not enabled when, at the effective filing date of the patent, [a PHOSITA] could not practice their *full scope* without undue experimentation."<sup>175</sup> But this rigid dichotomy has broken down.<sup>176</sup>

So it might seem that applying full-scope enablement would allay the overreaching concerns of the *Manson* majority.<sup>177</sup> But the story is not so simple. First, when strictly applied, a full scope enablement standard requires that the patent "enable *every* potential embodiment

<sup>171.</sup> In re Hogan, 559 F.2d 595, 605 (C.C.P.A. 1977); see also Jacob S. Sherkow, Patent Law's Reproducibility Paradox, 66 DUKE L.J. 845, 867–68 (2017) (exploring the relevance of advances in science or follow-on research on the enablement determination).

<sup>172.</sup> For a discussion of the predictable-unpredictable distinction, see *supra* note 4 and accompanying text.

<sup>173.</sup> The patentee is "generally allowed [broad] claims, when the art permits, which cover more than the specific embodiment shown." In re Vickers, 141 F.2d 522, 525 (C.C.P.A. 1944); id. at 527 ("In mechanical cases... broad claims may be supported by a single form of the apparatus disclosed in an applicant's application."); see also Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991) (concluding that enablement is satisfied "if the description enables any mode of making and using the claimed invention"); Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed. Cir. 1987) (holding that a patent need only disclose a single embodiment to satisfy enablement). An "embodiment" is a concrete, physical form of an invention described in a patent application or patent. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY 33 (7th ed. 2017).

<sup>174.</sup> Tun-Jen Chiang, Fixing Patent Boundaries, 108 MICH. L. REV. 523, 538 (2010).

<sup>175.</sup> Wyeth & Cordis Corp. v. Abbott Lab'ys, 720 F.3d 1380, 1384 (Fed. Cir. 2013) (emphasis added) (citing MagSil Corp. v. Hitachi Glob. Storage Techs., Inc., 687 F.3d 1377, 1380–81 (Fed. Cir. 2012)).

<sup>176.</sup> See, e.g., Sitrick v. Dreamworks, LLC, 516 F.3d 993, 1000–03 (Fed. Cir. 2008) (determining that a disclosure enabling video games did not support a broad claim that covered movies as well as video games); Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc., 501 F.3d 1274, 1283–85 (Fed. Cir. 2007) (determining that a disclosure enabling mechanical side-impact sensors was insufficient to support a broad claim encompassing both mechanical and electronic sensors because the two were "distinctly different"); Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1379–80 (Fed. Cir. 2007) (determining that a disclosure enabling an injector with a pressure jacket was insufficient to support a claim that covered injectors both with and without a pressure jacket); AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1244 (Fed. Cir. 2003) (determining that when the claims covered a Type 1 or a Type 2 aluminum coating, yet the patent only described a Type 2 coating, the claims were nonenabled because a PHOSITA could not fill in the gaps without undue experimentation).

<sup>177.</sup> See Sean B. Seymore, The Enablement Pendulum Swings Back, 6 NW. J. TECH. & INTELL. PROP. 278, 284–89 (2008) (describing the emergence of "full scope" enablement as a "lever to invalidate patents"); cf. James Farrand, Seth Weisberg, Rickard Killworth & Victoria Shapiro, "Reform" Arrives in Patent Enforcement: The Big Picture, 51 IDEA 357, 415–17 (2011) (describing the full scope enablement doctrine and noting that it "can invalidate many existing broad patent claims, particularly if it continues to be applied as broadly as it is being stated").

of the invention."<sup>178</sup> Returning to the hypothetical, this would compel the inventor to adequately enable every possible use of *Y* at the time of filing. This might be impossible for yet-unknown uses<sup>179</sup> and would probably invalidate a lot of patent claims. Second, Kevin Collins explains that the case law dealing with enabling after-arising technologies is inconsistent and chaotic:

[C]ourts exercise discretion and oscillate between the full-scope and single-embodiment doctrines to achieve the desired outcome. When they feel like the inventor has overreached, they invoke the full-scope doctrine and invalidate the claim. Alternatively, when they feel that the inventor deserves a right to exclude from the [after-arising technology], they employ the single-embodiment rule. <sup>181</sup>

This is not surprising since enablement is a flexible standard<sup>182</sup> that produces uncertain and inconsistent outcomes.<sup>183</sup>

I offer an approach that avoids this problem by introducing a new form of intellectual property—a research patent. It would allow the inventor to obtain a research claim for X using the following language:

1. X for use in research.

Research would include experimentation on X to understand its characteristics and experimentation with X to facilitate making something else. 184 So this would encompass both basic and applied

<sup>178.</sup> Sherkow, supra note 171, at 875 (emphasis added).

<sup>179.</sup> See Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1254 (Fed. Cir. 2004) ("[A] patent document cannot enable technology that arises after the date of application. The law does not expect an applicant to disclose knowledge invented or developed after the filing date. Such disclosure would be impossible." (citing *In re* Hogan, 559 F.2d 595, 605–06 (C.C.P.A. 1977))).

<sup>180.</sup> Alan L. Durham, Patent Scope and Enablement in Rapidly Developing Arts, 94 N.C. L. REV. 1101, 1116 (2016); see also Chiang, supra note 174, at 538 (explaining that full-scope enablement is "an impossible requirement that renders every patent either invalid or completely worthless"). Bernard Chao has argued that rigid application of the full-scope doctrine might be inequitable—at least for unforeseen embodiments falling within the scope of the claim. Bernard Chao, The Infringement Continuum, 35 CARDOZO L. REV. 1359, 1378 (2014).

<sup>181.</sup> Kevin Emerson Collins, Enabling After-Arising Technology, 34 J. CORP. L. 1083, 1088-89 (2009).

<sup>182.</sup> See supra note 114 and accompanying text (setting forth the Wands factors).

<sup>183.</sup> Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141, 1189–90 (2008); see also Chiang, supra note 174, at 542 (describing enablement as an "amorphous standard" that leads to great uncertainty).

<sup>184.</sup> Cf. Andrew S. Baluch, Note, Relating the Two Experimental Uses in Patent Law: Inventor's Negation and Infringer's Defense, 87 B.U. L. REV. 213, 231 n.134 (2007) (making a similar distinction); Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., concurring in part and dissenting in part) ("Use of an existing tool in one's research is quite different from study of the tool itself."). The experimenting on/with distinction for research related inventions has been the subject of judicial and scholarly commentary, often involving comparisons between chemical compounds and microscopes. Compare In re Fisher, 421 F.3d 1365, 1373 (Fed. Cir. 2005) (explaining that a microscope is useful because it immediately magnifies an object to reveal its structure but the claimed DNA sequence is not because it cannot provide information about the overall structure and function of the underlying gene), Ken Burchfiel, Merck KGaA v. Integra: More Answers Than Questions?, 6 J. HIGH TECH. L. 79, 90 (2006) ("Unlike a

research.<sup>185</sup> That said, the "for use in research" limitation would explicitly constrain the scope of the exclusory right.<sup>186</sup>

To illustrate, consider a synthetic chemist who invents a new compound S which is a steroid intermediate. Steroids are molecules built around a characteristic four-ring hydrocarbon skeleton that are pervasive in nature, vital to human health, and ubiquitous in pharmacology. Recall that an intermediate is a compound whose purpose is to serve as a research input for other (downstream) compounds. A research patent would, for example, permit research to explore S's chemical properties or functionalization of the skeleton.

Research patents would be easy to incorporate into the patent system. Substantively, the written description of the invention<sup>191</sup> would be sufficient to satisfy the utility requirement of § 101 and the how-to-use prong of the enablement requirement of § 112.<sup>192</sup> Otherwise, a

microscope, a chemical compound does not have a single, easily-defined utility as a 'research tool.' A microscope can be used to study diseases, but not to treat them. A chemical compound . . . may be useful both . . . in laboratory research, and as a therapeutic agent . . . ."), and Duffy, supra note 30, at 246–47 (arguing that a microscope is useful because "it has broad applicability to researchers generally" whereas the DNA sequences in Fisher "ha[d] particular applicability only in research directed toward understanding the alleged invention itself" and "would be highly likely to produce blocking patents"), with Fisher, 421 F.3d at 1380 (Rader, J., dissenting) (arguing that microscopes and claimed DNA sequences both advance research by "tak[ing] a researcher one step closer to identifying and understanding a previously unknown and invisible structure"), and Karshtedt, supra note 28, at 985 (criticizing patent law's distinction between these two types of research tools).

185. For the definition of basic research, see *supra* note 20. Applied research is "[o]riginal investigation undertaken in order to acquire new knowledge; directed primarily, however, toward a specific, practical aim or objective." NAT'L CTR. FOR SCI. & ENG'G STAT., NAT'L SCI. FOUND., *supra* note 20, at 4-105.

186. Adopting this claim format would likely require overturning the pre-Federal Circuit rule that statements of purpose in a claim are ignored. See In re Prindle, 297 F.2d 251, 253 (C.C.P.A. 1962) (agreeing with the Patent Board that "intended use expressions cannot serve to patentably distinguish claims from references which otherwise meet them"); In re Dense, 156 F.2d 76, 77 (C.C.P.A. 1946) ("In article claims, invention must be described in terms of structure and not those of intended use."). For criticism of the rule and an argument that inventors should be allowed to add a limitation on how an invention is made or used, see Mark A. Lemley, Without Preamble, 100 B.U. L. REV. 357, 377–84 (2020).

187. Recall that the utility of a chemical intermediate was at issue in the landmark case  $In\ re$  Nelson, 280 F.2d 172 (C.C.P.A. 1960), discussed  $supra\ Part\ I$ .

188. See generally JOAN E. STANDORA, ALEX BOGOMOLNIK & MALGORZATA SLUGOCKI, STEROIDS: HISTORY, SCIENCE, AND ISSUES (2017) (discussing the history, chemistry, and functions of natural steroids).

189. See supra note 62 and accompanying text (discussing intermediate compounds).

190. This is achieved by adding so-called "functional groups" to the skeleton. A functional group is "[a]n atom or group of atoms within a molecule that shows a characteristic set of physical and chemical properties." WILLIAM H. BROWN, BRENT L. IVERSON, ERIC V. ANSLYN & CHRISTOPHER S. FOOTE, ORGANIC CHEMISTRY, at G-5 (7th ed. 2013). A functional group represents a potential reaction site in a compound and, thus, determines a compound's chemical reactivity. See generally RICHARD C. LAROCK, COMPREHENSIVE ORGANIC TRANSFORMATIONS: A GUIDE TO FUNCTIONAL GROUP PREPARATIONS (2d ed. 1999) (detailing chemical reactions according to functional group).

191. See supra note 118 (discussing the written description requirement).

192. See supra Part I (explaining the utility requirement).

research patent would be essentially the same as a traditional patent. Fees and agency procedures would be identical. Thus, research patents would place little additional administrative burden on the Patent Office.

### B. Enforcing the Research Patent

Like traditional patents, a research patent would give the owner the statutory right "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." Recall that the most likely inventor of X is an academic researcher who would seek to extract the full value of the patent through licensing to others. 194 Licensing would allow the inventor to recoup the costs of X's initial development.

Unlicensed use of X during the patent term would constitute patent infringement. Patent law generally rejects an experimental use defense, let although there is a statutory exemption for research on pharmaceuticals for purposes related to FDA approval. If the owner of a research patent learns about research activity involving X, the owner may be able to stop the research activity with an injunction. Is

<sup>193. 35</sup> U.S.C. § 154(a)(1).

<sup>194.</sup> Cf. Eisenberg, supra note 43, at 1074 ("[T]he patent holder will see research users as potential customers rather than hostile rivals and will want to extend licenses to them in order to extract the full value of the patent monopoly.").

<sup>195. 35</sup> U.S.C. § 271(a); see also Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861 (Fed. Cir. 1984) ("Section 271(a) prohibits, on its face, any and all uses of a patented invention."), superseded by statute, 35 U.S.C. § 271(e) (1994), as recognized in Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997).

<sup>196.</sup> Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) (denying applicability of the "very narrow and strictly limited" common-law experimental use exception to university researchers).

<sup>197.</sup> The safe-harbor provision of the Hatch-Waxman Act of 1984 permits the use of a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . . " 35 U.S.C. § 271(e)(1). See Merck KGaA v. Integra Lifesciences I, Ltd. 545 U.S. 193, 205–08 (2005) (interpreting the statute to exempt preclinical use of patented compounds but expressing no opinion on "research tools"); Proveris Sci. Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1265–66 (Fed. Cir. 2008) (holding that research tools not subject to FDA approval do not qualify for the experimental use exception).

<sup>198. 35</sup> U.S.C. § 283 (permitting the grant of injunctive relief in patent cases). But there are practical reasons why this might not happen. First, infringing activity is hard to detect. See infra text accompanying notes 203–205 and sources cited therein (discussing the challenges of enforcing a research patent). Second, "even if the patentee does detect the infringement, it takes time to bring a lawsuit to completion, and preliminary injunctions are rarely granted in patent cases." Mark A. Lemley, The Fruit of the Poisonous Tree in IP Law, 103 IOWA L. REV. 245, 256 (2017) (citing Dennis Crouch, The Impact of eBay on Injunctive Relief in Patent Cases, PATENTLY-O (July 16, 2015), http://patentlyo.com/patent/2015/07/impact-injunctive-patent.html [https://perma.cc/74LC-ESYW]). Third, winning a patent infringement suit does not guarantee a permanent

As for damages, calculations based solely on the infringing research activity itself are likely to be small. 199 Mark Lemley explains an alternative approach to damages for infringing research:

[S]ome patentees have sought "reach-through royalties" calculated not based on the actual infringing use but on the value of the non-infringing downstream product. . . . The theory is that because the non-infringing downstream product would not have resulted but for the infringing research, the patentee's damages should include the value of the non-infringing material that resulted from that research.  $^{200}$ 

Given X's uncertain (downstream) value or utility,<sup>201</sup> the availability of reach-through royalties could provide a meaningful incentive for inventors to obtain research patents. The Federal Circuit has suggested that reach-through damages may be appropriate for infringement involving research tools.<sup>202</sup>

Admittedly, enforcement of a research patent would have practical challenges. There is no easy way to detect X's use in laboratories hidden from public view. <sup>203</sup> Infringement may never come to light unless and until the patent owner identifies X in a downstream

injunction. See eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 392 (2006) (rejecting the Federal Circuit's automatic permanent injunction rule for infringement).

199. Lemley, supra note 198, at 256. The patent statute allows a patentee to recover damages "adequate to compensate for the infringement." 35 U.S.C. § 284. The damages are "usually measured, depending on the circumstances and the proof, as the patent owner's lost profits or as a reasonable royalty." Beatrice Foods Co. v. New Eng. Printing & Lithographing Co., 899 F.2d 1171, 1173 (Fed. Cir. 1990); see 35 U.S.C. § 284 (discussing damages as a remedy for infringement).

200. Lemley, supra note 198, at 256 (footnote omitted). For a discussion of how to calculate reach-through damages for research tools, see James Gregory Cullem, Panning for Biotechnology Gold: Reach-Through Royalty Damage Awards for Infringing Uses of Patented Molecular Sieves, 39 IDEA 553, 562–63 (1999); and Janice M. Mueller, No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1, 58 (2001).

201. Robin C. Feldman, The Insufficiency of Antitrust Analysis for Patent Misuse, 55 HASTINGS L.J. 399, 441 (2003).

202. According to the court,

The value to a licensee of research tools lies, in part, in the point at which those tools are employed in the drug development continuum. A research tool enabling the identification of a drug candidate during high throughput screening, for instance, may supply more value to the ultimate invention than a research tool used to confirm an already recognized drug candidate's safety or efficacy . . . . Similarly, the amount Merck would agree to pay for Integra's RGD technology could be influenced by the point of placement of this technology in its drug development process.

Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 871 (Fed. Cir. 2003) (citations omitted), rev'd on other grounds, 545 U.S. 193 (2005).

203. Katherine J. Strandburg, User Innovator Community Norms: At the Boundary Between Academic and Industry Research, 77 FORDHAM L. REV. 2237, 2257 (2009); see also John P. Walsh, Ashish Arora & Wesley M. Cohen, Effects of Research Tool Patents and Licensing on Biomedical Innovation, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 324 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (noting that "infringement of research tool patents is often hard to detect").

product or application.<sup>204</sup> And even if the patent owner detects an unlicensed use of X, the owner might acquiesce to infringement if that use poses no threat to the owner's commercial interests (perhaps by another academic researcher).<sup>205</sup>

# C. What Happens When a Practical Use Is Discovered?

Discovering practical uses for X raises the possibility of downstream traditional patents. The scope of a downstream patent would be shaped primarily by patent law's aforementioned novelty rules.  $^{206}$  The general novelty rule prohibits issuing a patent that would "read on" subject matter identically disclosed in the prior art.  $^{207}$  Since the (earlier) research patent discloses X, the general rule only permits patenting of the newly discovered use, not the compound itself.  $^{208}$  One commentator has explained that

[i]f an inventor discovers a new, inventive use for a known chemical, he cannot receive a patent on that compound. He may, however, receive a patent on the use of that compound.... The discoverer of the new use who is restricted to a [method] patent acquires only the right to preclude others from using the chemical in the exact manner he has disclosed. He acquires no right to produce the compound, to sell it, or even to use it. 209

X's disclosure in the published research patent document is anticipatory prior art that bars a subsequent composition claim to the compound.<sup>210</sup>

<sup>204.</sup> See 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, 792 (2000) ("Infringement might remain undetected until . . . a product using the EST sequence becomes available."); cf. Robert P. Merges, Of Property Rules, Coase, and Intellectual Property, 94 COLUM. L. REV. 2655, 2658 (1994) (recognizing that with intellectual property rights, often "there is no smoky soot or wandering cattle to serve as an unambiguous marker" of infringement).

<sup>205.</sup> Eisenberg, supra note 43, at 1071–72. Patent owners may engage in this "rational forbearance" of unlicensed use because "scientific norms still generate social pressure to share materials, particularly with nonprofit entities." Peter Lee, Note, Patents, Paradigm Shifts, and Progress in Biomedical Science, 114 YALE L.J. 659, 677 (2004).

<sup>206.</sup> See supra notes 103-105 and accompanying text; 35 U.S.C. §§ 101-102 (laying the statutory groundwork for patent claims); In re Marshall, 578 F.2d 301, 304 (C.C.P.A. 1978) (citations omitted) (providing an example of an application of these rules).

<sup>207.</sup> See supra notes 106 and 113 and accompanying text. If a claim "reads on" a prior art reference, it is anticipated. Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999). 208. See Merck & Co., Inc. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1372 (Fed. Cir. 2003) ("The new use of a known composition is claimed as a method." (emphasis added)).

<sup>209.</sup> Eggert, *supra* note 25, at 780–81 (emphasis added). The narrow scope of method claims makes them harder to enforce and thus less valuable than composition claims. *See* Holbrook, *supra* note 150, at 1010 ("[M]ethods in the chemical and pharmaceutical industries are often viewed as second-best forms of protection."); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMMS. & TECH. L. REV. 345, 351 (2007) ("Patents on particular methods of treatment involving the use of a drug are generally considered less valuable[] because they cannot be used to stop competitors from selling the same product for other uses.").

<sup>210.</sup> Atlas Powder, 190 F.3d at 1346 (citing Titanium Metals Corp. v. Banner, 778 F.2d 775, 781 (Fed. Cir. 1985)).

So the general novelty rule only allows a (method) patent for the newly discovered use.<sup>211</sup>

But there is an important exception to the general rule for the original inventor. Section 102(a)(1) of the patent statute, the basic prior art rule under the AIA, 212 denies patentability if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention."213 This rule treats a pre-filing disclosure, including activity by the original inventor, as novelty destroying.214 This means that the disclosure of X in a published research patent document would bar subsequent composition a Section 102(b)(1)(A), however, is a novelty-preserving exception that excludes from the prior art "[a] disclosure made 1 year or less before the effective filing date of a claimed invention . . . [if] the disclosure was made by the inventor...."216 Thus, the AIA creates a one-year statutory grace period for pre-filing disclosures by the original inventor, including those in published patent documents.<sup>217</sup> So the grace period would allow the original inventor to obtain a valuable composition claim<sup>218</sup> to X as long as the subsequent traditional patent application is filed within a year of the publication of a research patent document.<sup>219</sup> This provides a big incentive for the original inventor to find uses for  $X^{220}$ 

<sup>211.</sup> See supra note 208 and accompanying text.

<sup>212.</sup> See supra note 109 and accompanying text.

<sup>213. 35</sup> U.S.C. § 102(a)(1).

<sup>214.</sup> MUELLER, supra note 12, at 360-62.

<sup>215.</sup> See supra note 210 and accompanying text.

<sup>216. 35</sup> U.S.C. § 102(b)(1)(A).

<sup>217.</sup> See Robert P. Merges, Priority and Novelty Under the AIA, 27 BERKELEY TECH. L.J. 1023, 1033 (2012):

<sup>[</sup>T]he term "disclosure" in AIA § 102(b)... mean[s] any prior art reference defined under AIA § 102(a). A disclosure under the AIA, then, means subject matter that is, prior to an applicant's filing date: "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public," under AIA § 102(a)(1).

<sup>218.</sup> See supra Part II.

<sup>219.</sup> This is because the grace period removes the prior disclosure of X from the prior art—as if it had never been made. Put differently, disclosures made by the original inventor during the grace period do not enter the public domain (and are thus not prior art). See 35 U.S.C. \$102(b)(1)(A). That the research patent can act as a placeholder makes it similar to a provisional patent application, which allows an inventor to obtain an early filing date for the invention before the inventor is ready to draft a claim or a full application. See id. \$111(b). The inventor must submit a regular, "nonprovisional" application within one year to get the benefit of the early filing date. See id. \$111(b)(5).

<sup>220.</sup> See supra note 43 and accompanying text.

#### III. POLICY IMPLICATIONS

### A. Justifying Research Patents

The classic rationale for patents is that we grant them to encourage inventions (and the disclosure of technical information about them) that the public would not otherwise get.<sup>221</sup> Rebecca Eisenberg has argued that allowing upstream patents on research inputs aligns with the classic rationale:

[T]he value of a newly invented chemical may derive as much from its usefulness in facilitating the discovery of other chemicals in future research as from its usefulness in its present form to non-research consumers. If a patent on the chemical allowed the inventor to capture the value of the chemical to non-research consumers but not its value as an input to subsequent research, patent incentives to derive new chemicals would be reduced.  $^{222}$ 

Relatedly, Robert Merges has argued that the prospect of getting a patent and the applicable patentability standard could factor into the initial decision of whether to pursue the research project in the first place.<sup>223</sup>

Of course, if an inventor would make X anyway, the classic rationale posits that the law does not need to encourage that work with a patent.<sup>224</sup> This might be the prevailing story for research patents because "[t]here are plenty of other incentives for university scientists to engage in research, including curiosity, academic prestige, and tenure and promotion."<sup>225</sup> Making a compound that seemed particularly

<sup>221.</sup> EDWARD C. WALTERSCHEID, THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE: A STUDY IN HISTORICAL PERSPECTIVE 143 (2002); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 Tex. L. Rev. 989, 993 (1997) ("Intellectual property is fundamentally about incentives to invent and create."); Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1597–98 (2011).

<sup>222.</sup> Eisenberg, supra note 43, at 1074 n.224.

<sup>223.</sup> Merges, supra note 105, at 11-12.

<sup>224.</sup> Mark A. Lemley, The Myth of the Sole Inventor, 110 MICH. L. REV. 709, 736 (2012); see also Holman, supra note 16, at 630 ("Critics charge that the incentive effects of research tool patents are generally modest.... Because research tools are often the product of publicly funded basic research, it can be argued that most of these technologies would have been discovered and disclosed to the public with or without the incentive of a patent."); Jerry G. Thursby & Marie C. Thursby, University Licensing, 23 OXFORD REV. ECON. POL'Y 620, 624 (2007) (explaining that the justification for university patenting does not come from the incentive to invent because "universities reward their researchers according to the norms of science").

<sup>225.</sup> Mark A. Lemley, Are Universities Patent Trolls?, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611, 621 (2008); Rai, supra note 35, at 92 (explaining that in academic science, "the highest levels of recognition and prestige are bestowed upon those who make original contributions to the common stock of knowledge"). Interestingly, patents and commercialization activities are becoming relevant for promotion, tenure, and career advancement. See Paul R. Sanberg, Morteza Gharib, Patrick T. Harker, Eric W. Kaler, Richard B. Marchase, Timothy D. Sands, Nasser Arshadi & Sudeep Sarkar, Changing the Academic Culture: Valuing Patents and Commercialization Toward Tenure and Career Advancement, 111 PROC. NAT'L ACAD. SCIS. 6542, 6542–47 (2014).

challenging or impossible could be an original contribution that bestows substantial recognition in the scientific community. <sup>226</sup> Aside from that, some scientists invent molecules for the joy of discovery <sup>227</sup> or the challenge of solving a puzzle. <sup>228</sup>

Research patents, however, better align with other rationales for patents: (1) disclosure and knowledge transfer and (2) innovation.

### 1. Disclosure and Knowledge Transfer

Patents and science share the goal of disseminating knowledge. A research patent would transfer knowledge about X from the inventor's research laboratory (1) to downstream researchers who would develop and commercialize it and (2) to the technical literature, which happens once the patent document publishes. The former is a formal technology transfer that communicates technical information about the invention to the licensee. The latter makes the research patent akin to a technical journal publication.

Both types of knowledge transfer depend on the disclosure—the written description of the invention included in the patent document. The aforementioned enablement requirement would ensure that the disclosure is adequate to teach a PHOSITA how to make and use X

<sup>226.</sup> See Rai, supra note 35, at 92 ("The greater the significance of the scientist's original contribution, the greater the recognition that she receives.").

 $<sup>227.\</sup> See\ generally\ F.\ A.\ COTTON,\ MY\ LIFE\ IN\ THE\ GOLDEN\ AGE\ OF\ CHEMISTRY:\ MORE\ FUN\ THAN\ FUN\ (2014).$ 

<sup>228.</sup> PAULA STEPHAN, HOW ECONOMICS SHAPES SCIENCE 5 (2012) (explaining that "enjoyment derived from the puzzle solving is part of the reward of doing science").

<sup>229.</sup> Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989) (stating that "the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure"); J. Jonas Anderson, Nontechnical Disclosure, 69 VAND. L. REV. 1573, 1585 (2016) ("[T]he patent system is designed to bring inventions out into public view."); KELLY MOORE, DISRUPTING SCIENCE: SOCIAL MOVEMENTS, AMERICAN SCIENTISTS, AND THE POLITICS OF THE MILITARY, 1945-1975, at 2 n.5 (2008) ("Science is considered to be simultaneously a body of knowledge . . . and the means by which knowledge is acquired and disseminated.").

<sup>230.</sup> The technical information disclosed in the patent document "add[s] to the sum of useful knowledge" upon publication. Graham v. John Deere Co., 383 U.S. 1, 6 (1966). Patent documents include issued patents and published patent applications. Since 1999, most patent applications publish eighteen months after the earliest effective filing date. 35 U.S.C. § 122(b)(1)(A). Once a patent application publishes, the information it discloses is considered publicly known. See id. § 102 (stating that patent publications serve as prior art against later filed patent).

<sup>231.</sup> Peter Lee, Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer, 100 CALIF. L. REV. 1503, 1516 (2012).

<sup>232.</sup> Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 624 n.11 (2010) ("Like technical journals..., patent [documents] show... the state of technology, set forth what others have already achieved, and provide technical information that others can avoid repeating.").

<sup>233.</sup> See supra note 118; Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 922 n.5 (Fed. Cir. 2004) ("[T]he role of the specification is to teach, both what the invention is (written description) and how to make and use it (enablement).").

without undue experimentation.<sup>234</sup> As Dan Burk and Mark Lemley have explained, "the underlying assumption in patent law is that the inventor 'has' the invention mentally, and so can give a sufficiently detailed description of that inventive conception—[thus] physically creating the invention is straightforward."<sup>235</sup> So a robust disclosure makes patents more useful for follow-on innovation.<sup>236</sup>

Yet, the current (harsh) utility standard for research inputs like X can hinder disclosure. It creates an incentive for inventors to keep X secret while a legally acceptable (practical) use is sought. As Jeanne Fromer has explained, "Until the inventor is closer to knowing whether the invention will receive patent protection, the inventor will typically not want to jeopardize the secrecy—and thus competitive profitability—of the invention."  $^{239}$ 

If disclosure is the "centerpiece of patent policy,"  $^{240}$  then secrecy is its antithesis.  $^{241}$  No disclosure means that knowledge about X may never become public. $^{242}$  So the inventor's choice between secrecy and disclosure can have far-reaching effects:

<sup>234.</sup> See supra note 119 and accompanying text.

<sup>235.</sup> Dan L. Burk & Mark A. Lemley, Is Patent Law Technology-Specific?, 17 BERKELEY TECH. L.J. 1155, 1174 n.77 (2002).

<sup>236.</sup> Timothy R. Holbrook, Possession in Patent Law, 59 SMU L. REV. 123, 131 (2006); see also Kevin Emerson Collins, The Structural Implications of Inventors' Disclosure Obligations, 69 VAND. L. REV. 1785, 1790–91 (2016) (discussing the public-knowledge theory of disclosure and its grounding in social benefit). For example, a robust disclosure reduces research-and-development waste. Kenneth W. Dam, The Economic Underpinnings of Patent Law, 23 J. LEGAL STUD. 247, 267 n.79 (1994). In licensing, a weak disclosure leads to incomplete technology transfer and thus delays innovation. See Lee, supra note 231, at 1516–18.

<sup>237.</sup> See Machin, supra note 11, at 440; Phanesh Koneru, To Promote the Progress of Useful Articles?: An Analysis of the Current Utility Standards of Pharmaceutical Products and Biotechnological Research Tools, 38 IDEA 625, 670 (1998) ("Manson... reflects a fundamental misunderstanding of the policy of promoting the progress in useful arts. Its focus on promoting useful articles, to the exclusion of the technical merits of the invention, is shortsighted.").

<sup>238.</sup> Anderson & Dyson, *supra* note 81, at 817; *cf.* Brenner v. Manson, 383 U.S. 519, 538 (1966) (Harlan, J., concurring in part and dissenting in part) (recognizing that an inventor may make the "abstractly logical choice . . . to maintain secrecy until a product use can be discovered").

<sup>239.</sup> Jeanne C. Fromer, Patent Disclosure, 94 IOWA L. REV. 539, 555 (2009).

<sup>240.</sup> Note, The Disclosure Function of the Patent System (or Lack Thereof), 118 HARV. L. REV. 2007, 2011 (2005).

<sup>241.</sup> J. Jonas Anderson, Secret Inventions, 26 BERKELEY TECH. L.J. 917, 919 (2011).

<sup>242.</sup> As the Court of Customs and Patent Appeals observed:

The man who secretes his invention makes easier and plainer the path of no one. He contributes nothing to the public. Over and over it has been repeated that the object of the patent system is through protection to stimulate invention, and inventors ought to understand that this is for the public good. Where an invention is made and hidden away it might as well never have been made at all, at least so far as the public is concerned.

Horwath v. Lee, 564 F.2d 948, 950 (C.C.P.A. 1977).

Innovators who have a choice between . . . secrecy and patent protection for, say, a chemical discovery will thereby be making a choice between inaccessible and accessible information. Subsequent researchers may rediscover the same compound or process, and competitors may eventually reverse engineer the secret, but the issuance of a patent will disclose what that innovation is, how to make it, how it differs from the prior art, [etc.]. This knowledge will thereby become publicly accessible sooner and with less reduplication of effort than the . . . secret option would produce. <sup>243</sup>

This is why the patent system encourages *early* public disclosure of inventions.<sup>244</sup>

Nevertheless, concerns about secrecy are often downplayed because it is assumed that the inventions emerging from academic research will be inevitably disclosed—perhaps in a peer-reviewed technical journal. This is an empirical proposition that is hard to confirm. One cannot, however, automatically assume that X will be published in a journal. A considerable amount of basic research results in academic science falls into oblivion.

Where do research patents fit in? First, a research patent would permit the inventor of X to disclose it (publicly or privately) without losing exclusive rights. <sup>249</sup> Using X without permission during the patent

<sup>243.</sup> Pamela Samuelson, Lecture, Enriching Discourse on Public Domains, 55 DUKE L.J. 783, 829 (2006); see also Martin J. Adelman, Property Rights Theory and Patent-Antitrust: The Role of Compulsory Licensing, 52 N.Y.U. L. REV. 977, 982 (1977) (explaining that one of the costs of secrecy is "reinvention, which from society's viewpoint is a waste of money, time, and talent"); Eisenberg, supra note 43, at 1028 (secrecy increases the likelihood of duplicative efforts of others who have no knowledge of the inventor's contribution).

<sup>244. &</sup>quot;Early public disclosure is a linchpin of the patent system." W.L. Gore & Assocs., Inc., v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir. 1983); see also In re Hogan, 559 F.2d 595, 606 (C.C.P.A. 1977) (explaining that patentability standards should be interpreted to promote "prompt, early disclosure"); Kitch, supra note 41, at 269–71 (discussing the patent system's emphasis on early disclosure and the rules and policies that promote it).

<sup>245.</sup> See Brenner v. Manson, 383 U.S. 519, 534 (downplaying the issue of secrecy because "if the inventor of a process cannot himself ascertain a 'use'...he has every incentive to make his invention known to those able to do so").

<sup>246.</sup> It is impossible to find out how many inventors opt out of the patent system because of utility hurdles. Machin, *supra* note 11, at 440 ("The scope of this problem will be difficult to determine because these inventions will suffer anonymous deaths.").

<sup>247.</sup> See Ajay Agrawal & Rebecca Henderson, Putting Patents in Context: Exploring Knowledge Transfer from MIT, 48 MGMT. Sci. 44, 58 (2002) (explaining that faculty researchers decide whether to publish and/or patent on a case-by-case basis).

<sup>248.</sup> Nonpublication occurs because of time constraints, flaws in the research design, fear that the project will not be accepted by a high-impact journal, a perception that more data is needed before submission, and a researcher not wanting competitors to know the seemingly fruitless paths that the researcher has been exploring. See Jonathan Knight, Null and Void, 422 NATURE 554, 554–55 (2003); Donald Kennedy, Editorial, The Old File-Drawer Problem, 305 SCIENCE 451, 451 (2004); STUART FIRESTEIN, FAILURE: WHY SCIENCE IS SO SUCCESSFUL 41 (2015).

<sup>249.</sup> See Kitch, supra note 41, at 277-79 (discussing how patents, as opposed to trade secrets, allow companies to efficiently disclose their inventions in the pursuit of commercialization). Of course, the inventor is subject to patent law's novelty requirement. Once disclosed, the inventor has one year to file a (research) patent application. See 35 U.S.C. § 102(a)(1), (b)(1)(A); Helsinn

term would allow the patent owner to sue for infringement.<sup>250</sup> Second, research patents would promote the patent system's goal of *early* disclosure<sup>251</sup> by allowing inventors of research inputs to obtain patent protection *before* a practical use is discovered.<sup>252</sup> Third, obtaining a research patent would facilitate disclosure *beyond* the patent system—a knowledge spillover. Timothy Holbrook has explained that "[a]n inventor who anticipates obtaining a patent on an invention will be *more* willing to publish a scientific article or other sort of disclosure to the public, because she knows her invention will eventually be protected by a patent."<sup>253</sup>

#### 2. Innovation

Innovation is the development and commercialization of an invention *after* its creation.<sup>254</sup> Innovation is generally made outside of academia by private firms.<sup>255</sup> This makes sense: academic scientists doing basic research tend to focus on pure scientific discovery and building fundamental knowledge rather than developing practical applications.<sup>256</sup> A patent provides the necessary incentive for firms to

Healthcare, S.A. v. Teva Pharms. USA, Inc., 139 S. Ct. 628, 633-34 (2019) (reaffirming pre-AIA precedent that secret commercialization efforts by the inventor can serve as novelty-defeating prior art).

- 250. See supra Part II.
- 251. See supra note 244 and accompanying text.
- 252. Publication of the patent document will provide society with the requisite knowledge to find practical uses for *X. Cf.* Koneru, *supra* note 237, at 646–47 ("[W]ith respect to a product patent, making a product is the invention, and that once the society knows how to make a product, it can eventually discover the highest and best use for that product.").
- 253. Holbrook, supra note 236, at 146 (emphasis added); Pierre Azoulay, Waverly Ding & Toby Stuart, The Impact of Academic Patenting on the Rate, Quality and Direction of (Public) Research Output, 57 J. INDUS. ECON. 637, 669–70 (2009) (providing empirical research showing that academic scientists engage in a "flurry" of publication activity around the time of filing a patent application).
- 254. Lemley, supra note 225, at 624 (citing Mark A. Lemley, Ex Ante Versus Ex Post Justifications for Intellectual Property, 71 U. CHI. L. REV. 129, 147 (2004)); see also F. Scott Kieff, Property Rights and Property Rules for Commercializing Inventions, 85 MINN. L. REV. 697, 753 (2001) (arguing that the patent system exists "in which a central goal is to facilitate commercialization of new goods and services"); Michael Abramowicz, The Danger of Underdeveloped Patent Prospects, 92 CORNELL L. REV. 1065, 1067 (2007) (explaining the importance of commercialization in fully developing the patent right). "Innovation is the multistage process whereby organizations transform ideas into new/improved products, service or processes, in order to advance, compete and differentiate themselves successfully in their marketplace." Anahita Baregheh, Jennifer Rowley & Sally Sambrook, Towards a Multidisciplinary Definition of Innovation, 47 MGMT. DECISIONS 1323, 1334 (2009).
  - 255. Thursby & Thursby, supra note 224, at 624.
- 256. Agrawal & Henderson, supra note 247, at 58; Robert E. Litan, Lesa Mitchell & E.J. Reedy, Commercializing University Innovations: Alternative Approaches, 8 INNOVATION POL'Y & ECON. 31, 32 (2007). The story is different in engineering and the applied sciences, where much university

invest in the often costly and risky development required to transform the nascent technology into a downstream application.<sup>257</sup>

It is also true that patents were long frowned upon in academic science.<sup>258</sup> University researchers viewed them as antithetical to traditional scientific norms of open sharing, discourse, and serving the public good.<sup>259</sup> These views have evolved for a variety of reasons—including a decline in federal support for basic research<sup>260</sup> and passage of the Bayh-Dole Act of 1980, which allows universities to patent and license inventions arising from federally funded research.<sup>261</sup> Now, every major research university has a technology transfer office tasked with collecting invention disclosures of early-stage research, obtaining patents, and licensing them to private firms for commercialization.<sup>262</sup>

Consistent with this alternative rationale for patents, Bayh-Dole's purpose is not to incentivize invention.<sup>263</sup> Rather, it seeks to

research gives attention to practical objectives. See David C. Mowery, Richard R. Nelson, Bhaven N. Sampat & Arvids A. Ziedonis, The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980, 30 RSCH. POLY 99, 101 (2001) ("Many important advances in applications have emerged from academic research... on the engineering and applied sciences.").

- 257. Thursby & Thursby, supra note 224, at 624; Holman, supra note 16, at 630.
- 258. Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 YALE L.J. 177, 181–84 (1987).
- 259. Lee, supra note 31, at 19; see also Rai, supra note 35, at 90 (explaining that in light of the strong norm in science that "scientific knowledge is ultimately a shared resource" for the public domain, "claiming property rights in invention is often seen as immoral"); Robert P. Merges, Property Rights Theory and the Commons: The Case of Scientific Research, 13 SOC. PHIL. & POL'Y 145, 145 (1996) ("[C]ommercializing the heretofore noble, pure, and otherwise untainted field of science is not just poor policy, but intrinsically bad." (emphasis omitted)). This way of thinking has gained even more popularity in the wake of the COVID-19 pandemic. For example, the Association of University Transfer Managers ("AUTM"), the world's leading association of technology transfer professionals, has encouraged IP owners to adopt a COVID-19 licensing strategy that calls for "adopting time-limited, non-exclusive royalty-free licenses, in exchange for the licensees' commitment to rapidly make and broadly distribute products and services to prevent, diagnose, treat and contain COVID-19. \*COVID-19 Licensing Guidelines\*, AUTM, https://autm.net/about-tech-transfer/covid19/covid-19-licensing-guidelines (last visited Oct. 11, 2020) [https://perma.cc/Y4AG-N7J5]. Academic signatories include Caltech, Cornell, Duke, Georgetown, Harvard, Johns Hopkins, MIT, Princeton, Stanford, Vanderbilt, and Yale. \*Id.\*
- 260. Bhaven N. Sampat, Patenting and U.S. Academic Research in the 20th Century: The World Before and After Bayh-Dole, 35 RSCH. POL'Y 772, 776 (2006); see also Jeffrey Mervis, Data Check: Federal Share of Basic Research Hits New Low, 355 SCIENCE 1005, 1005 (2017) ("Data from ongoing surveys by the National Science Foundation (NSF) show that federal agencies provided only 44% of the \$86 billion spent on basic research in 2015.").
- 261. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-211).
- 262. Lee, supra note 231, at 1514; Valerie Landrio McDevitt, Joelle Mendez-Hinds, David Winwood, Vinit Nijhawan, Todd Sherer, John F. Ritter & Paul R. Sandberg, More Than Money: The Exponential Impact of Academic Technology Transfer, 16 TECH. & INNOVATION 75, 75–84 (2014).
- 263. Rai, supra note 35, at 97 ("Bayh-Dole was not particularly concerned about invention in itself."); Thursby & Thursby, supra note 224, at 624 (explaining that Bayh-Dole focuses on ex post

stimulate innovation beyond invention—that is, to promote downstream application of university research results.  $^{264}$  Returning to X, there's a real likelihood that it could languish as an undeveloped or dead-end project,  $^{265}$  which is the fate of a lot of basic research.  $^{266}$  Aside from promoting disclosure,  $^{267}$  a research patent would open the door to monetizing X through commercialization and reach-through royalties.  $^{268}$ 

### B. Controlling Future Uses

The principal rationale for denying patents on research inputs like X is that such patents give the inventor too much control over the unknown. This includes "the ability to block technological progress by controlling the research that may be performed using the [input]." Relatedly, a patent on X could "creat[e] an 'anticommons' in which rights holders may impose excessive transaction costs or make the acquisition of licenses and other rights too burdensome to permit the pursuit of scientifically and socially worthwhile research."  $^{271}$ 

The anticommons hypothesis has received considerable scholarly attention. When Michael Heller and Rebecca Eisenberg

incentives); see also MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL MONOPOLY 228 (2008) (explaining that the quality and quantity of federally sponsored research has "remained roughly where it was [before passage of Bayh-Dole], meaning that patentability made no difference as far as general incentives are concerned").

264. WENDY H. SCHACHT, CONG. RSCH. SERV., RL32076, THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 8 (2012). The stated policy objective of Bayh-Dole is "to use the patent system to promote the utilization of inventions arising from federally supported research or development." 35 U.S.C. § 200.

265. Lemley, supra note 225, at 621; Rebecca S. Eisenberg, Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research, 82 VA. L. REV. 1663, 1664 (1996).

266. See supra note 248. Nonpublication is a bigger concern with industrial scientists. See generally Benoît Godin, Research and the Practice of Publication in Industries, 25 RSCH. POL'Y 587, 587 (1996). The highest priority for an industrial inventor is to generate results that show commercial promise. Diana Hicks, Published Papers, Tacit Competencies and Corporate Management of the Public/Private Character of Knowledge, 4 INDUS. & CORP. CHANGE 401, 413–14 (1995).

- 267. See infra Part III.
- 268. See supra Part II.
- 269. See supra note 154 and accompanying text.

270. Strandburg, *supra* note 78, at 123. For a general theoretical discussion, see Merges & Nelson, *supra* note 141, at 842–44, 894–908 (discussing how upstream patents can retard downstream innovation); and Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSPS. 29, 30–32 (1991) (same). These concerns are not present for upstream inventions in predictable fields. *See Collins, supra* note 9, at 1621 n.79.

271. John P. Walsh, Charlene Cho & Wesley M. Cohen, View from the Bench: Patents and Material Transfers, 309 SCIENCE 2002, 2002 (2005).

published it in 1998,<sup>272</sup> they argued that an anticommons would impose significant costs in biotechnology—a field where progress depends on the accessibility of (upstream) research inputs like proteins and DNA fragments.<sup>273</sup> But empirical research fails to show that the patenting of research inputs in biotechnology has adversely affected innovation.<sup>274</sup> The research includes studies of thousands of biotechnology patents<sup>275</sup> and surveys of attorneys, scientists, and technology managers about the impact of patents on their work.<sup>276</sup> There is "no evidence of academics being excluded from research due to patents inputs...[and] virtually no instances of industrial or academic researchers being stopped due to an inability to gain access to a large number of patents needed for a research project."277 A survey of the international research community by the American Association for the Advancement of Science reached the same conclusion.<sup>278</sup> Some commentators argue that patents on research tools actually promote research and development ("R&D") by "supporting an active market for technology."279 Other commentators argue that an anticommons

<sup>272.</sup> Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 SCIENCE 698, 698–99 (1998).

<sup>273.</sup> Id. at 699; Richard Li-dar Wang, Biomedical Upstream Patenting and Scientific Research: The Case for Compulsory Licenses Bearing Reach-Through Royalties, 10 YALE J.L. & TECH. 251, 261 (2008).

<sup>274.</sup> David E. Adelman, A Fallacy of the Commons in Biotech Patent Policy, 20 BERKELEY TECH. L.J. 985, 1029 (2005).

<sup>275.</sup> See, e.g., David E. Adelman & Kathryn L. DeAngelis, Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate, 85 Tex. L. Rev. 1677, 1680 (2007) (finding, based on dataset of fifty-two thousand biotechnology patents from January 1990 through December 2004, that there is "little evidence that the recent growth in biotechnology patenting is threatening innovation").

<sup>276.</sup> See John P. Walsh, Wesley M. Cohen & Charlene Cho, Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research, 36 RSCH. POL'Y 1184, 1185–86 (2007) (reporting on a survey of 507 academic biomedical researchers); Walsh et al., supra note 271, at 2002–03 (reporting the findings from a survey of 414 biotech researchers in academia, government, and nonprofit institutions); Walsh et al., supra note 203, at 285 (reporting the findings from a survey of seventy respondents which included intellectual property attorneys, scientists, and managers from biotech firms, pharmaceutical firms, and universities).

<sup>277.</sup> Wesley M. Cohen & John P. Walsh, Access—or Not—in Academic Biomedical Research, in Working Within the Boundaries of Intellectual Property 1, 15 (Rochelle C. Dreyfuss, Diane L. Zimmerman & Harry First eds., 2010) (footnotes omitted); see also Rebecca S. Eisenberg, Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research, 45 Hous. L. Rev. 1059, 1098 (2008) ("Survey results from scientists suggest that, although commercial scientists face more obstacles from intellectual property than academic scientists, in both settings it is rare for an ongoing project to be stopped because of patents.").

<sup>278.</sup> The survey results "offer very little evidence of an 'anticommons problem.' "AM. ASS'N FOR THE ADVANCEMENT OF SCI., INTERNATIONAL INTELLECTUAL PROPERTY EXPERIENCES: A REPORT OF FOUR COUNTRIES 12 (2007). The survey results "also suggest that IP-protected technologies remain relatively accessible to the broad scientific community, and not as constrained by IP protections as many have cautioned." *Id.* at 15.

<sup>279.</sup> Walsh et al., supra note 203, at 280.

objection is weak because the owner of a patent on a research input has no incentive to block downstream research.<sup>280</sup>

Patent scholars offer a host of reasons why an anticommons is not observed in academic science. First, it is widely believed that university researchers simply ignore patents.<sup>281</sup> Second (and contrariwise), some university researchers will negotiate a license to gain access to a patented technology.<sup>282</sup> Third, patent owners acquiesce to infringement by university researchers because of the high costs of detecting it, the low value of a potential lawsuit, and the social pressure to share with nonprofits.<sup>283</sup> Fourth, a researcher can invent around the patented technology.<sup>284</sup> And fifth, a potential infringer may opt to challenge the patent.<sup>285</sup>

The bottom line is that fears of the unknown are greatly overblown.<sup>286</sup> This has led to a rethinking of the anticommons hypothesis and its role in shaping patent policy.<sup>287</sup>

<sup>280.</sup> See, e.g., Duffy, supra note 30, at 242 ("Because the holder of an embryonic patent needs to have the patent developed by further research, the right holder has every incentive to try to lower the costs of that research. A patent holder gains nothing by blocking research needed to bring the innovation to market.").

<sup>281.</sup> Strandburg, *supra* note 203, at 2250 (describing the "norm of ignoring patents" among scientists); Mark A. Lemley, *Ignoring Patents*, 2008 MICH. St. L. REV. 19, 21 (same).

<sup>282.</sup> See Lori Pressman, Richard Burgess, Robert M. Cook-Deegan, Stephen J. McCormack, Io Nami-Wolk, Melissa Soucy & LeRoy Walters, The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey, 24 NATURE BIOTECH. 31, 31–39 (2006).

<sup>283.</sup> See supra notes 203–204 and accompanying text; Eisenberg, supra note 277, at 1062; Lee, supra note 205, at 677.

<sup>284.</sup> If X is patented, another researcher might make (a new) analogous compound X' to avoid infringement. Inventing around a patented technology is an activity that the patent system encourages. London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991); State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1235–36 (Fed. Cir. 1985).

<sup>285.</sup> Wesley M. Cohen & John P. Walsh, Real Impediments to Academic Biomedical Research, 8 INNOVATION POL'Y & ECON. 1, 12 (2007).

<sup>286.</sup> John Duffy argues that the Manson Court's fears are unrealistic:

<sup>[</sup>I]it is simply not true that granting one early patent to a whole field of new technology "shuts the door" to future inventions . . . . It is true that [the patent holder] *could* try to block off whole areas of research, but the patent holder has every economic incentive not to do so. The patent on the basic technology will have value only if further R&D is completed.

Duffy, supra note 30, at 241; see also Lawrence R. Velvel, A Critique of Brenner vs. Manson, 49 J. PAT. OFF. SOC'Y 5, 10 (1967) (arguing that the ability to obtain patents on newly discovered uses would prevent the owner of a composition patent from blocking off an entire field of research).

<sup>287.</sup> See sources cited supra note 277.

### C. Giving Research Its Due in Patent Law

Patent law is very much about research. The archetypal inventor is a scientist working in a research laboratory.<sup>288</sup> But even a sole inventor working in a garage to build a better mousetrap can be deemed a researcher.<sup>289</sup> Inventions that come about by accident—thus not the object of research—nevertheless often occur in research settings.<sup>290</sup>

So what explains the hostility toward granting patents on research inputs like X? To answer this question, it is necessary to look at technology specificity in patent law. In theory, patent law functions as a unitary system in that all inventions—regardless of technical field—must satisfy the same statutory patentability criteria.<sup>291</sup> But the technology-neutral nature of the patent statutes gives courts discretion to tailor patentability standards flexibly across technologies or industries.<sup>292</sup> Sometimes this must be done to adjust patent doctrines and accommodate new types of inventions as technology evolves.<sup>293</sup>

Technology specificity finds support in patent law, particularly when it is done for the sake of innovation.<sup>294</sup> For example, long ago the courts favored extraordinary technological advances by rewarding the owners of patents of these inventions "with exceptionally broad claim scope in exchange for their outsized technological contribution to society."<sup>295</sup> As Brian Love has described, this special treatment, "which helped inventors like Edison, Bell, and Marconi turn their inventions into the technological giants we know today as General Electric, AT&T, and RCA, has over time influenced many aspects of patent law, not to mention the very history of innovation."<sup>296</sup> Society really cared about

<sup>288.</sup> See generally MICHAEL E. GORMAN, TRANSFORMING NATURE: ETHICS, INVENTION AND DISCOVERY 69 (1998) (examining the processes of invention and discovery and how they are carried out).

<sup>289.</sup> This type of activity is "applied" research. See supra note 185.

<sup>290.</sup> Sean B. Seymore, *Serendipity*, 88 N.C. L. REV. 185, 188–90 (2009); Sean B. Seymore, *Atypical Inventions*, 86 NOTRE DAME L. REV. 2057, 2063–66 (2011).

<sup>291.</sup> See supra note 26. As a signatory to a multilateral intellectual property agreement, the United States agrees that patent rights shall be "enjoyable without discrimination as to... the field of technology" subject only to a few enumerated exceptions. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 33, 33 I.L.M. 81, 93–94 (1994) [hereinafter TRIPS Agreement].

<sup>292.</sup> Burk & Lemley, supra note 91, at 1576–77; Dan L. Burk & Mark A. Lemley, supra note 235, at 1156.

<sup>293.</sup> In theory, this allows the patent system "to adapt flexibly to both old and new technologies, encompassing 'anything under the sun that is made by man.'" Burk & Lemley, *supra* note 91, at 1576 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

<sup>294.</sup> BURK & LEMLEY, supra note 27, at 95.

 $<sup>295.\</sup> Brian\ J.\ Love,\ Interring\ the\ Pioneer\ Invention\ Doctrine,\ 90\ N.C.\ L.\ Rev.\ 379,\ 382\ (2012).$ 

<sup>296.</sup> Id. (footnote omitted).

these inventions because they brought radical benefits to everyday life.<sup>297</sup> Nowadays, the Patent Office and the courts may simply want to incentivize invention in certain fields over others.<sup>298</sup>

Plenty of research inputs have created benefits to everyday life and changed the world,<sup>299</sup> so again it is curious why they are subject to a clear but harsh utility standard. Recall that there is a fear that upstream patents on these research inputs are more likely to impede downstream innovation than those covering inventions with a known practical use.<sup>300</sup> Scott Kieff strongly disagrees with this notion:

It cannot be, however, that patents on inputs generally prevent the production of outputs. Entire industries have come and gone using scores of patented inputs. Every car is made using countless patented parts, fasteners, processes, and subsystems. Even the biological scientist manages to use a variety of patented machines, reagents, and equipment in the ordinary course of research. It does not appear that [critics] would argue that producers of biological innovations should not have to pay the licensing fee for ordinary inputs, including, for example, the intermittent windshield wiper subsystems on the car they drive to the laboratory in the morning.  $^{301}$ 

History reveals that predictions about the ill effects of patenting can be wrong. Consider *Diamond v. Chakrabarty*, the landmark 1980 case where the Supreme Court had to determine whether a genetically engineered bacterium is patent-eligible.<sup>302</sup> The Patent Office and several amici argued against eligibility because patenting genetic research would lead to a "parade of horribles" that could "pose a serious threat to the human race," including "[the] spread [of] pollution and disease, . . . a loss of genetic diversity, and . . . [a] practice [that] may tend to depreciate the value of human life."<sup>303</sup> The *Chakrabarty* Court declined the invitation to bring fear of the unknown into the patentability calculus: "Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of

<sup>297.</sup> Id. at 382 n.3; cf. John R. Thomas, The Question Concerning Patent Law and Pioneer Inventions, 10 HIGH TECH. L.J. 35, 37 (1995) ("[P]ioneer inventions are crucial to the sort of technological advance that the patent system is designed to encourage. They are the inventions with which we are most familiar, and those we care most about." (footnotes omitted)).

<sup>298.</sup> See Risch, supra note 29, at 1221 (exploring arguments that the bias may stem from a "simpl[e] desire to incentivize manufacturing instead of science"). This could run afoul of the technology nondiscrimination rule in the TRIPS Agreement. See supra note 291 and accompanying text.

<sup>299.</sup> See, e.g., K.C. NICOLAOU & TAMSYN MONTAGNON, MOLECULES THAT CHANGED THE WORLD (2008); JAMES WEI, GREAT INVENTIONS THAT CHANGED THE WORLD (2012); IRWIN W. SHERMAN, DRUGS THAT CHANGED THE WORLD: HOW THERAPEUTIC AGENTS SHAPED OUR LIVES (2016).

<sup>300.</sup> See supra note 154 and accompanying text; cf. Mayo Collaborative Servs. v. Prometheus Lab'ys., Inc., 566 U.S. 66, 71 (2012) ("And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.").

<sup>301.</sup> Kieff, supra note 254, at 720.

<sup>302. 447</sup> U.S. 303 (1980).

<sup>303.</sup> Id. at 316.

reward or slowed by want of incentives, but that is all."<sup>304</sup> The fears were *not* realized; indeed, *Chakrabarty* spawned the then-nascent biotechnology industry by making the fruits of research patent-eligible.<sup>305</sup>

The other possibility relates to the unpredictable nature of fields like chemistry. Once made, a chemical compound's practical usefulness often cannot be ascertained without additional research. Also, most laypersons (and judges) have *some* familiarity with predictable technologies like paper clips, but not so much with chemistry. Judge Learned Hand lamented this problem when he struggled with chemistry in addressing the patentability of purified adrenaline:

I cannot stop without calling attention to the extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon such questions as these. The inordinate expense of time is the least of the resulting evils, for only a trained chemist is really capable of passing upon such facts  $\dots$  309

So the harsh treatment might stem from a tendency to fear things that cannot be seen, let alone understood. This is related to the tendency of decisionmakers to be risk averse because they overweigh the likelihood of bad outcomes. 11

<sup>304.</sup> Id. at 317.

<sup>305.</sup> MERGES & DUFFY, supra note 173, at 98; see also Rebecca S. Eisenberg, The Story of Diamond v. Chakrabarty, in Intellectual Property Stories 356–57 (Jane C. Ginsburg & Rochelle Cooper Dreyfuss eds., 2006) (stating that Chakrabarty "was a watershed moment...for the biotechnology industry...[and] investment in biotechnology R&D has flourished in [its] wake").

<sup>306.</sup> See supra notes 4-5 and accompanying text.

<sup>307.</sup> See sources cited supra notes 4-14.

<sup>308.</sup> The broader point is that a court hearing a patent case may not "fully understand all of the science it encounters." Burk & Lemley, supra note 292, at 1197; see also Arti Rai, Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials, 2 WASH. U. J.L. & POL'Y 199, 213 (2000) (discussing scenarios where the Federal Circuit erroneously applied the patent statute because it "misapprehend[ed] the relevant technology"). For an example of a court explicitly noting its lack of knowledge of the underlying science in a patent case, see In re Perrigo, 48 F.2d 965, 966 (C.C.P.A. 1931).

<sup>309.</sup> Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 115 (C.C.S.D.N.Y. 1911), affd in part and rev'd in part, 196 F. 496 (2d. Cir. 1912).

<sup>310.</sup> Cf. Seymore, supra note 93, at 1128 (arguing that patent law has a "problem of scale," which "is in accord with the tendency of people to fear things that they cannot see, let alone understand"). This can be traced to the Latin proverb "[d]amnant quod non intellegunt," which literally means "[t]hey condemn what they do not understand." WALDO E. SWEET, LATIN PROVERBS: WISDOM FROM ANCIENT TO MODERN TIMES 87 (Georgia Irby-Massie & Scott Van Horn eds., 2002).

<sup>311.</sup> See Daniel Kahneman & Amos Tversky, Choices, Values, and Frames, 39 AM. PSYCH. 341, 343–45 (1984) (describing the cognitive phenomenon); see also Christine Jolls, Behavioral Economics Analysis of Redistributive Legal Rules, 51 VAND. L. REV. 1653, 1659–61 (1998) (describing over-pessimism); cf. W. KIP VISCUSI, FATAL TRADEOFFS 104 (1992) (suggesting that people overestimate low probability risks).

Sometimes technology-specific rules do more harm than good by jeopardizing the progress they seek to promote. To research inputs, the harsh utility requirement can lead to secrecy or delayed entry into the patent system unless and until a legally acceptable (practical) use is discovered. Granting research patents would avoid all these problems and give research its due in the U.S. patent system.

#### CONCLUSION

If the utility requirement is to do legitimate work in patent law,<sup>314</sup> it should be construed and applied to promote the greatest amount of scientific progress.<sup>315</sup> But the harsh standard currently applied to research inputs in unpredictable technologies does just the opposite. It is somewhat ironic that the unpredictable nature of these inventions—the attribute that fuels research, creates new possibilities, leads to paradigm shifts, and does other things that the patent system seeks to promote—is responsible for the hypothesized (and unrealized)

<sup>312.</sup> Wagner, *supra* note 46, at 1344 ("[N]ot all technological exceptionalism is benign. When the jurisprudential approach shifts from adaptation to prescription—from the application of consistent rules . . . to the promulgation of distinct rules to implement technology-based innovation policy—courts put at risk the very social progress they seek to enhance.").

<sup>313.</sup> Brenner v. Manson, 383 U.S. 519, 538-39 (1966) (Harlan, J., concurring in part and dissenting in part); see also Machin, supra note 11, at 439-40 (arguing that the current utility doctrine "comes at no small price," including fostering secrecy which, in turn, is detrimental to technological progress); Julian David Forman, A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications, 12 ALB. L.J. SCI. & TECH. 647, 669 (2002) (arguing that a heightened utility standard could hinder technological progress by delaying patent protection until later stages of R&D, thereby resulting in less investment in high-risk projects).

<sup>314. &</sup>quot;The only exceptions to the effective elimination of the utility requirement in patent law are in the fields of biology and chemistry." BURK & LEMLEY, supra note 27, at 111. One commentator makes a normative argument for the work that utility should do:

For the utility doctrine to be a vital component of patent law, it must impose at least minimal requirements on an invention. It must divide the world of inventions into "patentable" and "non-patentable" categories in a way that is different than the division imposed by the other requirements for patentability. In addition, the utility doctrine must further the patent system's goals consistent with the system's policies.

Machin, supra note 11, at 425 (footnote omitted); cf. Mayo Collaborative Servs. v. Prometheus Lab'ys., Inc., 566 U.S. 66, 90 (2012) (explaining that a particular statutory patentability requirement may be equipped to do work that others cannot). Patent scholars differ on the helpfulness of the utility requirement. Compare Risch, supra note 10, at 58 ("Usefulness can be... surprisingly helpful in patent law and policy.... [U]sefulness is not only relevant to patentability, but also critical to it.... The doctrine is especially helpful at the margins, where courts consider policy in deciding close cases; usefulness can often put a thumb on the scale."), with Sean B. Seymore, Making Patents Useful, 98 MINN. L. REV. 1046, 1073–77 (2014) (arguing that subjectivity, indifference to the technical substance of the disclosure, and superfluity make the utility requirement "substantively bankrupt").

<sup>315.</sup> Machin, supra note 11, at 439.

fears about blocking access to knowledge and impairing downstream uses that underlie the harsh standard.

This Article seeks to rectify this problem by proposing a research patent regime. This proposal would allow inventors to obtain patents on early-stage, basic research and extract their full value through licensing and enforcement. The limited scope of protection offered by research patents would allay concerns about overbreadth and control. The ultimate goal of research patents is to promote the disclosure, development, and use of research inputs—which all align with the patent system's basic goal to protect and promote advances in science and technology. Research patents also present an opportunity to recalibrate the role of utility in the patentability calculus and give research its due in the patent system.